The MassHealth Drug List

MassHealth Drug List

The MassHealth Drug List ("the List") is an alphabetical list of commonly prescribed drugs and therapeutic class tables. The List specifies which drugs need prior authorization (PA) when prescribed for MassHealth members. The PA requirements specified in the List reflect MassHealth's policy described in the pharmacy regulations and other communications from MassHealth, as well as MassHealth's and the Drug Utilization Review (DUR) Board's review of drugs within certain therapeutic classes. The List also specifies the generic over-the-counter drugs that are payable under MassHealth. Additional information can be found in the section titled "Prior Authorization Status of Drugs."

The MassHealth Drug List (MHDL) Therapeutic Tables provide a view of drugs within their respective therapeutic classes, along with PA requirements, clinical information about the drug, and evaluation criteria for PA for select therapeutic classes. The tables may not include all medications, dosage forms, and combination products within that therapeutic class. The criteria for PA identify the clinical information MassHealth considers when determining medical necessity for selected medications. The criteria are based upon generally accepted standards of practice, review of the medical literature, federal and state policies, as well as laws applicable to the Massachusetts Medicaid Program. The clinical information included in the criteria is not intended to serve as a source of comprehensive prescribing information. Prescribers and pharmacists should review the List and its applicable therapeutic class tables when prescribing a drug or filling a prescription for a MassHealth member.

As part of the state's efforts to promote clinically appropriate alternatives that are the most cost-effective in each class, MassHealth has entered into supplemental rebate agreements with drug manufacturers for certain drug classes. These drugs are listed on the MassHealth Supplemental Rebate/Preferred Drug List. Please note that MassHealth may still require PA for clinical reasons.

In general, MassHealth strongly advocates the use of generic drugs. However, in some circumstances, generic drugs may cost more than their brand-name equivalents. For this reason, MassHealth is implementing a policy allowing MassHealth to prefer selected brand-name drugs over generic drugs when the net cost of the brand-name drug adjusted for rebates is lower than the net cost of the generic equivalent. These preferred brand-name drugs are listed on the MassHealth Brand Name Preferred Over Generic Drug List.

MassHealth does not pay for immunizing biologicals (i.e., vaccines) and tubercular (TB) drugs that are available free of charge through local boards of public health or through the Massachusetts Department of Public Health without PA (130 CMR 406.413(C)). In cases where free vaccines are available to providers for specific populations (e.g., children, high risk, etc.), MassHealth will reimburse the provider only for individuals not eligible for the free vaccines. Notwithstanding the above, MassHealth will pay pharmacies for seasonal flu vaccine serum without PA, if the vaccine is administered in the pharmacy. Any drug that does not appear on the List requires PA, except for drugs described in 130 CMR 406.413(B) "Limitations on Coverage of Drugs - Drug Exclusions," which are not available to MassHealth adult members. Prescribers may request PA for such drugs for members under 21 years old to determine medical necessity (130 CMR 450.144(A)).

MassHealth members (including those in managed care plans), Health Safety Net patients, and Children's Medical Security Plan members do not have to pay copays for prescription drugs. This comprehensive no cost-sharing policy satisfies and exceeds the requirements of the PACT Act, Chapter 342 of the Acts of 2024, regarding coverage of medications for diabetes, asthma, and heart conditions.

Updates to the List

The updates to the List are effective immediately, unless otherwise specified. For medications that have new PA requirements, MassHealth's policy permits an otherwise valid prescription written before the effective date to be filled for the life of the prescription

without PA. Nevertheless, MassHealth encourages prescribers to reevaluate the medication regimens of their MassHealth patients, and consider either switching their MassHealth patients to a medication regimen that does not require PA or discontinuing the affected medication(s) as soon as possible, if clinically appropriate.

MassHealth encourages the use of specialized PA request forms for certain drugs or classes of drugs. These forms were created to help you provide the information MassHealth needs to evaluate your request. The specialized forms have the name of the drug or drug class in the title. If there is no specialized form, please use the General Drug Prior Authorization Request form. All forms are available at www.mass.gov/druglist.

Future Updates

MassHealth evaluates the prior-authorization status of drugs on an ongoing basis, and updates the MHDL accordingly. To sign up for e-mail alerts that will notify you when the List has been updated, go to the MassHealth Drug List at www.mass.gov/druglist . Click on Introduction to the MassHealth Drug List and then click on Subscribe to E-Mail Alerts in the Introduction section of the MHDL. Send the e-mail that automatically appears on your screen, and you will be subscribed. To get a paper copy of an updated List, submit a written request to the following address, fax number, or e-mail.

MassHealth Publications
P.O. Box 9152
Canton, MA 02021
Fax: 617-988-8973
E-mail: publications@mahealth.net

Include your MassHealth provider number, address, and a contact name with your request. MassHealth Publications will send you the latest version of the List. You will need to submit another written request each time you want a paper copy.

Prior Authorization Status of Drugs

Drugs may require PA for a variety of reasons. MassHealth determines the PA status of drugs on the List on the basis of the following:

- MassHealth program requirements; and
- ongoing evaluation of the drugs' utilization, therapeutic efficacy, safety, and cost.

Drugs are evaluated first on safety and effectiveness, and second on cost. Some drugs require PA because MassHealth and the Drug Utilization Review Board have concluded that there are more cost-effective alternatives. With regard to all such drugs, MassHealth also has concluded that the more costly drugs have no significant clinically meaningful therapeutic advantage in terms of safety, therapeutic efficacy, or clinical outcome compared to those less costly drugs used to treat the same condition. If applicable, the prescriber may submit to MassHealth documentation requesting an exception to step therapy, including written documentation in support of the exception, in accordance with M.G.L. c.118E, § 51A and the applicable PA form. Member stability due to the use of samples does not meet step therapy requirements.

Evaluation of a drug includes a thorough review by physicians and pharmacists using medical literature and consulting with specialists, other physicians, or both. References used may include *AHFS Drug Information; Drug Facts and Comparisons, Micromedex; National Comprehensive Cancer Network (NCCN); literature from peer-reviewed medical journals; Drug Topics Red Book, Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "*Orange Book*"); the *Massachusetts List of Interchangeable Drug Products;* and manufacturers' product information.

MassHealth may impose PA requirements in therapeutic classes in which it has designated a preferred product on the MassHealth Brand Name Preferred Over Generic Drug List or the MassHealth Supplemental Rebate/Preferred Drug List pursuant to the supplemental rebate agreement and preferred brand-name policies described above.

MassHealth may exclude otherwise-covered drugs from a population (including an identified patient sub-population) when it determines a drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome for such population. Any such exclusions will be implemented through the PA clinical criteria specified in the MassHealth Drug List. You may obtain the written basis for any such exclusion by making a request in writing to the MassHealth Pharmacy Program at masshealthdruglist@state.ma.us.

The MassHealth Pharmacy Online Processing System (POPS) uses diagnosis codes from medical claims for some drug classes when processing claims at pharmacies. This means that a prescriber may not need to submit a paper PA form if a member's diagnosis in POPS meets the criteria for that drug. MassHealth uses technical software called Smart PA to link diagnosis codes from medical claims during pharmacy claims adjudication. Smart PA is used in the MHDL to identify drugs for which this process is currently available. For this reason, MassHealth requests pharmacies to submit all claims through POPS, as some drugs that are designated as requiring PA on the MHDL will process at the pharmacy without a paper PA submitted.

In addition, if the limitations on covered drugs specified in 130 CMR 406.412(A) and 406.413(A) and (C) would result in inadequate treatment for a diagnosed medical condition, the prescriber may submit a written request, including written documentation of medical necessity, to MassHealth for PA for an otherwise noncovered drug.

List Conventions

The List uses the following conventions.

- Brand-name products are capitalized. Generic products are in lowercase.

- Formulations of a drug (for example, salt forms, sustained release, or syrups) are not specified on the List, unless a particular formulation requires PA and a different formulation does not.
- Combination products are listed with the individual ingredients separated by a slash mark (/).
- Only the generic and brand names of over-the-counter drugs that are payable by MassHealth appear on the List. Those over-the-counter drugs that are not listed require PA.
- Only the generic names of single and combination vitamins are listed. The brand names of such combinations are not listed, and therefore require PA.

Questions or Comments

Pharmacists and prescribers who have questions or comments about the MassHealth Drug List may contact the Drug Utilization Review Program at (800) 745-7318 or may e-mail the MassHealth Pharmacy Program at masshealthdruglist@state.ma.us. MassHealth does not answer all e-mail inquiries directly, but will use these inquiries to develop frequently asked questions about the MassHealth Drug List for its website.

When e-mailing a question or comment to the above e-mail address, please include your name, title, phone number, and fax number. This electronic mailbox should be used only for submitting questions or comments about the MassHealth Drug List. You will receive an automated response that acknowledges receipt of your e-mail. If you do not receive an automated reply, please resubmit your inquiry.

If a member has questions about the MassHealth Drug List, please refer the member to MassHealth Customer Service at (800) 841-2900 (TDD/TTY:711).

For more information about the MassHealth Pharmacy Program, including regulations, Pharmacy Facts, Publications, and Notices sent to prescribers and pharmacies, go to www.mass.gov/masshealth-pharmacy-program.

MassHealth Drug Utilization Review Program
P.O. Box 2586, Worcester, MA 01613-2586
Fax: (877) 208-7428 **Phone:** (800) 745-7318

July 2025 MassHealth Drug List Summary Update

MassHealth evaluates the prior authorization (PA) status for drugs on an ongoing basis and updates the MassHealth Drug List accordingly. This Summary Update document identifies changes to the MassHealth Drug List for the rollout effective July 1, 2025.

Additional information about these agents may be available within the MassHealth Drug List at www.mass.gov/druglist.

Additions

a. Effective July 1, 2025, the following newly marketed drugs have been added to the MassHealth Drug List.
- Alhemo (concizumab-mtci) – **PA**
- Bizengri (zenocutuzumab-zbco) – **PA**; MB
- Crenessity (crinecerfont) – **PA**
- Datroway (datopotamab deruxtecan-dlnk) – **PA**; MB
- Hercessi (trastuzumab-strf) – **PA**; MB
- Kebilidi (eladocagene exuparvovec-tneq) – **PA**; CO
- metronidazole 125 mg tablet – **PA**
- Opdivo Qvantig (nivolumab-hyaluronidase-nvhy) – **PA**; MB
- Otulfi (ustekinumab-aauz prefilled syringe) – **PA**
- Otulfi (ustekinumab-aauz vial) – **PA**; MB
- Pyzchiva (ustekinumab-ttwe prefilled syringe) - **PA**
- Pyzchiva (ustekinumab-ttwe vial) – **PA**; MB
- Qlosi (pilocarpine 0.4% ophthalmic solution) – **PA**
- Revuforj (revumenib) – **PA**
- Ryzumvi (phentolamine) – **PA**; MB
- Selarsdi (ustekinumab-aekn prefilled syringe) – **PA**
- Selarsdi (ustekinumab-aekn vial) - **PA**; MB
- Steqeyma (ustekinumab-stba prefilled syringe) – **PA**
- Steqeyma (ustekinumab-stba vial) – **PA**; MB
- ustekinumab-aekn, unbranded prefilled syringe – **PA**
- ustekinumab-ttwe, unbranded prefilled syringe – **PA**
- ustekinumab-ttwe, unbranded vial – **PA**; MB
- Xromi (hydroxyurea solution) – **PA**
- Yesintek (ustekinumab-kfce prefilled syringe, 45 mg/0.5 mL vial) – **PA**
- Yesintek (ustekinumab-kfce 130 mg/26 mL vial) – **PA**; MB

b. Effective April 23, 2025, the following COVID-19 treatment agent was added to the MassHealth Drug List on July 1, 2025.
- Paxlovid (nirmatrelvir/ritonavir 300/150-100 mg) [PD]

Change in Prior Authorization Status

a. Effective July 1, 2025, the following benzodiazepine agents will require PA within updated age limits. Pediatric Behavioral Health Medication Initiative criteria will still apply. For additional information, please see the Pediatric Behavioral Health Initiative documents found at www.mass.gov/druglist.
- alprazolam solution – **PA < 6 years and ≥ 13 years**

- lorazepam solution – **PA < 6 years and ≥ 13 years**

b. Effective July 1, 2025, the following benzodiazepine agent will require PA. Pediatric Behavioral Health Medication Initiative criteria will still apply. For additional information, please see the Pediatric Behavioral Health Initiative documents found at www.mass.gov/druglist.
   - diazepam 25 mg/5 mL solution – **PA**

c. Effective July 1, 2025, the following gastrointestinal agent will require PA.
   - Zegerid (omeprazole/sodium bicarbonate powder for oral suspension) – **PA**; M90

d. Effective July 1, 2025, the following opioid dependence agent will no longer require PA.
   - Brixadi (buprenorphine extended-release injection) [PD]

New or Revised Therapeutic Tables

Table 3 – Gastrointestinal Drugs - Histamine H2 Antagonists, Proton Pump Inhibitors, and Miscellaneous Gastroesophageal Reflux Agents
Table 5 – Immunological Agents
Table 6 – Nutrients, Vitamins, and Vitamin Analogs
Table 8 – Opioids and Analgesics
Table 10 – Dermatologic Agents - Acne and Rosacea
Table 14 – Headache Therapy
Table 18 – Cardiovascular Agents
Table 20 – Anticonvulsants
Table 22 – Acromegaly, Carcinoid Syndrome, and Cushing's Syndrome Agents
Table 23 – Respiratory Agents - Inhaled
Table 31 – Cerebral Stimulants and Miscellaneous Agents
Table 34 – Antibiotics - Ophthalmic
Table 35 – Antibiotics and Anti-Infectives - Oral and Inhaled
Table 36 – Drug and Alcohol Cessation Agents
Table 40 – Respiratory Agents - Oral
Table 45 – Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease Agents
Table 49 – Osteoporosis and Bone Metabolism Agents
Table 57 – Oncology Agents
Table 63 – Dermatologic Agents - Topical Chemotherapy, Genital Wart Treatment, and Miscellaneous Dermatologic Agents
Table 64 – Asthma/Allergy Monoclonal Antibodies
Table 65 – Enzyme and Metabolic Disorder Therapies
Table 69 – Barbiturates, Benzodiazepines, and Miscellaneous Antianxiety Agents
Table 71 – Pediatric Behavioral Health
Table 72 – Agents Not Otherwise Classified
Table 73 – Iron Agents and Chelators
Table 76 – Neuromuscular Agents - Duchenne Muscular Dystrophy and Spinal Muscular Atrophy
Table 79 – Pharmaceutical Compounds
Table 80 – Anti-Hemophilia Agents
Table 81 – Anti-Obesity Agents

Updated and New Prior Authorization Request Forms

- Anticonvulsant Prior Authorization Request
- Anti-Hemophilia Non-Gene Therapy Agents
- Asthma/Allergy Monoclonal Antibodies Prior Authorization Request
- Benzodiazepines and Other Anti-Anxiety Agents Prior Authorization Request
- Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease Agents Prior Authorization Request
- Breast Cancer Agents Prior Authorization Request

- Cerebral Stimulant and ADHD Drugs Prior Authorization Request
- Headache Therapy (Butalbital Combination Agents) Prior Authorization Request
- Health Safety Net Formulary Exceptions Prior Authorization Request
- Inhaled Respiratory Agents Prior Authorization Request
- One-Time Cell and Gene Therapies Prior Authorization Request
- Opioid Dependence and Reversal Agents Prior Authorization Request
- Opioids/Acetaminophen Analgesic Prior Authorization Request
- Oral Antibiotics and Anti-Infectives Prior Authorization Request
- Oral Respiratory Agents Prior Authorization Request
- Osteoporosis Agents and Calcium Regulators Prior Authorization Request
- Proton Pump Inhibitor Prior Authorization Request
- Targeted Immunomodulators Prior Authorization Request

Updated MassHealth Brand Name Preferred Over Generic Drug List

The MassHealth Brand Name Preferred Over Generic Drug List has been updated to reflect recent changes to the MassHealth Drug List.

a. Effective July 1, 2025, the following agents will be added to the MassHealth Brand Name Preferred Over Generic Drug List.
   - Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablet) – **PA**; BP
   - Depen (penicillamine tablet); BP, A90
   - Ridaura (auranofin); BP
   - Xeljanz (tofacitinib) – **PA**; BP
   - Xeljanz XR (tofacitinib extended-release) – **PA**; BP

b. Effective July 1, 2025, the following agents will be removed from the MassHealth Brand Name Preferred Over Generic Drug List.
   - Dermotic (fluocinolone oil, otic drops); A90

Updated MassHealth 90-day Initiative

The MassHealth 90-day Initiative has been updated to reflect recent changes to the MassHealth Drug List.
Effective July 1, 2025, the following agents may be allowed or mandated to be dispensed in up to a 90-day supply, as indicated below.

- Anoro (umeclidinium/vilanterol); A90
- Aptiom (eslicarbazepine) – **PA**; A90

Updated MassHealth Over-the-Counter Drug List

The MassHealth Over-the-Counter Drug List has been updated to reflect recent changes to the MassHealth Drug List.
Effective July 1, 2025, the following diabetic agent will no longer require PA within updated age limits.

- glucose products – **PA ≥ 21 years**; A90

Updated MassHealth Supplemental Rebate/Preferred Drug List

The MassHealth Supplemental Rebate/Preferred Drug List has been updated to reflect recent changes to the MassHealth Drug List.

a. Effective April 23, 2025, the following COVID-19 treatment agent was added to the MassHealth Supplemental Rebate/Preferred Drug List.
   - Paxlovid (nirmatrelvir/ritonavir 300/150-100mg) [PD]

b. Effective July 1, 2025, the following opioid dependence agent will be added to the MassHealth Supplemental Rebate/Preferred Drug List.
   - Brixadi (buprenorphine extended-release injection) [PD]

Updated MassHealth Quick Reference Guide

The MassHealth Quick Reference Guide has been updated to reflect recent changes to the MassHealth Drug List.

MassHealth Medication Therapy Management Program

The MassHealth Medication Therapy Management Program guide has been updated.

Updated and New Pharmacy Initiatives

- Opioid and Pain Initiative

Updated MassHealth Acute Hospital Carve-Out Drugs List

The MassHealth Acute Hospital Carve-Out Drugs list has been updated to reflect recent changes to the MassHealth Drug List.

Deletions

a. The following drugs have been removed from the MassHealth Drug List because they have been discontinued by the manufacturer.
   - Dacogen (decitabine); MB
   - Tegsedi (inotersen) – **PA**

b. The following drugs have been removed from the MassHealth Drug List. MassHealth does not pay for drugs that are manufactured by companies that have not signed rebate agreements with the U.S. Secretary of Health and Human Services.
   - Aczone (dapsone gel) – **PA**; A90
   - Olinvyk (oliceridine) – **PA**; MB
   - Triferic (ferric pyrophosphate citrate); MB

Corrections / Clarifications

a. The following drugs have been added to the MassHealth Drug List. These changes do not reflect any change in MassHealth policy.
   - butalbital/aspirin/caffeine tablet – **PA**
   - levofloxacin ophthalmic solution – **PA**; A90

b. The following listings have been clarified. These changes do reflect a change in MassHealth policy.
   - Nymalize (nimodipine oral solution) – **PA > 21 days treatment/365 days**; #

c. The following listings have been clarified. These changes do not reflect any change in MassHealth policy.
   - Ativan (lorazepam tablet) – **PA < 6 years**; #
   - ondansetron 16 mg orally disintegrating tablet – **PA**
   - Valium (diazepam 5 mg/5 mL solution, tablet) – **PA < 6 years**; #
   - Xanax (alprazolam tablet) – **PA < 6 years**; #
   - Zegerid (omeprazole/sodium bicarbonate capsule); #, M90

Abbreviations, Acronyms, and Symbols

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth

Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

PA Prior authorization is required. The prescriber must obtain prior authorization for the drug in order for the provider to receive reimbursement. Note: PA applies to both the brand-name and the FDA “A”-rated generic equivalent of listed product.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

CO Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements. All requests for one-time cell and gene therapies (as listed on the Acute Hospital Carve-Out Drugs List), including for members enrolled in an Accountable Care Partnership Plan (ACPP) or Managed Care Organization (MCO), will be reviewed by the MassHealth Drug Utilization Review (DUR) Program.

M90 Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

The List Uses the Following Symbols:

PA	Prior authorization is required. The prescriber must obtain PA for the drug in order for the pharmacy to receive payment. Note: PA applies to both the brand-name and the FDA "A"-rated generic equivalent of listed product.
#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
CO	Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements. All requests for one-time cell and gene therapies (as listed on the Acute Hospital Carve-Out Drug List), including for members enrolled in an Accountable Care Partnership Plan (ACPP) or Managed Care Organization (MCO), will be reviewed by the MassHealth Drug Utilization Review (DUR) Program.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
HSNE	This product is not payable under Health Safety Net for weight loss.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
o	PA status depends on the drug's formulation.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
1	Product may be available through the Massachusetts Department of Public Health (DPH). Please check with DPH for availability. MassHealth does not pay for immunizing biologicals (i.e., vaccines) and tubercular (TB) drugs that are available free of charge through local boards of public health or through the Massachusetts Department of Public Health without PA (130 CMR 406.413(C)). In cases where free vaccines are available to providers for specific populations (e.g. children, high risk, etc.), MassHealth will reimburse the provider only for individuals not eligible for the free vaccines. Notwithstanding the above, MassHealth will pay pharmacies for seasonal flu vaccine serum without PA, if the vaccine is administered in the pharmacy.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
CP	Compounded pharmaceutical products with a total allowed ingredient cost greater than or equal to $100 require PA. In addition, compounded pharmaceutical products with intradermal, topical, or transdermal route of administration (ROA) require PA. The following ROAs are excluded from the PA requirement for products with a total allowed ingredient cost greater than or equal to $100: infusion, intramuscular, intravenous, intravenous piggyback, intravenous push, subcutaneous. Compounded pharmaceutical products utilizing any PA-requiring agent or not covered ingredient as part of the compound require PA.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

Therapeutic Class and Clinical Criteria Tables

Prior Authorization Request Forms

Policy Initiatives

Other Information

PND Preferred Non-Drug Product. This product is a preferred non-drug product for which MassHealth has entered into a rebate agreement with product manufacturer.

Note: Any drug that does not appear on the List requires PA.

Alphabetic List

A

amiodarone injection; MB; See Table 18, Page 249

amiodarone tablet; M90; See Table 18, Page 249

Amitiza (lubiprostone) - PA; M90; See Table 61, Page 658

amitriptyline / chlordiazepoxide - PA; See Table 17, Page 235; See Table 69, Page 725; See Table 71, Page 741

amitriptyline / perphenazine - PA; A90; See Table 17, Page 235; See Table 24, Page 310; See Table 71, Page 741

amitriptyline tablet - PA < 6 years; A90; See Table 17, Page 235; See Table 71, Page 741

amivantamab-vmjw - PA; MB; See Table 57, Page 535

Amjevita (adalimumab-atto) - PA; See Table 5, Page 116

amlodipine / atorvastatin - PA; M90; See Table 13, Page 200; See Table 18, Page 249

amlodipine / benazepril; M90; See Table 18, Page 249

amlodipine / olmesartan / hydrochlorothiazide - PA; M90; See Table 18, Page 249

amlodipine / olmesartan; M90; See Table 18, Page 249

amlodipine / telmisartan - PA; M90; See Table 18, Page 249

amlodipine / valsartan / hydrochlorothiazide; M90; See Table 18, Page 249

amlodipine / valsartan; M90; See Table 18, Page 249

amlodipine solution - PA; See Table 18, Page 249

amlodipine suspension - PA; See Table 18, Page 249

amlodipine; M90; See Table 18, Page 249

ammonium lactate

Ammonul (sodium phenylacetate / sodium benzoate); #

Amondys 45 (casimersen) - PA; See Table 76, Page 837

amoxapine - PA; A90; See Table 17, Page 235; See Table 71, Page 741

amoxicillin / clavulanate 125/31.25 mg/5 mL suspension - PA; See Table 35, Page 397

amoxicillin / clavulanate chewable tablet, 200/28.5, 250/62.5, 400/57, 600/42.9 mg/5 mL suspension, tablet; A90; See Table 35, Page 397

amoxicillin / clavulanate extended-release - PA; A90; See Table 35, Page 397

amoxicillin; A90; See Table 35, Page 397

Amphadase (hyaluronidase); MB

amphetamine extended-release 1.25 mg/mL oral suspension - PA; See Table 31, Page 372; See Table 71, Page 741

amphetamine extended-release 2.5 mg/mL oral suspension - PA; See Table 31, Page 372; See Table 71, Page 741

amphetamine extended-release chewable tablet - PA; See Table 31, Page 372; See Table 71, Page 741

amphetamine extended-release orally disintegrating tablet - PA; BP; See Table 31, Page 372; See Table 71, Page 741

amphetamine salts - PA < 3 years or ≥ 21 years and PA > 3 units/day; See Table 31, Page 372; See Table 71, Page 741

amphetamine salts extended-release-Adderall XR - PA < 3 years or ≥ 21 years and PA > 2 units/day; BP, [PD]; See Table 31, Page 372; See Table 71, Page 741

amphetamine salts extended-release-Mydayis - PA; See Table 31, Page 372; See Table 71, Page 741

amphetamine sulfate - PA; See Table 31, Page 372; See Table 71, Page 741

amphetamine sulfate orally disintegrating tablet - PA; See Table 31, Page 372; See Table 71, Page 741

amphotericin B lipid complex; See Table 47, Page 478

amphotericin B liposome; See Table 47, Page 478

amphotericin B; See Table 47, Page 478

ampicillin / sulbactam; See Table 66, Page 707

ampicillin; A90; See Table 35, Page 397; See Table 66, Page 707

Ampyra (dalfampridine) - PA > 2 units/day; #, A90; See Table 52, Page 512

Amrix (cyclobenzaprine extended-release) - PA; A90; See Table 7, Page 155

Amtagvi (lifileucel) - PA; CO; See Table 75, Page 828

Amvuttra (vutrisiran) - PA; [PD], MB; See Table 72, Page 765

anacaulase-bcdb - PA; MB; See Table 72, Page 765

Anafranil (clomipramine) - PA; A90; See Table 17, Page 235; See Table 71, Page 741

anagrelide; A90; See Table 58, Page 646

anakinra - PA; See Table 5, Page 116

Anascorp (centruroides immune F(ab')2, equine); MB

anastrozole; A90; See Table 57, Page 535

Ancobon (flucytosine); BP, A90; See Table 47, Page 478

Androgel (testosterone 1% gel packet) - PA; See Table 55, Page 523

Androgel (testosterone 1.62% gel packet) - PA; See Table 55, Page 523

Angeliq (estradiol / drospirenone)

anidulafungin; See Table 47, Page 478

anifrolumab-fnia - PA; MB; See Table 72, Page 765

Anktiva (nogapendekin alfa inbakicept-pmln) - PA; MB; See Table 57, Page 535

Annovera (segesterone / ethinyl estradiol)

Anoro (umeclidinium / vilanterol); A90; See Table 23, Page 302

anti-inhibitor coagulant complex-Feiba NF; See Table 80, Page 857

antihemophilic factor / von willebrand factor complex, human; See Table 80, Page 857

antihemophilic factor, human-Humate-P; See Table 80, Page 857

antihemophilic factor, human-Koate-DVI; See Table 80, Page 857

antihemophilic factor, recombinant pegylated-Adynovate; See Table 80, Page 857

antihemophilic factor, recombinant pegylated-aucl-Jivi; [PD]; See Table 80, Page 857

antihemophilic factor, recombinant, fc-vwf-xten fusion protein-ehtl; See Table 80, Page 857

antihemophilic factor, recombinant, porcine sequence-Obizur; See Table 80, Page 857

antihemophilic factor, recombinant, single chain-Afstyla; See Table 80, Page 857

antihemophilic factor, recombinant-Advate; See Table 80, Page 857

antihemophilic factor, recombinant-Helixate; See Table 80, Page 857

antihemophilic factor, recombinant-Hemofil-M; See Table 80, Page 857

antihemophilic factor, recombinant-Kogenate; PD; See Table 80, Page 857

antihemophilic factor, recombinant-Kovaltry; PD; See Table 80, Page 857

antihemophilic factor, recombinant-Novoeight; See Table 80, Page 857

antihemophilic factor, recombinant-Nuwiq; See Table 80, Page 857

antihemophilic factor, recombinant-Recombinate; See Table 80, Page 857

antihemophilic factor, recombinant-Xyntha; PD; See Table 80, Page 857

antithymocyte globulin, equine; See Table 1, Page 87

antithymocyte globulin, rabbit; See Table 1, Page 87

Antivert (meclizine); #, *, A90

Anusol-HC (hydrocortisone hemorrhoidal cream); #, A90; See Table 33, Page 390

Anzemet (dolasetron) - PA; See Table 27, Page 347

Apadaz (benzhydrocodone / acetaminophen) - PA; See Table 8, Page 159

apalutamide - PA; See Table 57, Page 535

Apexicon-E (diflorasone cream / emollient) - PA; See Table 16, Page 229

Aphexda (motixafortide) - PA; MB; See Table 4, Page 111

Apidra (insulin glulisine) - PA; See Table 26, Page 330

apixaban; See Table 58, Page 646

Aplenzin (bupropion hydrobromide extended-release) - PA; See Table 17, Page 235; See Table 71, Page 741

Apokyn (apomorphine injection); #; See Table 48, Page 485

apomorphine film - PA; See Table 48, Page 485

apomorphine injection; See Table 48, Page 485

apraclonidine; M90; See Table 51, Page 506

apremilast - PA; See Table 5, Page 116

aprepitant 125 mg powder for oral suspension - PA > 6 units/28 days; A90; See Table 27, Page 347

aprepitant 40 mg, 125 mg capsule - PA > 2 units/28 days; A90; See Table 27, Page 347

aprepitant 80 mg - PA > 4 units/28 days; A90; See Table 27, Page 347

aprepitant injectable emulsion - PA; See Table 27, Page 347

aprepitant trifold pack - PA > 2 packs/28 days; A90; See Table 27, Page 347

Apretude (cabotegravir injection); PD; See Table 38, Page 420

Apriso (mesalamine 0.375 gram extended-release capsule); BP, A90; See Table 33, Page 390

aprocitentan - PA; See Table 18, Page 249

Aptensio XR (methylphenidate extended-release-Aptensio XR) - PA; See Table 31, Page 372; See Table 71, Page 741

Aptiom (eslicarbazepine) - PA; A90; See Table 20, Page 275; See Table 71, Page 741

Aptivus (tipranavir); See Table 38, Page 420

Aqneursa (levacetylleucine) - PA; See Table 65, Page 693

Aquasol A (vitamin A injection); See Table 6, Page 150

Aralast NP (alpha-1-proteinase inhibitor, human-Aralast NP); MB

Aranesp (darbepoetin alfa) - PA; See Table 4, Page 111

Arava (leflunomide); #, A90

Arazlo (tazarotene lotion) - PA; See Table 10, Page 180

Arcalyst (rilonacept) - PA; See Table 5, Page 116

Arexvy (respiratory syncytial virus vaccine, adjuvanted) - PA < 50 years; See Table 32, Page 383

arformoterol - PA; A90; See Table 23, Page 302

Aricept (donepezil 10 mg tablet) - PA < 6 years and PA > 2 units/day; #, A90; See Table 56, Page 529; See Table 71, Page 741

Aricept (donepezil 5 mg, 23 mg tablet) - PA < 6 years and PA > 1 unit/day; #, A90; See Table 56, Page 529; See Table 71, Page 741

Arikayce (amikacin liposome inhalation) - PA; See Table 35, Page 397

Arimidex (anastrozole); #, A90; See Table 57, Page 535

arimoclomol - PA; See Table 65, Page 693

aripiprazole extended-release injection - PA; See Table 24, Page 310; See Table 71, Page 741

aripiprazole film - PA; See Table 24, Page 310; See Table 71, Page 741

aripiprazole lauroxil 1,064 mg - PA < 10 years and PA > 1 injection/56 days; PD; See Table 24, Page 310; See Table 71, Page 741

aripiprazole lauroxil 441 mg, 662 mg, 882 mg - PA < 10 years and PA > 1 injection/28 days; PD; See Table 24, Page 310; See Table 71, Page 741

aripiprazole lauroxil 675 mg - PA < 10 years and PA > 1 injection/28 days; PD; See Table 24, Page 310; See Table 71, Page 741

aripiprazole orally disintegrating tablet - PA; A90; See Table 24, Page 310; See Table 71, Page 741

aripiprazole solution - PA < 10 years or ≥ 13 years and PA ≥ 10 mL/day; A90; See Table 24, Page 310; See Table 71, Page 741

aripiprazole tablet - PA < 10 years and PA > 2 units/day; A90; See Table 24, Page 310; See Table 71, Page 741

aripiprazole tablet with sensor - PA; See Table 24, Page 310; See Table 71, Page 741

Aristada (aripiprazole lauroxil 1,064 mg) - PA < 10 years and PA > 1 injection/56 days; PD; See Table 24, Page 310; See Table 71, Page 741

Aristada (aripiprazole lauroxil 441 mg, 662 mg, 882 mg) - PA < 10 years and PA > 1 injection/28 days; PD; See Table 24, Page 310; See Table 71, Page 741

Aristada Initio (aripiprazole lauroxil 675 mg) - PA < 10 years and PA > 1 injection/28 days; PD; See Table 24, Page 310; See Table 71, Page 741

Arixtra (fondaparinux); #; See Table 58, Page 646

armodafinil - PA < 6 years and PA > 1 unit/day; See Table 50, Page 500; See Table 71, Page 741

Armonair Digihaler (fluticasone propionate inhalation powder-Armonair Digihaler) - PA; See Table 23, Page 302

Arnuity (fluticasone furoate inhalation powder); See Table 23, Page 302

Aromasin (exemestane); #, A90; See Table 57, Page 535

Arranon (nelarabine) - PA; MB; See Table 57, Page 535

arsenic trioxide; See Table 57, Page 535

B

C

D

doxylamine / pyridoxine extended-release - PA; See Table 27, Page 347

doxylamine; *, A90

Drizalma (duloxetine sprinkle capsule) - PA; See Table 17, Page 235; See Table 71, Page 741

dronabinol - PA > 2 units/day; See Table 27, Page 347

dronedarone; A90; See Table 18, Page 249

droperidol

drospirenone

Droxia (hydroxyurea capsule); See Table 45, Page 466

droxidopa - PA; A90; See Table 18, Page 249

Drysol (aluminum chloride) - PA; See Table 63, Page 674

Duaklir (aclidinium / formoterol) - PA; See Table 23, Page 302

Duavee (estrogens, conjugated/bazedoxifene) - PA; See Table 49, Page 492

Duetact (glimepiride / pioglitazone) - PA; BP, M90; See Table 26, Page 330

Duexis (ibuprofen / famotidine) - PA < 60 years; #, A90; See Table 11, Page 188

dulaglutide - PA > 2 mL/28 days; PD; See Table 26, Page 330

Dulera (mometasone / formoterol); BP; See Table 23, Page 302

duloxetine 20 mg, 30 mg, 60 mg capsule - PA < 6 years; A90; See Table 17, Page 235; See Table 71, Page 741

duloxetine 40 mg capsule - PA; A90; See Table 17, Page 235; See Table 71, Page 741

duloxetine sprinkle capsule - PA; See Table 17, Page 235; See Table 71, Page 741

Duobrii (halobetasol / tazarotene lotion) - PA; See Table 16, Page 229

Duopa (carbidopa / levodopa enteral suspension) - PA; See Table 48, Page 485

dupilumab - PA; PD; See Table 64, Page 679

Dupixent (dupilumab) - PA; PD; See Table 64, Page 679

Duraclon (clonidine injection); #; See Table 8, Page 159

Duramorph (morphine, injection-Duramorph) - PA > 120 mg/day; See Table 8, Page 159

Durezol (difluprednate); #, A90; See Table 29, Page 358

Durolane (hyaluronate, stabilized) - PA; MB; See Table 77, Page 846

durvalumab - PA; MB; See Table 57, Page 535

Durysta (bimatoprost implant) - PA; MB; See Table 51, Page 506

dutasteride / tamsulosin - PA; M90; See Table 19, Page 272

dutasteride; M90; See Table 19, Page 272

duvelisib - PA; See Table 57, Page 535

Duvyzat (givinostat) - PA; See Table 76, Page 837

Dyanavel XR (amphetamine extended-release 2.5 mg/mL oral suspension) - PA; See Table 31, Page 372; See Table 71, Page 741

Dyanavel XR (amphetamine extended-release chewable tablet) - PA; See Table 31, Page 372; See Table 71, Page 741

Dymista (azelastine / fluticasone propionate); BP, M90; See Table 25, Page 326

Dysport (abobotulinumtoxinA) - PA; See Table 30, Page 365

E

Ebglyss (lebrikizumab-lbkz) - PA; PD; See Table 5, Page 116

ecallantide - PA; MB; See Table 60, Page 654

echothiophate iodide; See Table 51, Page 506

econazole 1% cream; A90; See Table 28, Page 353

eculizumab - PA; MB; See Table 72, Page 765

edaravone - PA; See Table 72, Page 765

Edarbi (azilsartan); See Table 18, Page 249

Edarbyclor (azilsartan / chlorthalidone); See Table 18, Page 249

Edecrin (ethacrynic acid tablet) - PA; M90; See Table 18, Page 249

Edluar (zolpidem 5 mg, 10 mg sublingual tablet) - PA; See Table 15, Page 222; See Table 71, Page 741

edoxaban - PA; See Table 58, Page 646

Edurant (rilpivirine); BP; See Table 38, Page 420

efavirenz / emtricitabine / tenofovir; A90; See Table 38, Page 420

efavirenz 400 mg / lamivudine 300 mg / tenofovir disoproxil fumarate 300 mg - PA; A90; See Table 38, Page 420

efavirenz 600 mg / lamivudine 300 mg / tenofovir disoproxil fumarate 300 mg - PA; A90; See Table 38, Page 420

efavirenz; A90; See Table 38, Page 420

Effexor XR (venlafaxine extended-release capsule) - PA < 6 years; #, A90; See Table 17, Page 235; See Table 71, Page 741

Effient (prasugrel); #, A90; See Table 58, Page 646

efgartigimod alfa-fcab - PA; MB; See Table 72, Page 765

efgartigimod alfa-fcab and hyaluronidase-qvfc - PA; MB; See Table 72, Page 765

efinaconazole - PA; See Table 28, Page 353

eflapegrastim-xnst; MB; See Table 4, Page 111

eflornithine - PA; See Table 57, Page 535

Efudex (fluorouracil 5% cream); BP, A90; See Table 63, Page 674

Egaten (triclabendazole) - PA; See Table 35, Page 397

Egrifta SV (tesamorelin) - PA; See Table 38, Page 420

elacestrant - PA; See Table 57, Page 535

eladocagene exuparvovec-tneq - PA; CO; See Table 65, Page 693

elafibranor - PA; See Table 61, Page 658

elagolix - PA; See Table 2, Page 95

elagolix / estradiol / norethindrone - PA; See Table 2, Page 95

Elahere (mirvetuximab soravtansine-gynx) - PA; MB; See Table 57, Page 535

elapegademase-lvlr - PA; See Table 65, Page 693

Elaprase (idursulfase) - PA; MB; See Table 65, Page 693

elbasvir / grazoprevir - PA; See Table 44, Page 451

electrolye solution, pediatric; *, A90

Elelyso (taliglucerase alfa) - PA; MB; See Table 65, Page 693

Elepsia XR (levetiracetam extended-release-Elepsia XR) - PA; See Table 20, Page 275

Elestrin (estradiol-Elestrin)

eletriptan - PA; A90; See Table 14, Page 211

F

G

H

I

Ixempra (ixabepilone); MB; See Table 57, Page 535

Ixiaro (japanese encephalitis vaccine); See Table 32, Page 383

Ixinity (factor IX human recombinant-Ixinity); See Table 80, Page 857

Iyuzeh (latanoprost solution - Iyuzeh) - PA; See Table 51, Page 506

Izervay (avacincaptad pegol) - PA; MB; See Table 72, Page 765

J

Jadenu (deferasirox 90 mg, 180 mg, 360 mg); #, A90; See Table 73, Page 820

Jakafi (ruxolitinib tablet) - PA; See Table 57, Page 535

Jalyn (dutasteride / tamsulosin) - PA; M90; See Table 19, Page 272

Janumet (sitagliptin / metformin - Janumet); See Table 26, Page 330

Janumet XR (sitagliptin / metformin extended-release); See Table 26, Page 330

Januvia (sitagliptin-Januvia); See Table 26, Page 330

japanese encephalitis vaccine; See Table 32, Page 383

Jardiance (empagliflozin); See Table 26, Page 330

Jatenzo (testosterone undecanoate capsule) - PA; See Table 55, Page 523

Jaypirca (pirtobrutinib) - PA; See Table 57, Page 535

Jelmyto (mitomycin pyelocalyceal solution) - PA; MB; See Table 57, Page 535

Jemperli (dostarlimab-gxly) - PA; MB; See Table 57, Page 535

Jentadueto (linagliptin / metformin); BP; See Table 26, Page 330

Jentadueto XR (linagliptin / metformin extended-release); BP; See Table 26, Page 330

Jesduvroq (daprodustat) - PA; MB; See Table 4, Page 111

Jevtana (cabazitaxel) - PA; MB; See Table 57, Page 535

Jivi (antihemophilic factor, recombinant pegylated-aucl-Jivi); PD; See Table 80, Page 857

Joenja (leniolisib) - PA; See Table 65, Page 693

Jornay PM (methylphenidate extended-release-Jornay PM) - PA; See Table 31, Page 372; See Table 71, Page 741

Journavx (suzetrigine) - PA < 18 years and PA > 29 units/60 days; PD; See Table 8, Page 159

Jublia (efinaconazole) - PA; See Table 28, Page 353

Juluca (dolutegravir / rilpivirine); PD; See Table 38, Page 420

Juxtapid (lomitapide) - PA; See Table 13, Page 200

Jylamvo (methotrexate 2 mg/mL oral solution) - PA; See Table 5, Page 116

Jynarque (tolvaptan-Jynarque) - PA; See Table 72, Page 765

Jynneos (smallpox / monkeypox vaccine, live); 1; See Table 32, Page 383

K

K-phos Neutral (potassium phosphate / dibasic sodium phosphate / monobasic sodium phosphate); A90

K-phos No.2 (potassium phosphate / sodium phosphate / phosphorus)

K-phos Original (potassium phosphate monobasic)

K-Tab (potassium chloride extended-release tablet); #, A90; See Table 6, Page 150

Kadcyla (ado-trastuzumab) - PA; MB; See Table 57, Page 535

Kalbitor (ecallantide) - PA; MB; See Table 60, Page 654

Kaletra (lopinavir / ritonavir); #, A90; See Table 38, Page 420

Kalydeco (ivacaftor) - PA; PD; See Table 21, Page 290

Kanjinti (trastuzumab-anns) - PA; MB; See Table 57, Page 535

Kanuma (sebelipase alfa) - PA; MB; See Table 65, Page 693

Kapspargo (metoprolol extended-release capsule) - PA; See Table 18, Page 249

Karbinal ER (carbinoxamine extended-release) - PA; A90; See Table 12, Page 195

Katerzia (amlodipine suspension) - PA; See Table 18, Page 249

Kazano (alogliptin / metformin) - PA; M90; See Table 26, Page 330

Kcentra (prothrombin complex concentrate, human)

Kebilidi (eladocagene exuparvovec-tneq) - PA; CO; See Table 65, Page 693

Kedrab (rabies immune globulin IM, human-Kedrab); See Table 1, Page 87

Kenalog (triamcinolone injection); #; See Table 5, Page 116

Kenalog (triamcinolone spray) - PA; A90; See Table 16, Page 229

Kepivance (palifermin); MB

Keppra (levetiracetam injection); MB; See Table 20, Page 275

Keppra (levetiracetam solution, tablet); #, A90; See Table 20, Page 275

Keppra XR (levetiracetam extended-release-Keppra XR); #, A90; See Table 20, Page 275

Kerendia (finerenone) - PA; See Table 18, Page 249

Kesimpta (ofatumumab prefilled syringe) - PA; See Table 52, Page 512

Ketalar (ketamine injection) - PA; MB; See Table 17, Page 235

ketamine injection - PA; MB; See Table 17, Page 235

ketoconazole cream, shampoo; A90; See Table 28, Page 353

ketoconazole foam - PA; A90; See Table 28, Page 353

ketoconazole tablet; A90; See Table 47, Page 478

ketoprofen extended-release - PA; A90; See Table 11, Page 188

ketoprofen; A90; See Table 11, Page 188

ketorolac 0.4% ophthalmic solution; A90; See Table 29, Page 358

ketorolac 0.45% ophthalmic solution; See Table 29, Page 358

ketorolac 0.5% ophthalmic solution; A90; See Table 29, Page 358

ketorolac nasal spray - PA; See Table 11, Page 188

ketorolac tablets and injection - PA > 20 units/30 days; See Table 11, Page 188

ketotifen; *, A90; See Table 29, Page 358

Keveyis (dichlorphenamide) - PA; See Table 72, Page 765

Kevzara (sarilumab) - PA; See Table 5, Page 116

Keytruda (pembrolizumab) - PA; MB; See Table 57, Page 535

Khapzory (levoleucovorin powder for injection) - PA; See Table 57, Page 535

Kimmtrak (tebentafusp-tebn) - PA; MB; See Table 57, Page 535

Kimyrsa (oritavancin) - PA; See Table 66, Page 707

Kineret (anakinra) - PA; See Table 5, Page 116

Kinrix (diphtheria / tetanus toxoids / acellular pertussis / poliovirus, inactivated vaccine); 1; See Table 32, Page 383

Kisqali (ribociclib) - PA; See Table 57, Page 535

Kisqali-Femara Co-Pack (ribociclib / letrozole) - PA; See Table 57, Page 535

Kisunla (donanemab-azbt) - PA; See Table 56, Page 529

Kitabis Pak (tobramycin inhalation solution-Kitabis Pak) - PA; BP, A90; See Table 35, Page 397

Klaron (sulfacetamide 10% lotion) - PA ≥ 21 years; #, A90; See Table 10, Page 180

Klonopin (clonazepam tablet) - PA < 6 years; #; See Table 69, Page 725; See Table 71, Page 741

Klor-Con (potassium chloride powder packet, extended-release tablet); #, A90; See Table 6, Page 150

Kloxxado (naloxone 8 mg nasal spray); PD; See Table 36, Page 410

Koate-DVI (antihemophilic factor, human-Koate-DVI); See Table 80, Page 857

Kogenate (antihemophilic factor, recombinant-Kogenate); PD; See Table 80, Page 857

Kombiglyze XR (saxagliptin / metformin extended-release) - PA; M90; See Table 26, Page 330

Konvomep (omeprazole / sodium bicarbonate suspension) - PA; See Table 3, Page 102

Korlym (mifepristone 300 mg) - PA; A90; See Table 22, Page 297

Korsuva (difelikefalin); MB

Koselugo (selumetinib) - PA; See Table 57, Page 535

Kovaltry (antihemophilic factor, recombinant-Kovaltry); PD; See Table 80, Page 857

Krazati (adagrasib) - PA; See Table 57, Page 535

Krintafel (tafenoquine) - PA > 2 units/365 days; See Table 35, Page 397

Krystexxa (pegloticase) - PA; MB; See Table 62, Page 670

Kuvan (sapropterin) - PA; See Table 65, Page 693

Kyleena (levonorgestrel-releasing intrauterine system 19.5 mg)

Kymriah (tisagenlecleucel) - PA; CO; See Table 75, Page 828

Kynmobi (apomorphine film) - PA; See Table 48, Page 485

Kyprolis (carfilzomib) - PA; MB; See Table 57, Page 535

L

L-Carnitine (levocarnitine)

l-glutamine - PA; See Table 45, Page 466

labetalol; M90; See Table 18, Page 249

lacosamide extended-release capsule - PA; See Table 20, Page 275

lacosamide injection; MB; See Table 20, Page 275

lacosamide tablet, solution; A90; See Table 20, Page 275

Lacrisert (hydroxypropyl cellulose ophthalmic insert); See Table 29, Page 358

lactase; *, A90

lactic acid / citric acid / potassium bitartrate vaginal gel

lactobacillus rhamnosus GG - PA ≥ 21 years; See Table 61, Page 658

lactulose packet - PA; See Table 61, Page 658

lactulose solution; A90; See Table 61, Page 658

Lagevrio (molnupiravir COVID EUA – December 23, 2021) - PA; See Table 72, Page 765

Lamictal (lamotrigine dispersible tablet) - PA < 6 years; #, A90; See Table 20, Page 275; See Table 71, Page 741

Lamictal (lamotrigine tablet starter kit) - PA; See Table 20, Page 275; See Table 71, Page 741

Lamictal (lamotrigine tablet) - PA < 6 years; #, A90; See Table 20, Page 275; See Table 71, Page 741

Lamictal ODT (lamotrigine orally disintegrating tablet starter kit) - PA; See Table 20, Page 275; See Table 71, Page 741

Lamictal ODT (lamotrigine orally disintegrating tablet) - PA; A90; See Table 20, Page 275; See Table 71, Page 741

Lamictal XR (lamotrigine extended-release tablet starter kit) - PA; See Table 20, Page 275; See Table 71, Page 741

Lamictal XR (lamotrigine extended-release tablet) - PA; A90; See Table 20, Page 275; See Table 71, Page 741

lamivudine / tenofovir disoproxil fumarate - PA; See Table 38, Page 420

lamivudine / zidovudine; A90; See Table 38, Page 420

lamivudine 10 mg/mL solution; A90; See Table 38, Page 420

lamivudine 100 mg tablet - PA > 1 unit/day; A90; See Table 44, Page 451

lamivudine 150 mg, 300 mg tablet; A90; See Table 38, Page 420

lamotrigine dispersible tablet - PA < 6 years; A90; See Table 20, Page 275; See Table 71, Page 741

lamotrigine extended-release tablet - PA; A90; See Table 20, Page 275; See Table 71, Page 741

lamotrigine extended-release tablet starter kit - PA; See Table 20, Page 275; See Table 71, Page 741

lamotrigine orally disintegrating tablet - PA; A90; See Table 20, Page 275; See Table 71, Page 741

lamotrigine orally disintegrating tablet starter kit - PA; See Table 20, Page 275; See Table 71, Page 741

lamotrigine tablet - PA < 6 years; A90; See Table 20, Page 275; See Table 71, Page 741

lamotrigine tablet starter kit - PA; See Table 20, Page 275; See Table 71, Page 741

Lampit (nifurtimox) - PA; See Table 35, Page 397

Lamzede (velmanase alfa-tycv) - PA; MB; See Table 65, Page 693

lanadelumab-flyo - PA; See Table 60, Page 654

lanolin; *; See Table 79, Page 854

Lanoxin (digoxin injection); MB; See Table 18, Page 249

lanreotide; See Table 22, Page 297

lansoprazole / amoxicillin / clarithromycin - PA; A90; See Table 3, Page 102

lansoprazole capsule - PA > 1 unit/day; M90; See Table 3, Page 102

lansoprazole orally disintegrating tablet; BP, M90; See Table 3, Page 102

lanthanum; A90

Lantus (insulin glargine-Lantus); BP, [PD]; See Table 26, Page 330

lapatinib; BP, A90; See Table 57, Page 535

laronidase - PA; MB; See Table 65, Page 693

larotrectinib - PA; See Table 57, Page 535

Lasix (furosemide tablet, injection); #, M90; See Table 18, Page 249

lasmiditan - PA; See Table 14, Page 211

latanoprost emulsion - PA; See Table 51, Page 506

latanoprost solution - Iyuzeh - PA; See Table 51, Page 506

latanoprost solution - Xalatan; M90; See Table 51, Page 506

latanoprostene - PA; See Table 51, Page 506

Latuda (lurasidone 20 mg, 40 mg, 60 mg, 120 mg) - PA < 10 years and PA > 1 unit/day; #, A90; See Table 24, Page 310; See Table 71, Page 741

Latuda (lurasidone 80 mg) - PA < 10 years and PA > 2 units/day; #, A90; See Table 24, Page 310; See Table 71, Page 741

Lazcluze (lazertinib) - PA; See Table 57, Page 535

lazertinib - PA; See Table 57, Page 535

lebrikizumab-lbkz - PA; [PD]; See Table 5, Page 116

lecanemab-irmb - PA; See Table 56, Page 529

ledipasvir / sofosbuvir - PA; [PD]; See Table 44, Page 451

leflunomide; A90

lemborexant - PA; See Table 15, Page 222; See Table 71, Page 741

Lemtrada (alemtuzumab 12 mg) - PA; MB; See Table 52, Page 512

lenacapavir - PA; See Table 38, Page 420

lenalidomide - PA; BP, A90; See Table 57, Page 535

leniolisib - PA; See Table 65, Page 693

Lenmeldy (atidarsagene autotemcel) - PA; CO; See Table 72, Page 765

lenvatinib - PA; See Table 57, Page 535

Lenvima (lenvatinib) - PA; See Table 57, Page 535

Leqembi (lecanemab-irmb) - PA; See Table 56, Page 529

Leqvio (inclisiran) - PA; See Table 13, Page 200

Lescol XL (fluvastatin extended-release) - PA; M90; See Table 13, Page 200

Letairis (ambrisentan) - PA; A90; See Table 43, Page 444

letermovir - PA; See Table 67, Page 715

letrozole; A90; See Table 57, Page 535

leucovorin; A90; See Table 57, Page 535

Leukeran (chlorambucil) - PA; See Table 57, Page 535

Leukine (sargramostim); See Table 4, Page 111

leuprolide - Fensolvi - PA; [PD]; See Table 2, Page 95

leuprolide 22.5 mg vial - PA; See Table 2, Page 95

leuprolide-Camcevi - PA; See Table 2, Page 95

leuprolide-Eligard - PA; See Table 2, Page 95

leuprolide-Lupron - PA; See Table 2, Page 95

levacetylleucine - PA; See Table 65, Page 693

levalbuterol inhalation solution - PA; A90; See Table 23, Page 302

levalbuterol inhaler; A90; See Table 23, Page 302

levamlodipine - PA; M90; See Table 18, Page 249

Levemir (insulin detemir); See Table 26, Page 330

levetiracetam extended-release-Elepsia XR - PA; See Table 20, Page 275

levetiracetam extended-release-Keppra XR; A90; See Table 20, Page 275

levetiracetam injection; MB; See Table 20, Page 275

levetiracetam solution, tablet; A90; See Table 20, Page 275

levetiracetam tablet for oral suspension - PA; BP; See Table 20, Page 275

Levo-T (levothyroxine-Levo-T); #, M90

levobunolol; M90; See Table 51, Page 506

levocarnitine

levocarnitine injection; MB

levocarnitine tablet, solution; A90

levocetirizine solution - PA; A90; See Table 12, Page 195

levocetirizine tablet; #, M90; See Table 12, Page 195

levodopa - PA; See Table 48, Page 485

levofloxacin ophthalmic solution - PA; A90; See Table 34, Page 393

levofloxacin; A90; See Table 35, Page 397; See Table 66, Page 707

levoketoconazole - PA; See Table 22, Page 297

levoleucovorin injection - PA; See Table 57, Page 535

levoleucovorin powder for injection - PA; See Table 57, Page 535

levomethylfolate tablet - PA > 1 unit/day; See Table 72, Page 765

levomilnacipran - PA; See Table 17, Page 235; See Table 71, Page 741

levonorgestrel / ethinyl estradiol

levonorgestrel / ethinyl estradiol / ferrous bisglycinate; M90

levonorgestrel / ethinyl estradiol 0.10/0.02 mg; M90

levonorgestrel / ethinyl estradiol 0.15/0.03 mg; M90

levonorgestrel / ethinyl estradiol 90/20 mcg; M90

levonorgestrel / ethinyl estradiol patch

levonorgestrel / ethinyl estradiol triphasic; M90

levonorgestrel / ethinyl estradiol-Loseasonique; M90

levonorgestrel / ethinyl estradiol-Quartette; M90

levonorgestrel / ethinyl estradiol-Seasonique; M90

levonorgestrel 1.5 mg tablet; *

levonorgestrel-releasing intrauterine system 13.5 mg

levonorgestrel-releasing intrauterine system 19.5 mg

levonorgestrel-releasing intrauterine system 52 mg-Liletta

levonorgestrel-releasing intrauterine system 52 mg-Mirena

levorphanol tablet - PA; See Table 8, Page 159

levothyroxine capsule-Tirosint - PA; M90; See Table 72, Page 765

levothyroxine-Ermeza

levothyroxine-Euthyrox; M90; See Table 72, Page 765

levothyroxine-Levo-T; M90

levothyroxine-Levoxyl; M90

levothyroxine-Synthroid; M90

levothyroxine-Thyquidity

M

metoprolol extended-release capsule - PA; See Table 18, Page 249

metoprolol extended-release tablet; M90; See Table 18, Page 249

metoprolol; M90; See Table 18, Page 249

metreleptin - PA; See Table 72, Page 765

Metro (metronidazole injection); #; See Table 66, Page 707

Metrocream (metronidazole 0.75% cream); A90; See Table 10, Page 180

Metrogel (metronidazole 1% gel) - PA; A90; See Table 10, Page 180

Metrolotion (metronidazole lotion) - PA; A90; See Table 10, Page 180

metronidazole 0.75% cream; A90; See Table 10, Page 180

metronidazole 0.75% gel; A90; See Table 10, Page 180

metronidazole 0.75% vaginal gel-Vandazole - PA; See Table 41, Page 436

metronidazole 0.75% vaginal gel; A90; See Table 41, Page 436

metronidazole 1% cream; See Table 10, Page 180

metronidazole 1% gel - PA; A90; See Table 10, Page 180

metronidazole 1.3% vaginal gel - PA; See Table 41, Page 436

metronidazole 125 mg tablet - PA; See Table 35, Page 397

metronidazole 250 mg, 500 mg tablet; A90; See Table 35, Page 397

metronidazole 375 mg capsule - PA; A90; See Table 35, Page 397

metronidazole injection; See Table 66, Page 707

metronidazole lotion - PA; A90; See Table 10, Page 180

metronidazole suspension - PA; See Table 35, Page 397

metyrosine; BP; See Table 18, Page 249

mexiletine; M90; See Table 18, Page 249

Miacalcin (calcitonin salmon injection) - PA; See Table 49, Page 492

micafungin; See Table 47, Page 478

Micardis (telmisartan); #, M90; See Table 18, Page 249

Micardis HCT (telmisartan / hydrochlorothiazide); #, M90; See Table 18, Page 249

miconazole / zinc oxide ointment; BP, A90; See Table 28, Page 353

miconazole buccal tablet - PA; See Table 47, Page 478

miconazole; *, A90; See Table 28, Page 353

Micrhogam (rho(d) immune globulin IM, human-Micrhogam); See Table 1, Page 87

midazolam injection; MB; See Table 69, Page 725

midazolam nasal spray - PA > 10 units/30 days; See Table 20, Page 275

midazolam syrup - PA < 6 years; See Table 69, Page 725; See Table 71, Page 741

midodrine; A90

midostaurin - PA; See Table 57, Page 535

Miebo (perfluorohexyloctane) - PA; See Table 29, Page 358

Mifeprex (mifepristone 200 mg); #; See Table 72, Page 765

mifepristone 200 mg; See Table 72, Page 765

mifepristone 300 mg - PA; A90; See Table 22, Page 297

migalastat - PA; See Table 65, Page 693

miglitol - PA; M90; See Table 26, Page 330

miglustat 100 mg - PA; BP; See Table 65, Page 693

miglustat 65 mg - PA; See Table 65, Page 693

Migranal (dihydroergotamine nasal spray) - PA; A90; See Table 14, Page 211

milnacipran

milrinone

Minastrin 24 Fe (ethinyl estradiol / norethindrone / ferrous fumarate chewable-Minastrin 24 Fe); #, M90

mineral oil; *, A90; See Table 61, Page 658

Minivelle (estradiol-Minivelle); BP, M90

Minocin (minocycline injection); See Table 66, Page 707

minocycline capsule; A90; See Table 35, Page 397

minocycline extended-release 45 mg, 90 mg, 135 mg tablet - PA; A90; See Table 35, Page 397

minocycline extended-release 55 mg, 65 mg, 80 mg, 105 mg, 115 mg tablet; A90; See Table 35, Page 397

minocycline injection; See Table 66, Page 707

minocycline tablet - PA; A90; See Table 35, Page 397

minoxidil; M90; See Table 18, Page 249

Miochol-E (acetylcholine chloride); MB; See Table 51, Page 506

Miostat (carbachol 0.01%); MB; See Table 51, Page 506

Miplyffa (arimoclomol) - PA; See Table 65, Page 693

mirabegron extended-release; BP, A90; See Table 46, Page 474

Mirapex ER (pramipexole extended-release) - PA; A90; See Table 48, Page 485

Mircera (methoxy polyethylene glycol / epoetin beta); MB; See Table 4, Page 111

Mirena (levonorgestrel-releasing intrauterine system 52 mg-Mirena)

mirikizumab-mrkz auto injection, prefilled syringe - PA; PD; See Table 5, Page 116

mirikizumab-mrkz vial - PA; See Table 5, Page 116

mirtazapine - PA < 6 years; A90; See Table 17, Page 235; See Table 71, Page 741

mirtazapine orally disintegrating tablet - PA; A90; See Table 17, Page 235; See Table 71, Page 741

Mirvaso (brimonidine 0.33% topical gel) - PA; A90; See Table 10, Page 180

mirvetuximab soravtansine-gynx - PA; MB; See Table 57, Page 535

misoprostol; A90

mitapivat - PA; See Table 65, Page 693

Mitigare (colchicine capsule) - PA; BP, A90; See Table 62, Page 670

mitomycin injection; MB; See Table 57, Page 535

mitomycin pyelocalyceal solution - PA; MB; See Table 57, Page 535

mitotane; See Table 57, Page 535

mitoxantrone; MB; See Table 57, Page 535

modafinil 100 mg - PA < 6 years and PA > 1.5 units/day; See Table 50, Page 500; See Table 71, Page 741

modafinil 200 mg - PA < 6 years and PA > 2 units/day; See Table 50, Page 500; See Table 71, Page 741

Moderna COVID-19 vaccine, mRNA; 1; See Table 32, Page 383

moexipril; M90; See Table 18, Page 249

N

Neupro (rotigotine transdermal system) - PA > 1 unit/day; See Table 48, Page 485

Neurontin (gabapentin capsule, solution, tablet) - PA < 6 years and PA > 3600 mg/day; #; See Table 71, Page 741; See Table 72, Page 765

Nevanac (nepafenac 0.1% ophthalmic suspension); See Table 29, Page 358

nevirapine extended-release - PA; A90; See Table 38, Page 420

nevirapine; A90; See Table 38, Page 420

Nexavar (sorafenib) - PA; BP, A90; See Table 57, Page 535

Nexiclon (clonidine extended-release 0.17 mg tablet) - PA; A90; See Table 18, Page 249; See Table 71, Page 741

Nexium (esomeprazole magnesium 2.5 mg, 5 mg, 10 mg suspension) - PA ≥ 2 years and PA > 1 unit/day; BP, M90; See Table 3, Page 102

Nexium (esomeprazole magnesium 20 mg, 40 mg suspension) - PA; BP, M90; See Table 3, Page 102

Nexium (esomeprazole magnesium capsule) - PA > 1 unit/day; #, M90; See Table 3, Page 102

Nexium IV (esomeprazole sodium IV) - PA; See Table 3, Page 102

Nexletol (bempedoic acid) - PA; See Table 13, Page 200

Nexlizet (bempedoic acid / ezetimibe) - PA; See Table 13, Page 200

Nexobrid (anacaulase-bcdb) - PA; MB; See Table 72, Page 765

Nexplanon (etonogestrel implant-Nexplanon)

Nexviazyme (avalglucosidase alfa-ngpt) - PA; MB; See Table 65, Page 693

Ngenla (somatrogon-ghla) - PA; See Table 9, Page 173

niacin extended-release tablet; M90; See Table 13, Page 200

niacin; *, M90; See Table 6, Page 150; See Table 13, Page 200

niacinamide; *, M90; See Table 6, Page 150; See Table 13, Page 200

nicardipine capsule - PA; M90; See Table 18, Page 249

nicardipine injection; MB; See Table 18, Page 249

nicotine gum, lozenge, patch; *, A90

nicotine inhalation system

nicotine nasal spray

nicotinic acid; *

Nicotrol Inhaler (nicotine inhalation system)

Nicotrol NS (nicotine nasal spray)

nifedipine capsule; M90; See Table 18, Page 249

nifedipine extended-release; M90; See Table 18, Page 249

nifedipine tablet; M90; See Table 18, Page 249

nifurtimox - PA; See Table 35, Page 397

nilotinib capsule; BP; See Table 57, Page 535

nilotinib tablet - PA; See Table 57, Page 535

nilutamide; A90; See Table 57, Page 535

nimodipine capsule - PA > 21 days treatment/365 days; See Table 18, Page 249

nimodipine oral solution - PA > 21 days treatment/365 days; See Table 18, Page 249

Ninlaro (ixazomib) - PA; See Table 57, Page 535

nintedanib - PA; See Table 40, Page 431

Nipent (pentostatin); MB; See Table 57, Page 535

niraparib - PA; See Table 57, Page 535

niraparib/abiraterone - PA; See Table 57, Page 535

nirmatrelvir / ritonavir 150 mg-100 mg - PA < 12 years and PA > 20 units/claim; PD; See Table 72, Page 765

nirmatrelvir / ritonavir 300-100 mg - PA < 12 years and PA > 30 units/claim; PD; See Table 72, Page 765

nirmatrelvir / ritonavir 300/150-100 mg; PD; See Table 72, Page 765

nirogacestat - PA; See Table 57, Page 535

nirsevimab-alip - PA ≥ 8 months of age; See Table 37, Page 417

nisoldipine - PA; M90; See Table 18, Page 249

nitazoxanide - PA; See Table 35, Page 397

nitisinone

nitisinone; A90

Nitro-Bid (nitroglycerin 2% ointment); #, A90; See Table 18, Page 249

Nitro-Dur (nitroglycerin patch); #, M90; See Table 18, Page 249

nitrofurantoin 25 mg/5 mL suspension - PA; A90; See Table 35, Page 397

nitrofurantoin 50 mg/5 mL suspension - PA; A90; See Table 35, Page 397

nitrofurantoin macrocrystals; A90; See Table 35, Page 397

nitrofurantoin monohydrate / macrocrystals; A90; See Table 35, Page 397

nitroglycerin 0.4% ointment

nitroglycerin 2% ointment; A90; See Table 18, Page 249

nitroglycerin injection; MB; See Table 18, Page 249

nitroglycerin lingual spray - PA; BP, A90; See Table 18, Page 249

nitroglycerin patch; M90; See Table 18, Page 249

nitroglycerin sublingual powder - PA; See Table 18, Page 249

nitroglycerin sublingual tablet; A90; See Table 18, Page 249

Nitrolingual (nitroglycerin lingual spray) - PA; BP, A90; See Table 18, Page 249

Nitrostat (nitroglycerin sublingual tablet); #, A90; See Table 18, Page 249

Nityr (nitisinone)

Nivestym (filgrastim-aafi); See Table 4, Page 111

nivolumab - PA; MB; See Table 57, Page 535

nivolumab / relatlimab-rmbw - PA; MB; See Table 57, Page 535

nivolumab-hyaluronidase-nvhy - PA; MB; See Table 57, Page 535

nizatidine 150 mg capsule - PA > 2 units/day; M90; See Table 3, Page 102

nizatidine 300 mg capsule - PA > 1 unit/day; M90; See Table 3, Page 102

Nocdurna (desmopressin sublingual tablet) - PA; See Table 46, Page 474

nogapendekin alfa inbakicept-pmln - PA; MB; See Table 57, Page 535

nonoxynol-9; A90

Norditropin (somatropin-Norditropin) - PA; See Table 9, Page 173

norethindrone / ethinyl estradiol / ferrous fumarate

norethindrone 0.35 mg; M90

norethindrone 5 mg; A90

norgestrel / ethinyl estradiol 0.3/0.03 mg; M90

norgestrel tablet-Opill; A90

O

P

phentolamine - PA; MB; See Table 72, Page 765
phenylephrine / ketorolac; MB
phenylephrine / promethazine; A90
phenylephrine ophthalmic solution
phenytoin chewable tablet; A90; See Table 20, Page 275
phenytoin extended 200 mg and 300 mg capsule; A90; See Table 20, Page 275
phenytoin extended 30 mg and 100 mg capsule; A90; See Table 20, Page 275
phenytoin injection; MB; See Table 20, Page 275
phenytoin suspension; A90; See Table 20, Page 275
Phesgo (pertuzumab / trastuzumab / hyaluronidase-zzxf) - PA; MB; See Table 57, Page 535
Phexxi (lactic acid / citric acid / potassium bitartrate vaginal gel)
Phos-Flur (sodium fluoride oral rinse); A90
Phoslyra (calcium acetate)
Phospholine Iodide (echothiophate iodide); See Table 51, Page 506
phytonadione; A90
Piasky (crovalimab-akkz) - PA; MB; See Table 72, Page 765
Pifeltro (doravirine); PD; See Table 38, Page 420
pilocarpine 0.4% ophthalmic solution - PA; See Table 72, Page 765
pilocarpine 1%, 2%, 4% ophthalmic solution; M90; See Table 51, Page 506
pilocarpine 1.25% ophthalmic solution - PA; See Table 72, Page 765
pilocarpine tablet; A90
pimavanserin - PA; See Table 24, Page 310
pimecrolimus - PA; A90; See Table 42, Page 439
pimozide - PA < 10 years; A90; See Table 24, Page 310; See Table 71, Page 741
pindolol; M90; See Table 18, Page 249
pioglitazone / metformin; M90; See Table 26, Page 330
pioglitazone; M90; See Table 26, Page 330
piperacillin / tazobactam; See Table 66, Page 707
piperonyl butoxide / pyrethrins; *; See Table 54, Page 520
Piqray (alpelisib-Piqray) - PA; See Table 57, Page 535
pirfenidone - PA; A90; See Table 40, Page 431
piroxicam; A90; See Table 11, Page 188
pirtobrutinib - PA; See Table 57, Page 535
pitavastatin calcium - PA; M90; See Table 13, Page 200
pitavastatin magnesium - PA; See Table 13, Page 200
pitolisant - PA; See Table 50, Page 500
plasminogen, human-tvmh - PA; See Table 65, Page 693
Plavix (clopidogrel); #, A90; See Table 58, Page 646
plazomicin - PA; See Table 66, Page 707
plecanatide - PA; See Table 61, Page 658
Plegridy (peginterferon beta-1a) - PA; See Table 52, Page 512
Plenvu (polyethylene glycol-electrolyte solution-Plenvu); See Table 61, Page 658
plerixafor; MB
pneumococcal 13-valent conjugate vaccine; 1; See Table 32, Page 383
pneumococcal 15-valent conjugate vaccine; See Table 32, Page 383
pneumococcal 20-valent conjugate vaccine; See Table 32, Page 383
pneumococcal 21-valent conjugate vaccine; See Table 32, Page 383
pneumococcal 23-valent polysaccharide vaccine; 1; See Table 32, Page 383
Pneumovax (pneumococcal 23-valent polysaccharide vaccine); 1; See Table 32, Page 383
podofilox gel; BP, A90; See Table 63, Page 674
podofilox solution; A90; See Table 63, Page 674
Pokonza (potassium chloride powder for oral solution) - PA; See Table 6, Page 150
polatuzumab vedotin-piiq - PA; MB; See Table 57, Page 535
poliovirus vaccine, inactivated; 1; See Table 32, Page 383
Polivy (polatuzumab vedotin-piiq) - PA; MB; See Table 57, Page 535
polyethylene glycol / sodium sulfate / potassium chloride / magnesium sulfate / sodium chloride - PA; See Table 61, Page 658
polyethylene glycol 3350; *, A90; See Table 61, Page 658
polyethylene glycol-electrolyte solution-Golytely; A90; See Table 61, Page 658
polyethylene glycol-electrolyte solution-Moviprep; BP, A90; See Table 61, Page 658
polyethylene glycol-electrolyte solution-Plenvu; See Table 61, Page 658
polyethylene glycol-electrolyte solution; A90; See Table 61, Page 658
pomalidomide - PA; See Table 57, Page 535
Pomalyst (pomalidomide) - PA; See Table 57, Page 535
Pombiliti (cipaglucosidase alfa-atga) - PA; MB; See Table 65, Page 693
ponatinib - PA; See Table 57, Page 535
ponesimod - PA; See Table 52, Page 512
Ponvory (ponesimod) - PA; See Table 52, Page 512
Portrazza (necitumumab) - PA; MB; See Table 57, Page 535
posaconazole injection - PA; BP; See Table 47, Page 478
posaconazole powder for oral suspension - PA; See Table 47, Page 478
posaconazole suspension - PA; A90; See Table 47, Page 478
posaconazole tablet; A90; See Table 47, Page 478
potassium bicarbonate; A90; See Table 6, Page 150
potassium chloride extended-release capsule; A90; See Table 6, Page 150
potassium chloride extended-release tablet; A90; See Table 6, Page 150
potassium chloride injection; See Table 6, Page 150
potassium chloride oral solution; A90; See Table 6, Page 150
potassium chloride powder for oral solution - PA; See Table 6, Page 150
potassium chloride powder packet, extended-release tablet; A90; See Table 6, Page 150
potassium citrate / citric acid; A90
potassium citrate / sodium citrate / citric acid; A90
potassium citrate; A90
potassium iodide - PA > 1 mL/day; See Table 72, Page 765
potassium phosphate / dibasic sodium phosphate / monobasic sodium phosphate;

Q

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S

Steqeyma (ustekinumab-stba prefilled syringe) - PA; See Table 5, Page 116

Steqeyma (ustekinumab-stba vial) - PA; MB; See Table 5, Page 116

Stimufend (pegfilgrastim-fpgk); See Table 4, Page 111

Stiolto (tiotropium / olodaterol) - PA; See Table 23, Page 302

stiripentol - PA; See Table 20, Page 275

Stivarga (regorafenib) - PA; See Table 57, Page 535

Strattera (atomoxetine) - PA < 6 years; #, A90; See Table 31, Page 372; See Table 71, Page 741

Strensiq (asfotase alfa) - PA; See Table 65, Page 693

streptomycin; See Table 66, Page 707

streptozocin; MB; See Table 57, Page 535

Stribild (elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil fumarate); See Table 38, Page 420

Striverdi (olodaterol) - PA; See Table 23, Page 302

Stromectol (ivermectin tablet); #; See Table 35, Page 397

Sublocade (buprenorphine extended-release injection); PD; See Table 36, Page 410

Suboxone (buprenorphine / naloxone film ≤ 24 mg/day); BP, PD; See Table 36, Page 410

Suboxone (buprenorphine / naloxone film) - PA > 32 mg/day; BP, PD; See Table 36, Page 410

Suboxone (buprenorphine / naloxone film) - PA > 90 days (> 24 mg/day and ≤ 32 mg/day); BP, PD; See Table 36, Page 410

succimer

Sucraid (sacrosidase) - PA; See Table 65, Page 693

sucralfate; A90

sucroferric oxyhydroxide

sufentanil injection; See Table 8, Page 159

Suflave (polyethylene glycol / sodium sulfate / potassium chloride / magnesium sulfate / sodium chloride) - PA; See Table 61, Page 658

Sular (nisoldipine) - PA; M90; See Table 18, Page 249

sulfacetamide / prednisolone sodium phosphate ophthalmic solution; A90; See Table 34, Page 393

sulfacetamide 10% lotion - PA ≥ 21 years; A90; See Table 10, Page 180

sulfacetamide ophthalmic ointment, solution; A90; See Table 34, Page 393

sulfadiazine; A90; See Table 35, Page 397

sulfamethoxazole / trimethoprim injection; See Table 66, Page 707

sulfamethoxazole / trimethoprim suspension; A90; See Table 35, Page 397

sulfamethoxazole / trimethoprim tablet; See Table 35, Page 397

Sulfamylon (mafenide); #, A90; See Table 41, Page 436

sulfasalazine delayed-release; A90; See Table 33, Page 390

sulfasalazine; A90; See Table 33, Page 390

Sulfatrim (sulfamethoxazole / trimethoprim suspension); #, A90; See Table 35, Page 397

sulindac; A90; See Table 11, Page 188

sumatriptan / naproxen - PA; A90; See Table 14, Page 211

sumatriptan 10 mg nasal spray - PA; See Table 14, Page 211

sumatriptan 5 mg, 20 mg nasal spray - PA > 18 units/30 days and PA < 6 years; A90; See Table 14, Page 211

sumatriptan injection-Imitrex - PA; See Table 14, Page 211

sumatriptan injection-Zembrace - PA; See Table 14, Page 211

sumatriptan tablet - PA > 18 units/30 days; A90; See Table 14, Page 211

sunitinib - PA; BP, A90; See Table 57, Page 535

Sunlenca (lenacapavir) - PA; See Table 38, Page 420

Sunosi (solriamfetol) - PA; See Table 50, Page 500

Supartz (hyaluronate-Supartz) - PA; MB; See Table 77, Page 846

Supprelin LA (histrelin) - PA; MB; See Table 2, Page 95

Suprep (sodium sulfate / potassium sulfate / magnesium sulfate); BP, A90; See Table 61, Page 658

Sustol (granisetron extended-release injection) - PA > 2 units/28 days; See Table 27, Page 347

Susvimo (ranibizumab); MB

Sutab (sodium sulfate / magnesium sulfate / potassium chloride) - PA; See Table 61, Page 658

Sutent (sunitinib) - PA; BP, A90; See Table 57, Page 535

sutimlimab-jome - PA; MB; See Table 72, Page 765

suvorexant - PA; See Table 15, Page 222; See Table 71, Page 741

suzetrigine - PA < 18 years and PA > 29 units/60 days; PD; See Table 8, Page 159

Syfovre (pegcetacoplan 150 mg/mL vial) - PA; MB; See Table 72, Page 765

Sylvant (siltuximab) - PA; MB; See Table 5, Page 116

Symbicort (budesonide / formoterol); BP, PD, A90; See Table 23, Page 302

Symbyax (olanzapine / fluoxetine) - PA; A90; See Table 17, Page 235; See Table 24, Page 310; See Table 71, Page 741

Symdeko (tezacaftor / ivacaftor) - PA; PD; See Table 21, Page 290

Symfi (efavirenz 600 mg / lamivudine 300 mg / tenofovir disoproxil fumarate 300 mg) - PA; A90; See Table 38, Page 420

Symfi Lo (efavirenz 400 mg / lamivudine 300 mg / tenofovir disoproxil fumarate 300 mg) - PA; A90; See Table 38, Page 420

Symlinpen (pramlintide); See Table 26, Page 330

Sympazan (clobazam film) - PA; See Table 20, Page 275

Symproic (naldemedine) - PA; See Table 61, Page 658

Symtuza (darunavir / cobicistat / emtricitabine / tenofovir alafenamide); PD; See Table 38, Page 420

Synagis (palivizumab) - PA; See Table 37, Page 417

Synalar (fluocinolone 0.025% cream); #, A90; See Table 16, Page 229

Synalar (fluocinolone ointment); #, A90; See Table 16, Page 229

Synalar (fluocinolone solution); #, A90; See Table 16, Page 229

Synarel (nafarelin) - PA; See Table 2, Page 95

Synjardy (empagliflozin / metformin); See Table 26, Page 330

Synjardy XR (empagliflozin / metformin extended-release); See Table 26, Page 330

Synojoynt (hyaluronate-Synojoynt) - PA; MB; See Table 77, Page 846

Synribo (omacetaxine mepesuccinate) - PA; See Table 57, Page 535

Synthroid (levothyroxine-Synthroid); #, M90

Synvisc (hylan G-F20-Synvisc) - PA; MB; See Table 77, Page 846

Synvisc-One (hylan G-F20-Synvisc-One) - PA; MB; See Table 77, Page 846

Syprine (trientine 250 mg capsule); BP, A90; See Table 65, Page 693

T

Tabrecta (capmatinib) - PA; See Table 57, Page 535

Taclonex (betamethasone / calcipotriene topical suspension) - PA; BP, A90; See Table 16, Page 229

tacrolimus extended-release capsule; See Table 5, Page 116

tacrolimus extended-release tablet - PA; See Table 5, Page 116

tacrolimus granules - PA; See Table 5, Page 116

tacrolimus immediate-release capsule; A90; See Table 5, Page 116

tacrolimus injection; MB; See Table 5, Page 116

tacrolimus topical; A90; See Table 42, Page 439

tadalafil suspension - PA; See Table 43, Page 444

tadalafil tablet-Adcirca - PA; A90; See Table 43, Page 444

tadalafil tablet-Cialis - PA; See Table 19, Page 272

Tadliq (tadalafil suspension) - PA; See Table 43, Page 444

tafamidis - PA; See Table 72, Page 765

tafasitamab-cxix - PA; See Table 57, Page 535

tafenoquine - PA > 2 units/365 days; See Table 35, Page 397

Tafinlar (dabrafenib) - PA; See Table 57, Page 535

tafluprost - PA; BP, M90; See Table 51, Page 506

tagraxofusp-erzs - PA; MB; See Table 57, Page 535

Tagrisso (osimertinib) - PA; See Table 57, Page 535

Takhzyro (lanadelumab-flyo) - PA; See Table 60, Page 654

talazoparib - PA; See Table 57, Page 535

Talicia (omeprazole / amoxicillin / rifabutin) - PA; See Table 3, Page 102

taliglucerase alfa - PA; MB; See Table 65, Page 693

talimogene laherparepvec - PA; MB; See Table 57, Page 535

talquetamab-tgvs - PA; MB; See Table 75, Page 828

Taltz (ixekizumab) - PA; [PD]; See Table 5, Page 116

Talvey (talquetamab-tgvs) - PA; MB; See Table 75, Page 828

Talzenna (talazoparib) - PA; See Table 57, Page 535

Tamiflu (oseltamivir 30mg) - PA > 20 units/ claim and PA > 40 units/ 365 days; #; See Table 39, Page 428

Tamiflu (oseltamivir 45 mg and 75 mg) - PA > 10 units/ claim and PA > 20 units/ 365 days; #; See Table 39, Page 428

Tamiflu (oseltamivir suspension) - PA > 180 mL/ claim and PA > 360 mL/ 365 days; #; See Table 39, Page 428

tamoxifen solution; See Table 57, Page 535

tamoxifen tablet; M90; See Table 57, Page 535

tamsulosin; M90; See Table 19, Page 272

Tapazole (methimazole); #, M90

tapinarof - PA; See Table 42, Page 439

Tarceva (erlotinib) - PA; A90; See Table 57, Page 535

Targretin (bexarotene); BP, A90; See Table 57, Page 535

tarlatamab-dlle - PA; MB; See Table 75, Page 828

Tarpeyo (budesonide 4 mg delayed-release capsule) - PA; See Table 5, Page 116

Tascenso ODT (fingolimod orally disintegrating tablet) - PA; See Table 52, Page 512

Tasigna (nilotinib capsule); BP; See Table 57, Page 535

tasimelteon - PA; BP, A90; See Table 50, Page 500

Tasmar (tolcapone) - PA; A90; See Table 48, Page 485

taurolidine/heparin - PA; MB; See Table 66, Page 707

tavaborole - PA; A90; See Table 28, Page 353

Tavalisse (fostamatinib) - PA; See Table 68, Page 719

Tavneos (avacopan) - PA; See Table 72, Page 765

Taytulla (ethinyl estradiol / norethindrone / ferrous fumarate); #, M90

tazarotene cream, gel - PA; A90; See Table 10, Page 180

tazarotene foam - PA; BP; See Table 10, Page 180

tazarotene lotion - PA; See Table 10, Page 180

tazemetostat - PA; See Table 57, Page 535

Tazverik (tazemetostat) - PA; See Table 57, Page 535

TBO-filgrastim; See Table 4, Page 111

tebentafusp-tebn - PA; MB; See Table 57, Page 535

Tecartus (brexucabtagene autoleucel) - PA; CO; See Table 75, Page 828

Tecelra (afamitresgene autoleucel) - PA; CO; See Table 75, Page 828

Tecentriq (atezolizumab) - PA; MB; See Table 57, Page 535

Tecentriq Hybreza (atezolizumab-hyaluronidase-tqjs) - PA; MB; See Table 57, Page 535

Tecfidera (dimethyl fumarate) - PA > 2 units/day; #, A90; See Table 52, Page 512

teclistamab-cqyv - PA; MB; See Table 75, Page 828

Tecvayli (teclistamab-cqyv) - PA; MB; See Table 75, Page 828

tedizolid injection - PA; See Table 66, Page 707

tedizolid tablet - PA; See Table 35, Page 397

teduglutide injection - PA; BP; See Table 61, Page 658

Teflaro (ceftaroline); BP; See Table 66, Page 707

Tegretol (carbamazepine-Tegretol) - PA < 6 years; #, A90; See Table 20, Page 275; See Table 71, Page 741

Tegretol XR (carbamazepine extended-release) - PA < 6 years; BP, A90; See Table 20, Page 275; See Table 71, Page 741

Tekturna (aliskiren) - PA; BP, M90; See Table 18, Page 249

telavancin - PA; See Table 66, Page 707

telmisartan / hydrochlorothiazide; M90; See Table 18, Page 249

telmisartan; M90; See Table 18, Page 249

telotristat ethyl - PA; See Table 22, Page 297

U

V

vitamin A (retinol); *, M90; See Table 6, Page 150

vitamin A and D ointment; *

vitamin A injection; See Table 6, Page 150

vitamin B complex; *, M90; See Table 6, Page 150

vitamin B-1 (thiamine); *, M90; See Table 6, Page 150

vitamin B-12 (cyanocobalamin); o, M90; See Table 6, Page 150

vitamin B-2 (riboflavin); *, M90; See Table 6, Page 150

vitamin B-3 (niacin); *, M90; See Table 6, Page 150; See Table 13, Page 200

vitamin B-6 (pyridoxine); *, M90; See Table 6, Page 150

vitamin C (ascorbic acid); *, M90; See Table 6, Page 150

vitamin D; *, M90; See Table 6, Page 150

vitamin E, oral; *, M90; See Table 6, Page 150

vitamins, multiple / minerals; *, M90; See Table 6, Page 150

vitamins, multiple; *, M90; See Table 6, Page 150

vitamins, pediatric; *, M90; See Table 6, Page 150

vitamins, prenatal; *, M90; See Table 6, Page 150

Vitrakvi (larotrectinib) - PA; See Table 57, Page 535

Vitrase (hyaluronidase, ovine); MB

Vivelle-Dot (estradiol-Vivelle-Dot); BP, M90

Vivimusta (bendamustine); MB; See Table 57, Page 535

Vivitrol (naltrexone injection); PD; See Table 36, Page 410

Vivjoa (oteseconazole) - PA; See Table 47, Page 478

Vivotif Berna (typhoid vaccine capsule); See Table 32, Page 383

Vizimpro (dacomitinib) - PA; See Table 57, Page 535

Vocabria (cabotegravir tablet); See Table 38, Page 420

voclosporin - PA; See Table 5, Page 116

Vogelxo (testosterone 1% gel tube, packet, pump) - PA; See Table 55, Page 523

von willebrand factor / coagulation factor VIII complex; See Table 80, Page 857

von willebrand factor, recombinant; See Table 80, Page 857

Vonjo (pacritinib) - PA; See Table 57, Page 535

vonoprazan - PA; See Table 3, Page 102

vonoprazan / amoxicillin - PA; See Table 3, Page 102

vonoprazan / amoxicillin / clarithromycin - PA; See Table 3, Page 102

Vonvendi (von willebrand factor, recombinant); See Table 80, Page 857

Voquezna (vonoprazan) - PA; See Table 3, Page 102

Voquezna Dual Pak (vonoprazan / amoxicillin) - PA; See Table 3, Page 102

Voquezna Triple Pak (vonoprazan / amoxicillin / clarithromycin) - PA; See Table 3, Page 102

Voranigo (vorasidenib) - PA; See Table 57, Page 535

vorapaxar - PA; See Table 58, Page 646

vorasidenib - PA; See Table 57, Page 535

voretigene neparvovec-rzyl - PA; CO; See Table 72, Page 765

voriconazole injection, tablet; See Table 47, Page 478

voriconazole suspension - PA; A90; See Table 47, Page 478

vorinostat; See Table 57, Page 535

vortioxetine - PA; See Table 17, Page 235; See Table 71, Page 741

Vosevi (sofosbuvir / velpatasvir / voxilaprevir) - PA; See Table 44, Page 451

vosoritide - PA; See Table 72, Page 765

Votrient (pazopanib) - PA; BP, A90; See Table 57, Page 535

Vowst (fecal microbiota spores, live-brpk) - PA; See Table 61, Page 658

Voxzogo (vosoritide) - PA; See Table 72, Page 765

Voydeya (danicopan) - PA; See Table 72, Page 765

Vpriv (velaglucerase alfa) - PA; MB; See Table 65, Page 693

Vraylar (cariprazine) - PA; PD; See Table 24, Page 310; See Table 71, Page 741

Vtama (tapinarof) - PA; See Table 42, Page 439

Vuity (pilocarpine 1.25% ophthalmic solution) - PA; See Table 72, Page 765

Vumerity (diroximel fumarate) - PA; See Table 52, Page 512

Vusion (miconazole / zinc oxide ointment); BP, A90; See Table 28, Page 353

vutrisiran - PA; PD, MB; See Table 72, Page 765

Vyalev (foscarbidopa / foslevodopa) - PA; See Table 48, Page 485

Vyepti (eptinezumab-jjmr) - PA; MB; See Table 14, Page 211

Vyjuvek (beremagene geperpavec-svdt) - PA; See Table 72, Page 765

Vyloy (zolbetuximab-clzb) - PA; MB; See Table 57, Page 535

Vyndamax (tafamidis) - PA; See Table 72, Page 765

Vyndaqel (tafamidis) - PA; See Table 72, Page 765

Vyondys 53 (golodirsen) - PA; See Table 76, Page 837

Vytorin (ezetimibe / simvastatin) - PA > 1 unit/day; #, M90; See Table 13, Page 200

Vyvanse (lisdexamfetamine capsule) - PA < 3 years or ≥ 21 years and PA > 2 units/day; BP; See Table 31, Page 372; See Table 71, Page 741

Vyvanse (lisdexamfetamine chewable tablet) - PA; BP; See Table 31, Page 372; See Table 71, Page 741

Vyvgart (efgartigimod alfa-fcab) - PA; MB; See Table 72, Page 765

Vyvgart Hytrulo (efgartigimod alfa-fcab and hyaluronidase-qvfc) - PA; MB; See Table 72, Page 765

Vyxeos (daunorubicin / cytarabine) - PA; MB; See Table 57, Page 535

Vyzulta (latanoprostene) - PA; See Table 51, Page 506

W

Wainua (eplontersen) - PA; See Table 72, Page 765

Wakix (pitolisant) - PA; See Table 50, Page 500

warfarin; A90; See Table 58, Page 646

Wegovy (semaglutide injection-Wegovy for Health Safety Net) - PA; HSNE; See Table 82, Page 874

Wegovy (semaglutide injection-Wegovy for MassHealth) - PA; HSNE; See Table 81, Page 865

Welchol (colesevelam); #, M90; See Table 13, Page 200; See Table 26, Page 330

Welireg (belzutifan) - PA; See Table 57, Page 535

Wellbutrin SR (bupropion hydrochloride sustained-release-Wellbutrin SR) - PA < 6 years; #, A90; See Table 17, Page 235; See Table 71, Page 741

Wellbutrin XL (bupropion hydrochloride extended-release 150 mg, 300 mg tablet) - PA < 6 years and PA > 1 unit/day; #, A90; See Table 17, Page 235; See Table 71, Page 741

Wilate (von willebrand factor / coagulation factor VIII complex); See Table 80, Page 857

Winlevi (clascoterone) - PA; See Table 10, Page 180

Winrevair (sotatercept-csrk) - PA; See Table 43, Page 444

Winrho SDF (rho(d) immune globulin IV, human-Winrho SDF); MB; See Table 1, Page 87

witch hazel; *, A90

X

Xaciato (clindamycin vaginal gel) - PA; See Table 41, Page 436

Xadago (safinamide) - PA; See Table 48, Page 485

Xalatan (latanoprost solution - Xalatan); #, M90; See Table 51, Page 506

Xalkori (crizotinib) - PA; See Table 57, Page 535

Xanax (alprazolam tablet) - PA < 6 years; #; See Table 69, Page 725; See Table 71, Page 741

Xanax XR (alprazolam extended-release) - PA < 6 years and PA > 2 units/day; #; See Table 69, Page 725; See Table 71, Page 741

xanomeline / trospium - PA; See Table 24, Page 310; See Table 71, Page 741

Xarelto (rivaroxaban 10 mg, 15 mg, 20 mg tablet, starter pack); BP; See Table 58, Page 646

Xarelto (rivaroxaban 2.5 mg tablet) - PA > 2 units/day; BP, A90; See Table 58, Page 646

Xarelto (rivaroxaban suspension) - PA ≥ 18 years; See Table 58, Page 646

Xatmep (methotrexate 2.5 mg/mL oral solution) - PA; See Table 5, Page 116

Xcopri (cenobamate) - PA; See Table 20, Page 275

Xdemvy (lotilaner) - PA; See Table 29, Page 358

Xeljanz (tofacitinib) - PA; BP; See Table 5, Page 116

Xeljanz XR (tofacitinib extended-release) - PA; BP; See Table 5, Page 116

Xeloda (capecitabine); #, A90; See Table 57, Page 535

Xelpros (latanoprost emulsion) - PA; See Table 51, Page 506

Xelstrym (dextroamphetamine transdermal) - PA; See Table 31, Page 372; See Table 71, Page 741

Xembify (immune globulin subcutaneous injection, human-klhw) - PA; See Table 1, Page 87

Xenazine (tetrabenazine) - PA; M90; See Table 74, Page 824

Xenical (orlistat) - PA; BP, HSNE, A90; See Table 81, Page 865

Xenpozyme (olipudase alfa-rpcp) - PA; MB; See Table 65, Page 693

Xeomin (incobotulinumtoxinA) - PA; See Table 30, Page 365

Xepi (ozenoxacin) - PA; See Table 41, Page 436

Xerava (eravacycline) - PA; See Table 66, Page 707

Xerese (acyclovir / hydrocortisone); See Table 67, Page 715

Xermelo (telotristat ethyl) - PA; See Table 22, Page 297

Xgeva (denosumab-Xgeva) - PA; See Table 49, Page 492

Xhance (fluticasone propionate 93 mcg nasal spray) - PA; See Table 25, Page 326

Xiaflex (collagenase clostridium histolyticum) - PA; See Table 72, Page 765

Xifaxan (rifaximin 200 mg); See Table 35, Page 397

Xifaxan (rifaximin 550 mg) - PA; See Table 35, Page 397

Xigduo XR (dapagliflozin / metformin extended-release); BP, M90; See Table 26, Page 330

Xiidra (lifitegrast) - PA; See Table 29, Page 358

Xipere (triamcinolone ophthalmic suspension-Xipere); MB

Xofluza (baloxavir) - PA; See Table 39, Page 428

Xolair (omalizumab) - PA; See Table 64, Page 679

Xolremdi (mavorixafor) - PA; See Table 4, Page 111

Xopenex HFA (levalbuterol inhaler); #, A90; See Table 23, Page 302

Xospata (gilteritinib) - PA; See Table 57, Page 535

Xphozah (tenapanor 20 mg, 30 mg tablet) - PA; See Table 72, Page 765

Xpovio (selinexor) - PA; See Table 57, Page 535

Xromi (hydroxyurea solution) - PA; See Table 45, Page 466

Xtandi (enzalutamide) - PA; See Table 57, Page 535

Xultophy (insulin degludec / liraglutide) - PA; See Table 26, Page 330

Xuriden (uridine triacetate) - PA; See Table 65, Page 693

Xylocaine (lidocaine vial); #

Xylocaine-Epi (lidocaine / epinephrine); #

Xylocaine-MPF (lidocaine vial, preservative free); #

Xyntha (antihemophilic factor, recombinant-Xyntha); PD; See Table 80, Page 857

Xyosted (testosterone enanthate) - PA; See Table 55, Page 523

Xyrem (sodium oxybate) - PA; BP; See Table 50, Page 500

Xywav (calcium oxybate / magnesium oxybate / potassium oxybate / sodium oxybate) - PA; See Table 50, Page 500

Y

Yasmin (ethinyl estradiol / drospirenone-Yasmin); #, M90

Yaz (ethinyl estradiol / drospirenone-Yaz); #, M90

Ycanth (cantharidin) - PA; PD, MB; See Table 63, Page 674

yellow fever vaccine, live; See Table 32, Page 383

yellow fever vaccine; See Table 32, Page 383

Yervoy (ipilimumab) - PA; MB; See Table 57, Page 535

Yescarta (axicabtagene ciloleucel) - PA; CO; See Table 75, Page 828

Yesintek (ustekinumab-kfce 130 mg/26 mL vial) - PA; MB; See Table 5, Page 116

Yesintek (ustekinumab-kfce prefilled syringe, 45 mg/0.5 mL vial) - PA; See Table 5, Page 116

YF-Vax (yellow fever vaccine); See Table 32, Page 383

Yonsa (abiraterone 125 mg) - PA; See Table 57, Page 535

Yorvipath (palopegteriparatide) - PA; See Table 49, Page 492

Yuflyma (adalimumab-aaty) - PA; See Table 5, Page 116

Yupelri (revefenacin) - PA; See Table 23, Page 302

Yusimry (adalimumab-aqvh) - PA; See Table 5, Page 116

Yutiq (fluocinolone ophthalmic implant-Yutiq); MB

Z

zafirlukast - PA; M90; See Table 40, Page 431

zaleplon - PA < 6 years and PA > 1 unit/day; See Table 15, Page 222; See Table 71, Page 741

Zaltrap (ziv-aflibercept) - PA; MB; See Table 57, Page 535

Zanaflex (tizanidine capsule) - PA; A90; See Table 7, Page 155

Zanaflex (tizanidine tablet); #, A90; See Table 7, Page 155

zanamivir - PA < 5 years and PA > 20 inhalations/ claim and PA > 40 inhalations/ 365 days; See Table 39, Page 428

zanidatamab-hrii - PA; MB; See Table 57, Page 535

Zanosar (streptozocin); MB; See Table 57, Page 535

zanubrutinib - PA; See Table 57, Page 535

Zarontin (ethosuximide); #, A90; See Table 20, Page 275

Zarxio (filgrastim-sndz); See Table 4, Page 111

zavegepant - PA; See Table 14, Page 211

Zavesca (miglustat 100 mg) - PA; BP; See Table 65, Page 693

Zavzpret (zavegepant) - PA; See Table 14, Page 211

Zegalogue (dasiglucagon); See Table 78, Page 848

Zegerid (omeprazole / sodium bicarbonate capsule); #, M90; See Table 3, Page 102

Zegerid (omeprazole / sodium bicarbonate powder for oral suspension) - PA; M90; See Table 3, Page 102

Zejula (niraparib) - PA; See Table 57, Page 535

Zelapar (selegiline orally disintegrating tablet) - PA; See Table 48, Page 485

Zelboraf (vemurafenib) - PA; See Table 57, Page 535

Zemaira (alpha-1-proteinase inhibitor, human-Zemaira); MB

Zembrace (sumatriptan injection-Zembrace) - PA; See Table 14, Page 211

Zemdri (plazomicin) - PA; See Table 66, Page 707

Zemplar (paricalcitol capsule) - PA; M90; See Table 6, Page 150

Zemplar (paricalcitol injection); MB; See Table 6, Page 150

zenocutuzumab-zbco - PA; MB; See Table 57, Page 535

Zenpep DR (pancrelipase-Zenpep DR); See Table 65, Page 693

Zepatier (elbasvir / grazoprevir) - PA; See Table 44, Page 451

Zepbound (tirzepatide-Zepbound for Health Safety Net) - PA; HSNE; See Table 82, Page 874

Zepbound (tirzepatide-Zepbound for MassHealth) - PA; PD, HSNE; See Table 81, Page 865

Zeposia (ozanimod for multiple sclerosis) - PA; See Table 52, Page 512

Zeposia (ozanimod for ulcerative colitis) - PA; See Table 5, Page 116

Zepzelca (lurbinectedin) - PA; MB; See Table 57, Page 535

Zerbaxa (ceftolozane / tazobactam) - PA; See Table 66, Page 707

Zerviate (cetirizine ophthalmic solution) - PA; See Table 29, Page 358

Zestoretic (lisinopril / hydrochlorothiazide); #, M90; See Table 18, Page 249

Zestril (lisinopril); #, M90; See Table 18, Page 249

Zetia (ezetimibe); #, M90; See Table 13, Page 200

Zetonna (ciclesonide 37 mcg nasal aerosol) - PA > 1 inhaler/30 days; See Table 25, Page 326

Ziagen (abacavir); #, A90; See Table 38, Page 420

Ziana (clindamycin / tretinoin-Ziana) - PA; A90; See Table 10, Page 180

zidovudine; A90; See Table 38, Page 420

Ziextenzo (pegfilgrastim-bmez); See Table 4, Page 111

Ziihera (zanidatamab-hrii) - PA; MB; See Table 57, Page 535

Zilbrysq (zilucoplan) - PA; See Table 72, Page 765

zileuton - PA; See Table 40, Page 431

zileuton extended-release - PA; See Table 40, Page 431

Zilretta (triamcinolone extended-release injectable suspension) - PA; MB; See Table 5, Page 116

zilucoplan - PA; See Table 72, Page 765

Zimhi (naloxone 5 mg / 0.5 mL syringe); See Table 36, Page 410

zinc oxide; *; See Table 79, Page 854

zinc sulfate; A90

Zinecard (dexrazoxane); #

Zinplava (bezlotoxumab) - PA; See Table 61, Page 658

Zioptan (tafluprost) - PA; BP, M90; See Table 51, Page 506

ziprasidone capsule - PA < 10 years and PA > 2 units/day; A90; See Table 24, Page 310; See Table 71, Page 741

ziprasidone injection; See Table 24, Page 310

Zirabev (bevacizumab-bvzr) - PA; MB; See Table 57, Page 535

Zirgan (ganciclovir ophthalmic gel)

Zithromax (azithromycin injection, suspension, tablet); #, A90; See Table 35, Page 397

Zithromax (azithromycin powder packet) - PA; A90; See Table 35, Page 397

Zithromax (azithromycin); #, A90; See Table 66, Page 707

Zituvimet (sitagliptin / metformin - Zituvimet) - PA; See Table 26, Page 330

Zituvimet XR (sitagliptin / metformin extended-release - Zituvimet XR) - PA; See Table 26, Page 330

Zituvio (sitagliptin-Zituvio) - PA; BP, M90; See Table 26, Page 330

ziv-aflibercept - PA; MB; See Table 57, Page 535

Zocor (simvastatin 5 mg, 10 mg, 20 mg, 40 mg) - PA > 1.5 units/day; #, M90; See Table 13, Page 200

Zofran (ondansetron tablet); #, A90; See Table 27, Page 347

Zokinvy (lonafarnib) - PA; See Table 72, Page 765

zolbetuximab-clzb - PA; MB; See Table 57, Page 535

zoledronic acid 4 mg; MB; See Table 49, Page 492

zoledronic acid 5 mg; MB; See Table 49, Page 492

Zolgensma (onasemnogene abeparvovec-xioi) - PA; CO, PD; See Table 76, Page

MassHealth Evaluation Criteria
Table 1 - Immune Globulins

Drug Category: Vaccines and Immune Serums

Medication Class/Individual Agents: Immune Serums

I. Prior-Authorization Requirements

Immune Globulins				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
antithymocyte globulin, equine	Atgam			**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** ***Please note: Gammagard, Gammaked, and Gamunex-C can be administered subcutaneously for primary immunodeficiency disorders (PID), or intravenously for PID as well as other indications.*** *Rate and Route of Administration:* • Administer only at rate, route, and concentration indicated for product; an IV administration rate that is too rapid may lead to a precipitous drop in blood pressure, fluid overload, and a possible thrombotic event. Cautious use in patients with history of cardiovascular disease or thrombotic episodes. *Renal Risk:* • IGIV (human) products have been associated with renal dysfunction, acute renal failure, and osmotic nephrosis. Risk factors include age >/= 66 years, preexisting renal dysfunction, volume depletion, concurrent use of nephrotoxic drugs, diabetes, and sepsis. *Hypersensitivity Reactions:* • Reportedly rare, however incidence may increase with use of large IM doses or repeated injections of immune
antithymocyte globulin, rabbit	Thymoglobulin			
cytomegalovirus immune globulin IV, human	Cytogam		MB	
hepatitis B immune globulin IM, human-Hyperhep B	Hyperhep B			
hepatitis B immune globulin IM, human-Nabi-HB	Nabi-HB			
hepatitis B immune globulin IV, human-Hepagam B	Hepagam B			
immune globluin IV, human-stwk	Alyglo	PA		
immune globulin IM, human-Gamastan S/D	Gamastan S/D	PA		
immune globulin injection, human-Gammagard	Gammagard	PA		
immune globulin injection, human-Gammaked	Gammaked	PA		
immune globulin injection, human-Gamunex-C	Gamunex-C	PA		
immune globulin IV, human-Bivigam	Bivigam	PA		
immune globulin IV, human-Flebogamma	Flebogamma	PA		
immune globulin IV, human-Gammagard S/D	Gammagard S/D	PA		
immune globulin	Gammaplex	PA		

Immune Globulins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
IV, human-Gammaplex			
immune globulin IV, human-ifas	Panzyga	PA	
immune globulin IV, human-Octagam	Octagam	PA	
immune globulin IV, human-Privigen	Privigen	PA	
immune globulin IV, human-slra	Asceniv	PA	
immune globulin subcutaneous injection, human / hyaluronidase human recombinant	Hyqvia	PA	
immune globulin subcutaneous injection, human-Cuvitru	Cuvitru	PA	
immune globulin subcutaneous injection, human-hipp	Cutaquig	PA	
immune globulin subcutaneous injection, human-Hizentra	Hizentra	PA	
immune globulin subcutaneous injection, human-klhw	Xembify	PA	
rabies immune globulin IM, human-Hyperrab	Hyperrab		
rabies immune globulin IM, human-Kedrab	Kedrab		
rho(d) immune globulin IM, human-Hyperrho	Hyperrho		
rho(d) immune globulin IM, human-Micrhogam	Micrhogam		
rho(d) immune globulin IM, human-Rhogam	Rhogam		
rho(d) immune globulin IV, human-Rhophylac	Rhophylac		MB
rho(d) immune globulin IV, human-Winrho SDF	Winrho SDF		MB

Clinical Notes

globulins.

Live Virus Vaccines (measles, mumps, rubella, varicella):

- Antibodies present in immune globulin preparations may interfere with the immune response of live virus vaccines, especially when large doses of immunoglobulins are given. For many immune globulins, a live virus vaccine should not be administered within 3 months of immune globulin administration. A few immune globulins require an even longer period (5-11 months) before a live virus vaccine should be given. Check individual manufacturer's recommendations for each product.

Immune Globulins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
tetanus immune globulin IM, human	Hypertet		

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Chronic inflammatory demyelinating polyneuropathy (CIDP)
- Dermatomyositis in adults (DM)
- Immune thrombocytopenia (ITP)
- Kawasaki disease (mucocutaneous lymph node syndrome)
- Multifocal Motor Neuropathy (MMN)
- Prevention of recurrent infection in B-cell chronic lymphocytic leukemia (CLL)
- Primary immunodeficiency disorder (e.g., primary/congenital agammaglobulinemia, severe combined immunodeficiency (SCID), Wiskott-Aldrich Syndrome, common variable immunodeficiency (CVID), hypogammaglobulinemia, X-linked agammaglobulinemia)

non-FDA-approved, for example:

- Antibody mediated rejection (AMR)
- Autoimmune autonomic ganglionopathy (AAG)
- Autoimmune encephalitis, including anti-NMDA receptor encephalitis
- Autoimmune small fiber neuropathy
- CMV-solid organ transplant
- Guillain-Barré Syndrome
- Immune-mediated necrotizing myopathy (IMNM)
- Immune neutropenia [Autoimmune neutropenia (AIN), Chronic benign neutropenia]
- Interstitial lung disease (ILD)
- Multiple myeloma
- Myasthenia gravis
- Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS)
- Pemphigus vulgaris (PV)
- Polymyositis (PM)
- Prevention of recurrent infection in pediatric HIV members
- Specific antibody deficiency (SAD)
- Stiff person syndrome (SPS)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Antibody mediated rejection (AMR)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Autoimmune encephalitis, anti-NMDA receptor encephalitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested dose is 2 g/kg/day divided over two to five days, followed by 1 g/kg once monthly; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Autoimmune small fiber neuropathy and autoimmune autonomic ganglionopathy (AAG)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested dose is 1 g/kg/monthly, administered in weekly divided doses, up to a maximum of 2 g/kg monthly; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Chronic inflammatory demyelinating polyneuropathy

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing for member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

CMV-Solid organ transplant

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- member will also receive antiviral therapy with ganciclovir, foscarnet, or cidofovir; **and**
- for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Dermatomyositis in adults
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - one of the following:
    - member has severe disease; **or**
    - inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, chloroquine, hydroxychloroquine, methotrexate, mycophenolate mofetil, rituximab; **and**
  - appropriate dosing for member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Gamastan S/D
- Documentation of the following is required:
  - one of the following:
    - use for protection against Hepatitis A virus in unvaccinated member who has been exposed to the virus in the previous 2 weeks **OR** cannot receive hepatitis A vaccine (i.e., hypersensitivity or child less than one year of age); **or**
    - use to prevent or modify symptoms of measles if exposed within the last 6 days; **or**
    - use for passive immunization against varicella in immunosuppressed member when Varicella-Zoster Immune Globulin (human) is not available; **or**
    - use for post-exposure prophylaxis of rubella in a pregnant member; **and**
  - appropriate dosing for member and diagnosis.

Guillain-Barré Syndrome
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested dose is ≤ 2 g/kg; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Immune-mediated necrotizing myopathy (IMNM)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - one of the following:
    - member has severe disease; **or**
    - inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, chloroquine, cyclophosphamide, cyclosporin, hydroxychloroquine, methotrexate, mycophenolate mofetil, plasma exchange, rituximab, tacrolimus; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Immune neutropenia (AIN, Chronic benign neutropenia)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - recurrent infections despite prophylactic antibiotics and colony-stimulating factors; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Immune thrombocytopenia

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - platelets < 30,000 /μL; **or**
    - clinically significant bleeding; **or**
    - history of significant bleeding; **or**
    - risk of significant bleeding; **or**
    - medical necessity to raise platelet count within 12 to 24 hours; **and**
  - appropriate dosing for member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Interstitial lung disease (ILD)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: azathioprine, mycophenolate mofetil; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Kawasaki disease

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - onset of illness occurred within previous 10 days; **or**
    - member has unexplained persistent fever; **or**
    - member has evidence of aneurysm; **or**
    - member exhibits signs of persistent inflammation; **and**
  - appropriate drug and dosing for the member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Multifocal motor neuropathy

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing for the member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Multiple myeloma

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - recurrent infections despite prophylactic antibiotics; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Myasthenia gravis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:

- member has severe or rapidly worsening disease, and requested agent will be used as initial therapy followed by longer-acting immunomodulating agents; **or**
- inadequate response, adverse reaction, or contraindication to all of the following: pyridostigmine, systemic corticosteroids, one immunomodulating agent (e.g., azathioprine, cyclosporine, mycophenolate); **and**

- for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one antibiotic or contraindication to all antibiotics; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Pemphigus vulgaris (PV)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - inadequate response, adverse reaction, or contraindication to rituximab; **and**
  - requested dose is ≤ 2 g/kg; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Polymyositis (PM)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - one of the following:
    - member has severe disease; **or**
    - inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, chloroquine, cyclophosphamide, cyclosporin, hydroxychloroquine, methotrexate, mycophenolate mofetil, plasma exchange, rituximab, tacrolimus; **and**
  - requested dose is 1 g/kg per day on 2 consecutive days every 4 weeks (total monthly dose: 2 g/kg); **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Prevention of recurrent infection in B-cell chronic lymphocytic leukemia

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing for member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Prevention of recurrent infection in pediatric HIV members

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is < 18 years of age; **and**
  - CD4 count is ≥ 200 cells/microliter (within the last three months); **and**
  - requested dose is 400 mg/kg every 28 days; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Primary immunodeficiency disorders

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - laboratory documentation supporting diagnosis (e.g., deficient serum IgG [or subclasses IgG1, IgG2, IgG3, and IgG4], IgM, and/or IgA levels, assessment of functional antibody production, immunophenotype of B cells [flow cytometry] or genetic testing); **and**
  - serum IgG (or subclasses IgG1, IgG2, IgG3, and IgG4), IgM, and/or IgA levels are provided via medical records or written on PA with dates drawn and reference ranges; **and**
  - appropriate dosing for the member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Specific antibody deficiency (SAD)

- Documentation of the following is required:
  - appropriate diagnosis with moderate or severe polysaccharide non-responsiveness; **and**
  - evidence of recurrent infections requiring antibiotic therapy; **and**
  - requested dose is 400 to 600 mg/kg IV every four weeks or a corresponding subcutaneous dose; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Stiff Person Syndrome (SPS)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one benzodiazepine or contraindication to all benzodiazepines; **and**
  - inadequate response, adverse reaction, or contraindication to baclofen; **and**
  - requested dose is 2 g/kg, divided over two to three infusions; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

MassHealth Evaluation Criteria

Table 2 - Hormones - Gonadotropin-Releasing Hormone Analogs

Drug Category: Hormones

Medication Class/Individual Agents: Gonadotropin-Releasing Hormone Analogs

I. Prior-Authorization Requirements

Hormones – Gonadotropin-Releasing Hormone Analogs			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
degarelix	Firmagon	PA	
elagolix	Orilissa	PA	
elagolix / estradiol / norethindrone	Oriahnn	PA	
histrelin	Supprelin LA	PA	MB
leuprolide - Fensolvi	Fensolvi PD	PA	
leuprolide 22.5 mg vial		PA	
leuprolide-Camcevi	Camcevi	PA	
leuprolide-Eligard	Eligard	PA	
leuprolide-Lupron	Lupron	PA	
nafarelin	Synarel	PA	
relugolix	Orgovyx	PA	
relugolix / estradiol / norethindrone	Myfembree	PA	
triptorelin-Trelstar	Trelstar	PA	MB
triptorelin-Triptodur	Triptodur	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- central precocious puberty (CPP) – Fensolvi, Lupron Ped, Supprelin LA, Synarel, Triptodur
- endometriosis – Lupron, Myfembree, Orilissa, Synarel
- prostatic cancer (advanced) – Camcevi, Eligard, Firmagon, leuprolide 22.5 mg vial, Lupron, Trelstar

- prostatic cancer (castration-sensitive, metastatic) – Orgovyx
- uterine leiomyomata – Lupron, Myfembree, Oriahnn

Non-FDA-approved, for example:

- abnormal uterine bleeding – Eligard, Fensolvi, leuprolide 22.5 mg vial, Lupron, Myfembree, Orilissa, Synarel, Triptodur
- catamenial epilepsy – Trelstar
- endometriosis - extended duration of therapy – Lupron, Myfembree, Orilissa, Synarel
- Gender Dysphoria – Eligard, Fensolvi, leuprolide 22.5 mg vial, Lupron, Lupron Ped, Supprelin LA, Triptodur
- GnRH stimulation test for CPP diagnosis – Fensolvi, Lupron Ped, Supprelin LA, Synarel, Triptodur
- ovarian suppression/preservation – Eligard, Fensolvi, Lupron
- paraphilia – Camcevi, Eligard, Fensolvi, Firmagon, leuprolide 22.5 mg vial, Lupron, Myfembree, Oriahnn, Orgovyx, Orilissa, Supprelin LA, Synarel, Trelstar, Triptodur
- premenstrual dysphoric disorder (PMDD) – Eligard, leuprolide 22.5 mg vial, Lupron, Myfembree, Orilissa, Synarel
- uterine leiomyomata - extended duration of therapy – Lupron, Myfembree, Oriahnn

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Abnormal uterine bleeding (Eligard, Fensolvi, leuprolide 22.5 mg vial, Lupron, Myfembree, Orilissa, Synarel, Triptodur)

- Documentation of the following is required:
  - severity of menstrual bleeding (e.g., anemia, hemoglobin levels, abdominal pain, interference with daily activities); **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: hormonal contraceptives, non-contraceptive estrogen-progestin formulations; **and**
  - inadequate response, adverse reaction, or contraindication to tranexamic acid; **and**
  - for Fensolvi, Myfembree, Orilissa, and Triptodur, inadequate response, adverse reaction, or contraindication to one of the following: Eligard, leuprolide 22.5 mg vial, Lupron; **and**
  - for Lupron Depot 7.5 mg, Lupron Depot 22.5 mg every three months, Lupron Depot 30 mg, and Lupron Depot 45 mg every six months, clinical rationale for use instead of the equivalent dose of Eligard; **and**

- one of the following:
  - if member is a surgical candidate, expected date of surgery; **or**
  - if member is not a surgical candidate, one of the following:
    - requested agent is Myfembree; **or**
    - member is being treated with add-back therapy for bone loss; **or**
    - yearly BMD scan has been performed to indicate that the member does not need to be treated for osteoporosis.

Advanced prostate cancer (Camcevi, Eligard, Firmagon, leuprolide 22.5 mg vial, Trelstar)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an oncologist or urologist; **and**
  - appropriate dose and frequency of the requested agent.

SmartPA: Claims for Camcevi, Eligard, and Firmagon will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for prostate cancer.†

Advanced prostate cancer (Lupron)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an oncologist or urologist; **and**
  - appropriate dose and frequency; **and**
  - for Lupron Depot 7.5 mg, Lupron Depot 22.5 mg, Lupron Depot 30 mg, and Lupron Depot 45 mg, clinical rationale for use instead of the equivalent dose of Eligard.

Advanced prostate cancer (Orgovyx)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an oncologist or urologist; **and**
  - appropriate dose and frequency; **and**
  - inadequate response, adverse reaction, or contraindication to Firmagon; **and**
  - inadequate response, adverse reaction, or contraindication to Eligard, leuprolide 22.5 mg vial, or Lupron.

Catamenial epilepsy (Trelstar)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or endocrinologist or consult notes from a neurologist or endocrinologist are provided; **and**
  - inadequate response or adverse reaction to two anticonvulsants; **and**
  - inadequate response or adverse reaction to one or contraindication to all progesterone therapy or synthetic progestin therapy; **and**
  - requested dose is 3.75 mg every four weeks.

Endometriosis (Lupron, Synarel)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dose and frequency of the requested agent; **and**
  - inadequate response or adverse reaction to one or contraindication to all non-steroidal anti-inflammatory drugs (NSAIDs); **and**
  - inadequate response or adverse reaction to one or contraindication to all hormonal contraceptives.

Endometriosis (Myfembree, Orilissa)

- Documentation of the following is required:

- appropriate diagnosis; **and**
- appropriate dose and frequency of the requested agent; **and**
- inadequate response or adverse reaction to one or contraindication to all non-steroidal anti-inflammatory drugs (NSAIDs); **and**
- inadequate response or adverse reaction to one or contraindication to all hormonal contraceptives; **and**
- inadequate response, adverse reaction, or contraindication to Lupron; **and**
- for Myfembree, requested quantity is ≤ one unit/day.

Endometriosis - extended duration of therapy (Lupron, Myfembree, Orilissa, Synarel)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - anticipated duration of therapy; **and**
  - for Lupron, Orilissa, and Synarel one of the following:
    - member is being treated with add-back therapy for bone loss; **or**
    - yearly bone mineral density (BMD) scan has been performed to indicate that the member does not need to be treated for osteoporosis.

Gender dysphoria (Eligard)

- Documentation of the following is required:
  - diagnosis of one of the following:
    - gender dysphoria; **or**
    - transgenderism; **or**
    - therapy after gender reassignment surgery; **and**
  - one of the following:
    - for the 7.5 mg syringe, requested quantity is ≤ one unit/28 days (one month); **or**
    - for the 22.5 mg syringe, requested quantity is ≤ one unit/84 days (three months); **or**
    - for the 30 mg syringe, requested quantity is ≤ one unit/112 days (four months); **or**
    - for the 45 mg syringe, requested quantity is ≤ one unit/168 days (six months).

SmartPA: Claims for Eligard 7.5 mg, 22.5 mg, 30 mg, and 45 mg syringe within quantity limits will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for gender dysphoria or personal history of gender reassignment surgery.†

Gender dysphoria (Fensolvi, Triptodur)

- Documentation of the following is required:
  - diagnosis of one of the following:
    - gender dysphoria; **or**
    - transgenderism; **or**
    - therapy after gender reassignment surgery; **and**
  - requested quantity is ≤ one unit/112 days (four months).

SmartPA: Claims for Fensolvi and Triptodur within quantity limits will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for gender dysphoria or personal history of gender reassignment surgery.†

Gender dysphoria (leuprolide 22.5 mg vial, Lupron, Lupron Ped)

- Documentation of the following is required:
  - diagnosis of one of the following:
    - gender dysphoria; **or**
    - transgenderism; **or**
    - therapy after gender reassignment surgery; **and**
  - for Lupron 7.5 mg, 22.5 mg, 30 mg, and 45 mg adult kit, clinical rationale for use instead of the equivalent dose of Eligard; **and**

- one of the following:
  - for leuprolide 14 mg 2-week kit, and 14 mg 2-week vial, requested quantity is ≤ two units/28 days (one month); **or**
  - for the 3.75 mg kit, 7.5 mg kit, 11.25 mg pediatric 1-month kit, and 15 mg pediatric kit, requested quantity is ≤ one unit/28 days (one month); **or**
  - for the 11.25 mg 3-month kit, 22.5 mg kit, 30 mg pediatric kit, and leuprolide 22.5 mg vial, requested quantity is ≤ one unit/84 days (three months); **or**
  - for the 30 mg adult kit, requested quantity is ≤ one unit/112 days (four months); **or**
  - for the 45 mg kit, requested quantity is ≤ one unit/168 days (six months).

SmartPA: Claims for leuprolide 14 mg 2-week kit, 14 mg 2-week vial, leuprolide 22.5 mg vial, Lupron 3.75 mg kit, 7.5 mg pediatric kit, 11.25 mg kit, 15 mg kit, 22.5 mg pediatric kit, 30 mg pediatric kit, and 45 mg pediatric kit within quantity limits will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for gender dysphoria or personal history of gender reassignment surgery.†

Gender dysphoria (Supprelin LA)

- Documentation of the following is required:
  - diagnosis of one of the following:
    - gender dysphoria; **or**
    - transgenderism; **or**
    - therapy after gender reassignment surgery; **and**
  - requested quantity is ≤ one unit/365 days (one year).

SmartPA: Claims for Supprelin LA within quantity limits will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for gender dysphoria or personal history of gender reassignment surgery.†

GnRH stimulation test for CPP diagnosis (Fensolvi, Lupron Ped, Supprelin LA, Synarel, Triptodur)

- Documentation of the following is required:
  - product will be used for a stimulation test to diagnose CPP.

Idiopathic or neurogenic central precocious puberty (CPP) (Fensolvi, Lupron Ped, Supprelin LA, Synarel, Triptodur)

- Documentation of the following is required:
  - diagnosis of CPP with onset of secondary sex characteristics before age eight years (female sex assigned at birth/biologic females) or nine years (male sex assigned at birth/biologic males); **and**
  - prescriber is a pediatric endocrinologist or consult notes from a pediatric endocrinologist are provided; **and**
  - appropriate dose and frequency; **and**
  - one of the following:
    - member is currently less than 11 years of age (female sex assigned at birth/biologic females) or 12 years of age (male sex assigned at birth/biologic males); **or**
    - member is ≥ 11 years of age and less than 12 years of age (female sex assigned at birth/biologic females) or ≥ 12 years of age and less than 13 years of age (male sex assigned at birth/biologic males) and requires one additional year of prolonged therapy due to developmental delay; **and**
  - for Triptodur, inadequate response or adverse reaction to one or contraindication to both of the following: Fensolvi, Lupron Ped.
- For recertification, member must be less than 11 years of age (female sex assigned at birth/biologic females) or less than 12 years of age (male sex assigned at birth/biologic males), or for member with developmental disability that requires extended treatment, member must be less than 12 years of age (female sex assigned at birth/biologic females) or less than 13 years of age (male sex assigned at birth/biologic males).

Ovarian suppression/preservation (Eligard, Fensolvi, Lupron)

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- member is currently being treated with a chemotherapeutic agent; **and**
- appropriate dose and frequency; **and**
- for Lupron Depot 7.5 mg, Lupron Depot 22.5 mg every three months, Lupron Depot 30 mg, and Lupron Depot 45 mg every six months, clinical rationale for use instead of the equivalent dose of Eligard.

Paraphilia (Camcevi, Eligard, Fensolvi, Firmagon, leuprolide 22.5 mg vial, Lupron, Myfembree, Oriahnn, Orgovyx, Orilissa, Supprelin LA, Synarel, Trelstar, Triptodur)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is under the care of a specialist (or being prescribed by specialist) to treat the disorder.

Premenstrual Dysphoric Disorder (PMDD) (Eligard, leuprolide 22.5 mg vial, Lupron, Myfembree, Orilissa, Synarel)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dose and frequency; **and**
  - inadequate response or adverse reaction to two or contraindication to all SSRIs; **and**
  - inadequate response or adverse reaction to one or contraindication to all hormonal contraceptives; **and**
  - for Lupron Depot 7.5 mg, Lupron Depot 22.5 mg, Lupron Depot 30 mg, and Lupron Depot 45 mg, clinical rationale for use instead of the equivalent dose of Eligard; **and**
  - for Myfembree and Orilissa, inadequate response or adverse reaction to one or contraindication to all of the following: Eligard, leuprolide 22.5 mg vial, Lupron; **and**
  - for Myfembree, requested quantity is ≤ one unit/day.

Uterine leiomyomata (Lupron, Myfembree, Oriahnn)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - anticipated surgery date or clinical rationale why surgical intervention is not appropriate; **and**
  - inadequate response or adverse reaction to one or contraindication to all hormonal contraceptives; **and**
  - for Oriahnn, both of the following:
    - inadequate response, adverse reaction, or contraindication to Lupron; **and**
    - requested quantity is ≤ two units/day; **and**
  - for Myfembree, both of the following:
    - inadequate response, adverse reaction, or contraindication to both of the following: Lupron, Oriahnn; **and**
    - requested quantity is ≤ one unit/day; **and**
  - appropriate dose and frequency.

Uterine leiomyomata - extended duration of therapy (Lupron, Myfembree, Oriahnn)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for Myfembree and Oriahnn, one of the following:
    - updated surgery date; **or**
    - clinical rationale why surgery is not an option; **or**
  - for Lupron, one of the following:
    - updated surgery date; **or**
    - all of the following:
      - clinical rationale why surgery is not an option; **and**
      - one of the following:
        - member is being treated with add-back therapy for bone loss; **or**

- yearly bone mineral density (BMD) scan has been performed to indicate that the member does not need to be treated for osteoporosis.

†**Note**: The decision on whether PA is required is based on information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria

Table 3 - Gastrointestinal Drugs - Histamine H2 Antagonists, Proton Pump Inhibitors, and Miscellaneous Gastroesophageal Reflux Agents

Drug Category: Gastrointestinal Drugs

Medication Class/Individual Agents: Histamine H2 Antagonists, Proton Pump Inhibitors, Miscellaneous Gastroesophageal Reflux Agents

I. Prior-Authorization Requirements

Gastrointestinal Drugs – Proton Pump Inhibitors (PPIs)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
dexlansoprazole	Dexilant	PA	BP, M90	**Optimize Dosing Regimen:** • For maximum efficacy, a PPI must be taken in a fasting state, just before or with breakfast. In general for members on PPIs, it is not necessary to prescribe other antisecretory agents (e.g., H_2 antagonists, prostaglandins). If an antisecretory agent is prescribed with a PPI, the PPI should not be taken within six hours of the H_2 antagonist or prostaglandin. **Once Daily (QD) Dosing versus Twice Daily (BID) Dosing:** • QD dosing is adequate for most individuals except for H. pylori treatment (PPI is BID for the first two weeks of therapy). For pathological hypersecretory conditions, such as Zollinger-Ellison syndrome, a BID PPI regimen may be needed for high total daily doses. When/if a second dose is prescribed, it should be taken just before the evening meal. **Apparent PPI Non-responder:** • Careful history should be obtained to ensure appropriate timing of drug administration and no significant drug interactions before prescribing a second dose or switching to another PPI. **Duration of Therapy:** • DU – four weeks (QD dosing) • GU – eight weeks (QD dosing) • H. pylori – two weeks (BID dosing) + two more weeks if DU using QD dosing and six more weeks if GU using QD dosing • acute symptomatic gastroesophageal reflux disease (GERD) – four to eight weeks (QD dosing) **Nasogastric (NG) Tube Administration:**
esomeprazole magnesium 2.5 mg, 5 mg, 10 mg suspension	Nexium	PA - ≥ 2 years and PA > 1 unit/day	BP, M90	
esomeprazole magnesium 20 mg, 40 mg suspension	Nexium	PA	BP, M90	
esomeprazole magnesium capsule	Nexium	PA - > 1 unit/day	# , M90	
esomeprazole sodium IV	Nexium IV	PA		
lansoprazole capsule	Prevacid	PA - > 1 unit/day	# , M90	
lansoprazole orally disintegrating tablet	Prevacid Solutab		BP, M90	
omeprazole / sodium bicarbonate capsule	Zegerid		# , M90	
omeprazole / sodium bicarbonate powder for oral suspension	Zegerid	PA	M90	
omeprazole / sodium bicarbonate suspension	Konvomep	PA		
omeprazole 10 mg		PA - > 1 unit/day	M90	
omeprazole 20 mg capsule		PA - > 4 units/day	M90	
omeprazole 40 mg		PA - > 2 units/day	M90	
omeprazole suspension	Prilosec	PA		
omeprazole suspension compounding kit	First-Omeprazole	PA		
pantoprazole 40	Protonix		BP, M90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
mg suspension				Omeprazole capsules, lansoprazole capsules, and esomeprazole capsules may be opened and mixed in a small amount of liquid (see specific product information for further information on liquids compatible with capsule contents and the recommended techniques for NG tube administration). **Tablet/Capsule Administration:** PPI tablets or the contents of PPI capsules should not be chewed, split, or crushed. For members who have difficulty swallowing PPI capsules, the capsule can be opened and the intact granules can be sprinkled on applesauce. See specific product information for further information on liquids and foods compatible with capsule contents.
pantoprazole IV	Protonix IV		#	
pantoprazole tablet	Protonix	PA - > 4 units/day	# , M90	
rabeprazole delayed-release capsule	Aciphex Sprinkle	PA		
rabeprazole delayed-release tablet	Aciphex	PA - > 1 unit/day	# , M90	

Gastrointestinal Drugs – Miscellaneous Gastroesophageal Reflux Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
metoclopramide nasal spray	Gimoti	PA		

Gastrointestinal Drugs – Combination H. Pylori Medication

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
bismuth subcitrate / metronidazole / tetracycline	Pylera		BP, A90	The separate ingredients of the combination products are available without prior authorization (PA). **Please note: lansoprazole, omeprazole, and pantoprazole are available without PA (within quantity limits).**
lansoprazole / amoxicillin / clarithromycin		PA	A90	
omeprazole / amoxicillin / rifabutin	Talicia	PA		
omeprazole / clarithromycin / amoxicillin	Omeclamox-Pak	PA		
vonoprazan / amoxicillin	Voquezna Dual Pak	PA		
vonoprazan / amoxicillin / clarithromycin	Voquezna Triple Pak	PA		

Gastrointestinal Drugs – Histamine H2 Antagonists

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
cimetidine solution		PA	A90	**Optimize Dosing Regimen:** • For duodenal ulcer (DU) or gastric ulcer (GU) treatment,
cimetidine tablet			*, M90	
famotidine				

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
injection				administer total daily dose between evening meal and bedtime; ulcer healing is directly proportional to degree of nocturnal acid reduction. **Duration of Therapy:** • DU – four weeks • GU – eight weeks
famotidine suspension			A90	
famotidine tablet	Pepcid		# , *, M90	
nizatidine 150 mg capsule		PA - > 2 units/day	M90	
nizatidine 300 mg capsule		PA - > 1 unit/day	M90	

Gastrointestinal Drugs – Potassium-Competitive Acid Blockers (PCABs)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
vonoprazan	Voquezna	PA		

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- active benign gastric ulcer
- diabetic gastroparesis
- extraesophageal symptoms/conditions secondary to gastric reflux (e.g., asthma, non-cardiac chest pain, etc.)
- GERD
- healing of erosive esophagitis, ulcerative GERD, DUs, GUs
- H. pylori eradication
- non-erosive reflux disease (NERD)
- non-ulcer or functional dyspepsia
- pathological hypersecretory syndromes (e.g., Zollinger-Ellison, Barrett's esophagus)
- reduction of risk of upper GI bleeding in critically ill patients

Non-FDA-approved, for example:

- extraesophageal symptoms/conditions secondary to gastric reflux (e.g., asthma, non-cardiac chest pain, etc.)
- GERD
- healing of erosive esophagitis, ulcerative GERD, DUs, GUs
- H. pylori eradication
- pathological hypersecretory syndromes (e.g., Zollinger-Ellison)
- non-ulcer or functional dyspepsia

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

cimetidine solution

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to cimetidine tablets; **and**
  - requested quantity is ≤ eight mL/day; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age.

Gimoti

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following:
    - metoclopramide tablets; **and**
    - metoclopramide solution.

lansoprazole/amoxicillin/clarithromycin, and Omeclamox-Pak

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the combination product instead of the conventionally packaged formulation.

metoclopramide vial

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: metoclopramide solution, metoclopramide tablets; **and**
  - requested quantity is ≤ eight mL/day.

nizatidine 150 mg capsule > two units/day, nizatidine 300 mg capsule > one unit/day

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a gastrointestinal (GI) specialist or consult notes from a GI specialist are provided; **and**
  - medical records documenting inadequate response (defined as ≥ 14 days of therapy) to the requested agent dosed at 300 mg daily.

Talicia

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - clinical rationale for use instead of other multi-drug regimens for the treatment of H. pylori; **or**
    - inadequate response or adverse reaction to one or contraindication to all of the following:
      - bismuth quadruple therapy; **or**
      - concomitant therapy consisting of a PPI, clarithromycin, amoxicillin, and metronidazole; **or**
      - clarithromycin triple therapy.

Note: In general, esomeprazole 2.5 mg, 5 mg, and 10 mg suspension for members ≥ two years of age and all other PPIs have a quantity limit of one unit/day for members ≥ 13 years of age (with the exception of esomeprazole 2.5 mg, 5mg, and 10 mg suspension where there is no quantity limit for members < 2 years of age, omeprazole 20 mg capsules and pantoprazole tablets where the quantity limit is four units/day, omeprazole 40 mg capsules where the quantity limit is two units/day, and dexlansoprazole, lansoprazole orally disintegrating tablet, omeprazole/sodium bicarbonate capsule and suspension, and pantoprazole 40 mg suspension).

Aciphex Sprinkle, dexlansoprazole, esomeprazole 20 mg and 40 mg suspension, and Prilosec powder for suspension

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ one unit/day; **and**
  - one of the following:
    - inadequate response (defined as ≥ 28 days of therapy) or adverse reaction to one or contraindication to all of the following: esomeprazole magnesium capsule 40 mg daily, lansoprazole 30 mg daily, omeprazole 40 mg daily, pantoprazole 40 mg daily, rabeprazole tablet 20 mg daily; **or**
    - both of the following:
      - member has G-tube/swallowing disorder; **and**
      - inadequate response (defined as ≥ 28 days of therapy) or adverse reaction to one or contraindication to all of the following: esomeprazole magnesium capsule 40 mg daily, lansoprazole 30 mg daily, omeprazole 40 mg daily.

Aciphex Sprinkle > one unit/day, esomeprazole 20 mg and 40 mg suspension > one unit/day, and Prilosec powder for suspension > one unit/day

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- one of the following:
  - diagnosis of abnormal secretion of gastrin/Zollinger-Ellison, Barrett's Esophagus, or esophagitis; **or**
  - medical records documenting an inadequate response to once daily dosing of the requested agent (defined as ≥ 14 days of therapy); **and**
- one of the following:
  - inadequate response (defined as ≥ 28 days of therapy) or adverse reaction to one or contraindication to all of the following: esomeprazole magnesium capsule 40 mg daily, lansoprazole 30 mg daily, omeprazole 40 mg daily, pantoprazole 40 mg daily, rabeprazole tablet 20 mg daily; **or**
  - both of the following:
    - member has G-tube/swallowing disorder; **and**
    - inadequate response (defined as ≥ 28 days of therapy) or adverse reaction to one or contraindication to all of the following: esomeprazole magnesium capsule 40 mg daily, lansoprazole 30 mg daily, omeprazole 40 mg daily.

esomeprazole magnesium capsule > one unit/day, lansoprazole capsule > one unit/day, and rabeprazole delayed-release tablet > one unit/day for uncomplicated GERD, extraesophageal symptoms/conditions secondary to gastric reflux, healing/maintenance of healed duodenal ulcers, H. pylori eradication, non-ulcer or functional dyspepsia, risk reduction/healing of drug-induced gastric ulcer

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to both of the following:
    - omeprazole 40 mg daily; **and**
    - pantoprazole 40 mg daily; **and**
  - medical records documenting an inadequate response (defined as ≥ 14 days of therapy) to once daily dosing of the requested agent.

SmartPA: Claims for esomeprazole magnesium capsule > one unit/day, lansoprazole capsule > one unit/day, and rabeprazole delayed-release tablet > one unit/day will usually process at the pharmacy without a PA request if the member is < 13 years of age.†

esomeprazole magnesium capsule > one unit/day, lansoprazole capsule > one unit/day, omeprazole 20 mg capsule > four units/day, omeprazole 40 mg > two units/day, pantoprazole tablet > four units/day, and rabeprazole delayed-release tablet > one unit/day for abnormal secretion of gastrin/Zollinger-Ellison, Barrett's Esophagus, esophagitis

- Documentation of appropriate diagnosis is required.

SmartPA: Claims for esomeprazole magnesium capsule > one unit/day, lansoprazole capsule > one unit/day, omeprazole 20 mg capsule > four units/day, omeprazole 40 mg > two units/day, pantoprazole tablet > four units/day, and rabeprazole delayed-release tablet > one unit/day will usually process at the pharmacy without a PA request if the member is < 13 years of age or there is a history of MassHealth medical claims for abnormal secretion of gastrin/Zollinger-Ellison, Barrett's esophagus, or erosive esophagitis.†

esomeprazole 2.5 mg, 5mg, and 10 mg suspension > one unit/day for members ≥ two years of age for uncomplicated GERD, extraesophageal symptoms/conditions secondary to gastric reflux, healing/maintenance of healed duodenal ulcers, H. pylori eradication, non-ulcer or functional dyspepsia, risk reduction/healing of drug-induced gastric ulcer

- Documentation of the following is required:
  - appropriate diagnosis; and
  - medical records documenting an inadequate response (defined as ≥ 14 days of therapy) to once daily dosing of the requested agent.

esomeprazole 2.5 mg, 5mg, and 10 mg suspension > one unit/day for members ≥ two years of age for abnormal secretion of gastrin/Zollinger-Ellison, Barrett's Esophagus, esophagitis

- Documentation of appropriate diagnosis is required.

SmartPA: Claims for esomeprazole 2.5 mg, 5 mg, and 10 mg suspension for > one unit/day for members ≥ two years of age will usually process at the pharmacy without a PA request if the member is < 2 years of age or there is a history of MassHealth medical

claims for abnormal secretion of gastrin/Zollinger-Ellison, Barrett's esophagus, or erosive esophagitis.†

esomeprazole magnesium OTC

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to both of the following:
    - omeprazole 40 mg daily; **and**
    - pantoprazole 40 mg daily; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to one or contraindication to both of the following: lansoprazole 30 mg capsule daily, rabeprazole 20 mg tablet daily; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to prescription esomeprazole capsules at an equivalent dose to the requested dose.

esomeprazole sodium IV

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for intravenous route of administration; **and**
  - inadequate response, adverse reaction, or contraindication to pantoprazole IV.

First-Omeprazole

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member is < 13 years of age; **or**
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow.

Konvomep

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to omeprazole/sodium bicarbonate powder for oral suspension (Zegerid); **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to two or contraindication to all of the following: esomeprazole suspension, lansoprazole orally disintegrating tablet, omeprazole capsule, pantoprazole suspension.

lansoprazole OTC

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to both of the following:
    - omeprazole 40 mg daily; **and**
    - pantoprazole 40 mg daily; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to prescription lansoprazole capsules at an equivalent dose to the requested dose.

omeprazole 10 mg > one unit/day

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale for omeprazole 10 mg above quantity limits when omeprazole 20 mg capsules are available up to four capsules/day without PA.

omeprazole 20 mg capsule > four units/day, omeprazole 40 mg > two units/day, and pantoprazole tablet > four units/day for uncomplicated GERD, extraesophageal symptoms/conditions secondary to gastric reflux, healing/maintenance of healed duodenal ulcers, H. pylori eradication, non-ulcer or functional dyspepsia, risk reduction/healing of drug-induced gastric ulcer

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response (defined as ≥ 14 days of therapy) to the agent dosed at 80 mg daily; **and**
  - prescriber is a GI specialist or consult notes from a GI specialist are provided.

SmartPA: Claims for omeprazole 20 mg capsule > four units/day, omeprazole 40 mg > two units/day, and pantoprazole tablet > four units/day will usually process at the pharmacy without a PA request if the member is < 13 years of age.†

omeprazole OTC

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to pantoprazole 40 mg daily; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to one of the following: esomeprazole magnesium 40 mg capsule daily, lansoprazole 30 mg capsule daily, rabeprazole 20 mg tablet daily; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to prescription omeprazole at an equivalent dose to the requested dose.

omeprazole/sodium bicarbonate OTC

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to both of the following:
    - omeprazole 40 mg daily; **and**
    - pantoprazole 40 mg daily; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to one or contraindication to all of the following:
    - esomeprazole magnesium 40 mg capsule daily; **or**
    - lansoprazole 30 mg capsule daily; **or**
    - rabeprazole 20 mg tablet daily; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to prescription omeprazole at an equivalent dose to the requested dose.

omeprazole/sodium bicarbonate powder for oral suspension

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to two or contraindication to all of the following: esomeprazole solution, lansoprazole orally disintegrating tablet, omeprazole capsule, pantoprazole suspension.

Brand-name Protonix

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ four units/day; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to omeprazole 40 mg daily; **and**
  - inadequate response (defined as ≥14 days of therapy), adverse reaction, or contraindication to one of the following:
    - esomeprazole magnesium 40 mg capsule daily; **or**
    - lansoprazole 30 mg capsule daily; **or**
    - rabeprazole 20 mg tablet daily; **and**
  - medical records documenting an adverse reaction or inadequate response to a generic equivalent of the requested product.
- For requested quantity > four units/day will be evaluated on a case-by-case basis taking into account the member's diagnosis, documentation of GI consult, and medical records of prior trials of the requested agent.

Voquezna

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age: **and**
  - prescriber is a gastroenterologist or consult notes from a gastroenterologist are provided; **and**
  - requested quantity is ≤ one tablet/day; **and**
  - one of the following:
    - both of the following:
      - diagnosis of LA grade C or D erosive esophagitis; **and**
      - inadequate response (defined as ≥ 28 days of therapy) or adverse reaction to one or contraindication to all of the following: dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole or rabeprazole; **or**
    - inadequate response (defined as ≥ 28 days of therapy) or adverse reaction to three or contraindication to all of the following: dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole or rabeprazole.

Voquezna Dualpak and Voquezna Triplepak

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age: **and**
  - requested quantity is ≤ eight tablets/day; **and**
  - medical necessity for the requested agent instead of other multi-drug regimens available without PA; **and**
  - one of the following:
    - for Voquezna Dualpak, member has not utilized an amoxicillin-containing regimen for the current infection; **or**
    - for Voquezna Triplepak, member has not utilized an amoxicillin- or a clarithromycin-containing regimen for the current infection.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria

Table 4 - Hematologic Agents - Hematopoietic and Miscellaneous Hematologic Agents

Drug Category: Blood and Circulation Agents

Medication Class/Individual Agents: Hematopoietic Agents

I. Prior-Authorization Requirements

Hematologic Agents – Chemokine receptor type 4 (CXCR4) inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
mavorixafor	Xolremdi	PA	
motixafortide	Aphexda	PA	MB

Hematopoietic Agents – Erythropoiesis-Stimulating Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
darbepoetin alfa	Aranesp	PA	
epoetin alfa-epbx	Retacrit	PA	
epoetin alfa-Epogen	Epogen	PA	
epoetin alfa-Procrit	Procrit	PA	
methoxy polyethylene glycol / epoetin beta	Mircera		MB

Hematopoietic Agents – Colony-Stimulating Factors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
eflapegrastim-xnst	Rolvedon		MB
filgrastim	Neupogen		
filgrastim-aafi	Nivestym		
filgrastim-ayow	Releuko		
filgrastim-sndz	Zarxio		
pegfilgrastim	Neulasta		
pegfilgrastim-apgf	Nyvepria		
pegfilgrastim-bmez	Ziextenzo		
pegfilgrastim-cbqv	Udenyca		
pegfilgrastim-fpgk	Stimufend		
pegfilgrastim-jmdb	Fulphila		
pegfilgrastim-pbbk	Fylnetra		

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

For PA drugs, an FDA-approved indication must be met. For unlabeled uses, approval will be considered based on current medical evidence.

Monitoring:

- colony-stimulating factors (G-CSF, GM-CSF) – Certain drugs, such as corticosteroids and lithium, may potentiate the myeloproliferative effects of colony-stimulating factors; GM-CSF: fluid retention, occasional transient supraventricular arrhythmias, and dyspnea may occur. Use cautiously in members with cardiac or pulmonary disease.
- erythropoietin – Evaluate iron status before and during therapy. Transferrin saturation should be at least 20% and serum ferritin at least 100 ng/mL. Most members will eventually require supplemental iron.
- oprelvekin – Fluid retention will occur. Use cautiously in members with congestive heart failure (CHF) or preexisting fluid collections (e.g., ascites, pericardial, or pleural effusions).

Please note for evaluation criteria of inadequate response to

Hematopoietic Agents – Colony-Stimulating Factors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
sargramostim	Leukine		
TBO-filgrastim	Granix		

Hematopoietic Agents – Hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
daprodustat	Jesduvroq	PA	MB
vadadustat	Vafseo	PA	MB

Hematopoietic Agents – Interleukins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
oprelvekin	Neumega		

Clinical Notes
erythropoiesis-stimulating agent (ESA) treatment, hyporesponsiveness is defined as the need for > 300 units/kg per week of subcutaneous epoetin alfa, > 450 units/kg per week of intravenous epoetin alfa, or > 1.5 mcg/kg per week of darbepoetin alfa, no increase in hemoglobin (Hb) concentration from baseline after the first month of ESA treament with appropriate weight-based dosing, or two ESA dose increases up to 50% beyond the dose previously stabilized on to maintain a stable Hb concentration, or an ESA dose increase beyond double the initial weight-based dose or previous stable dose.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Anemia due to chemotherapy treatment for cancer (Aranesp, Epogen, Procrit, Retacrit)
- Anemia due to chronic renal failure (Aranesp, Epogen, Procrit, Retacrit)
- Anemia due to a myelosuppressive medication regimen for HIV (Aranesp, Epogen, Procrit, Retacrit)
- Decrease the need for blood transfusions during surgery (Aranesp, Epogen, Procrit, Retacrit)
- Dialysis dependent anemia of chronic kidney disease (Vafseo, Jesduvroq)
- Multiple myeloma requiring autologous hematopoietic cell transplantation (Aphexda)
- Warts, hypogammaglobulinemia, infections, and myelokathexis (WHIM) syndrome with CXCR4 mutation (Xolremdi)

non-FDA-approved, for example:

- Anemia due to a myelosuppressive medication regimen for Hepatitis C (Aranesp, Epogen, Procrit, Retacrit).
- Anemia due to myelodysplastic syndrome (MDS)
- Anemia post-renal transplant
- Idiopathic sideroblastic anemia

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may result in additional restrictions.

Aphexda

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an oncologist or hematologist or consult notes from an oncologist or hematologist are provided; **and**
  - requested agent will be used in combination with a granulocyte colony stimulating factor (G-CSF); **and**
  - clinical rationale for use of the requested agent instead of plerixafor; **and**
  - appropriate dosing.

Aranesp, Epogen, Procrit, and Retacrit for anemia due to chronic renal failure

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - Hemoglobin (Hb) < 10 g/dL (dated within the last 60 days); **and**
  - member is not receiving hemodialysis; **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**
  - for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit; **and**
  - glomerular filtration rate (GFR) ≤ 60 mL/min.
- For recertification, documentation of the following is required:
  - Hb level ≤ 12 g/dL (dated within the last 60 days); **or**
  - Hb level > 12 g/dL (dated within the last 60 days) and the request addresses if the erythropoietin dose is to be held or reduced to remain with the appropriate target.

Aranesp, Epogen, Procrit, and Retacrit for anemia due to chemotherapy treatment for cancer

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - Hb < 10 g/dL (dated within the last 60 days); **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**
  - for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit.

- For recertification, documentation of the following is required:
  - Hb level ≤ 12 g/dL (dated within the last 60 days); **and**
  - member continues to receive the causative agent.

Aranesp, Epogen, Procrit, and Retacrit for anemia due to a myelosuppressive medication regimen for HIV

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - Hb < 10 g/dL (dated within the last 60 days); **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**
  - for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit; **and**
  - member is on myelosuppressive medication for the treatment of HIV that includes zidovudine or zidovudine-containing products.
- For recertification, documentation of the following is required:
  - Hb level ≤ 12 g/dL (dated within the last 60 days); **and**
  - member continues to receive the causative agent.

Aranesp, Epogen, Procrit, and Retacrit for anemia due to idiopathic sideroblastic anemia/myelodysplastic syndrome

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - Hb < 10 g/dL (dated within the last 60 days); **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**
  - for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit.
- For recertification, documentation of the following is required:
  - Hb level ≤ 12 g/dL (dated within the last 60 days); **or**
  - Hb level > 12 g/dL (dated within the last 60 days) and the request addresses if the erythropoietin dose is to be held or reduced to remain with the appropriate target.

Aranesp, Epogen, Procrit, and Retacrit for anemia due to a myelosuppressive medication regimen for Hepatitis C

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**
  - for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit; **and**
  - one of the following:
    - Hb < 10 g/dL (dated within the last 60 days) and member is currently being treated with a hepatitis C regimen containing an interferon product, with or without ribavirin; **or**
    - Hb < 10 g/dL (dated within the last 60 days) and member is currently being treated with a hepatitis C regimen containing ribavirin without interferon, and ribavirin dose reduction to 600 mg per day has been attempted; **or**
    - member is currently being treated with a hepatitis C regimen containing ribavirin without interferon and ribavirin dose reduction to 600 mg per day is not indicated by one of the following:
      - Hb < 8.5 g/dL (dated within the last 60 days); **or**
      - Hb < 12 g/dL (dated within the last 60 days) and member has a history of cardiac disease.
- For recertification, documentation that the member continues to receive the causative agent is required.

Aranesp, Epogen, Procrit, and Retacrit for anemia due to renal transplant

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - Hb < 10 g/dL (dated within the last 60 days); **and**
  - member is not receiving hemodialysis; **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**

- for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit.

- For recertification, documentation of the following is required:
  - Hb level ≤ 12 g/dL (dated within the last 60 days); **or**
  - Hb level > 12 g/dL (dated within the last 60 days) and the request addresses if the erythropoietin dose is to be held or reduced to remain with the appropriate target.

Aranesp, Epogen, Procrit, and Retacrit to decrease the need for blood transfusions due to surgery

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - Hb ≤ 13 g/dL (dated within the last 30 days); **and**
  - surgery is planned within the next 3 months and date is provided; **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**
  - for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit.

Jesduvroq and Vafseo

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a nephrologist or consult notes from a nephrologist are provided; **and**
  - one of the following:
    - for Jesduvroq, member has been receiving hemodialysis or peritoneal dialysis for ≥ four months; **or**
    - for Vafseo, member has been receiving hemodialysis or peritoneal dialysis for ≥ three months; **and**
  - appropriate dosing; **and**
  - inadequate response (defined as indicated by hyporesponsiveness) or adverse reaction to one or contraindication to all of the following: Aranesp, Epogen or Procrit, Mircera, Retacrit.

Xolremdi

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic testing confirming diagnosis of WHIM syndrome; **and**
  - member is ≥ 12 years of age; **and**
  - prescriber is an immunologist or hematologist or consult notes from an immunologist or hematologist are provided; **and**
  - baseline absolute neutrophil count (ANC) ≤ 0.4 x 10^3/μL; **and**
  - appropriate dosing; **and**
  - requested quantity is ≤ four units/day.

MassHealth Evaluation Criteria
Table 5 - Immunological Agents

Drug Category: Immunological Agents

Medication Class/Individual Agents: Anti-TNF-Alpha, Corticosteroid, Immunosuppressant, Interleukin Antagonist, Miscellaneous, Topical

I. Prior-Authorization Requirements

Immunological Agents – Anti-TNF-Alpha			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
adalimumab	Humira PD	PA	BP
adalimumab-aacf	Idacio	PA	
adalimumab-aacf, unbranded		PA	
adalimumab-aaty	Yuflyma	PA	
adalimumab-aaty, unbranded		PA	
adalimumab-adaz	Hyrimoz	PA	
adalimumab-adaz, unbranded		PA	
adalimumab-adbm	Cyltezo	PA	
adalimumab-adbm, unbranded		PA	
adalimumab-afzb	Abrilada	PA	
adalimumab-aqvh	Yusimry	PA	
adalimumab-atto	Amjevita	PA	
adalimumab-bwwd	Hadlima	PA	
adalimumab-fkjp	Hulio	PA	
adalimumab-fkjp, unbranded		PA	
adalimumab-ryvk	Simlandi	PA	
adalimumab-ryvk, unbranded		PA	
certolizumab	Cimzia	PA	
etanercept	Enbrel PD	PA	
golimumab	Simponi	PA	
golimumab for infusion	Simponi Aria	PA	
infliximab, unbranded		PA	
infliximab-abda	Renflexis	PA	
infliximab-axxq	Avsola	PA	
infliximab-dyyb	Inflectra	PA	
infliximab-dyyb	Zymfentra	PA	
infliximab-Remicade	Remicade	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

For PA drugs, one of the following FDA-approved indications must be met. For unlabeled uses, approval is considered based on current medical evidence.

Immunological agents warnings and precautions:

- Chronic obstructive pulmonary disease, concomitant use of biologic therapy, use of live vaccines in previous three months, viral hepatitis, hypersensitivity reactions, tuberculosis, injection site reactions, infusion reactions, infections, demyelinating disease, heart failure, malignancy, induction of autoimmunity. See manufacturers' information for full details on each agent.

Monoclonal antibodies warning and precautions:

- History of malignancy, members with human immunodeficiency virus (HIV) infection, lymphopenia, malignancy, serious infections, immunosuppression, allergic reactions, hepatic injury, immune-mediated thrombocytopenia or hemolytic anemia, psoriasis worsening and variants; see manufacturers' information for full details.

Immunological Agents – Interleukin (IL)-6 Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
sarilumab	Kevzara	PA	
tocilizumab auto-injection, prefilled syringe	Actemra	PA	
tocilizumab vial	Actemra	PA	MB
tocilizumab-aazg auto-injection, prefilled syringe	Tyenne	PA	
tocilizumab-aazg vial	Tyenne	PA	MB
tocilizumab-bavi	Tofidence	PA	MB

Immunological Agents – Interleukin (IL)-13 Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
lebrikizumab-lbkz	Ebglyss PD	PA	
tralokinumab-ldrm	Adbry PD	PA	

Immunological Agents – Corticosteroids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betamethasone injection	Celestone		#
budesonide 4 mg delayed-release capsule	Tarpeyo	PA	
budesonide oral suspension	Eohilia	PA	
deflazacort	Emflaza	PA	BP
dexamethasone 20 mg tablet	Hemady	PA	
dexamethasone injection			
dexamethasone solution, tablet	Decadron		# , A90
dexamethasone tablet pack		PA	A90
fludrocortisone			A90
hydrocortisone injection	Solu-Cortef		#
hydrocortisone sprinkle capsule	Alkindi	PA	
hydrocortisone tablet	Cortef		# , A90
methylprednisolone	Medrol		# , A90
methylprednisolone acetate	Depo-Medrol		#
methylprednisolone sodium	Solu-Medrol		#

Immunological Agents – Corticosteroids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
succinate			
prednisolone 10 mg/5 mL oral solution		PA	A90
prednisolone 15 mg/5 mL, 25 mg/5 mL oral solution			A90
prednisolone 20 mg/5 mL oral solution		PA	A90
prednisolone 5 mg/5 mL oral solution	Pediapred		# , A90
prednisolone orally disintegrating tablet		PA	A90
prednisolone tablet		PA	A90
prednisone			A90
prednisone delayed-release	Rayos	PA	
triamcinolone extended-release injectable suspension	Zilretta	PA	MB
triamcinolone injection	Kenalog		#
vamorolone	Agamree	PA	

Immunological Agents – Miscellaneous Interleukin Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
basiliximab	Simulect		MB
canakinumab	Ilaris	PA	
rilonacept	Arcalyst	PA	
siltuximab	Sylvant	PA	MB

Immunological Agents – Immunosuppressants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
azathioprine 50 mg tablet	Imuran		# , A90
azathioprine 75 mg, 100 mg tablet		PA	A90
azathioprine injection			MB
belatacept	Nulojix	PA	
cyclosporine	Sandimmune		# , A90

Immunological Agents – Immunosuppressants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
capsule			
cyclosporine injection	Sandimmune		MB
cyclosporine modified	Neoral		# , A90
cyclosporine solution	Sandimmune	PA	
everolimus 0.25 mg, 0.5 mg, 0.75 mg, 1 mg	Zortress		BP, A90
mycophenolate mofetil capsule, suspension, tablet	Cellcept		# , A90
mycophenolate mofetil injection	Cellcept		MB
mycophenolate mofetil suspension-Myhibbin	Myhibbin	PA	
mycophenolic acid	Myfortic		# , A90
sirolimus solution, tablet	Rapamune		# , A90
tacrolimus extended-release capsule	Astagraf XL		
tacrolimus extended-release tablet	Envarsus XR	PA	
tacrolimus granules	Prograf	PA	
tacrolimus immediate-release capsule	Prograf		# , A90
tacrolimus injection	Prograf		MB
voclosporin	Lupkynis	PA	

Immunological Agents – Interleukin (IL)-17A and IL-17F Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bimekizumab-bkzx	Bimzelx	PA	

Immunological Agents – Janus Kinase (JAK) Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
abrocitinib	Cibinqo	PA	
baricitinib	Olumiant	PA	

Immunological Agents – Janus Kinase (JAK) Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ritlecitinib	Litfulo	PA	
tofacitinib	Xeljanz	PA	BP
tofacitinib extended-release	Xeljanz XR	PA	BP
upadacitinib extended-release tablet	Rinvoq	PA	
upadacitinib solution	Rinvoq LQ	PA	

Immunological Agents – Interleukin (IL)-17A Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
brodalumab	Siliq	PA	
ixekizumab	Taltz PD	PA	
secukinumab auto-injection, prefilled syringe	Cosentyx	PA	
secukinumab vial	Cosentyx	PA	MB

Immunological Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
apremilast	Otezla	PA	
etrasimod	Velsipity	PA	
methotrexate 2 mg/mL oral solution	Jylamvo	PA	
methotrexate 2.5 mg/mL oral solution	Xatmep	PA	
methotrexate subcutaneous injection-Otrexup	Otrexup	PA	
methotrexate subcutaneous injection-Rasuvo	Rasuvo	PA	
methotrexate tablet			A90
ozanimod for ulcerative colitis	Zeposia	PA	
vedolizumab	Entyvio	PA	

Immunological Agents – Interleukin (IL)-23 Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
guselkumab	Tremfya	PA	
mirikizumab-mrkz	Omvoh PD	PA	

Immunological Agents – Interleukin (IL)-23 Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
auto injection, prefilled syringe			
mirikizumab-mrkz vial	Omvoh	PA	
risankizumab-rzaa auto-injection, on-body injector, prefilled syringe	Skyrizi PD	PA	
risankizumab-rzaa vial	Skyrizi	PA	
tildrakizumab-asmn	Ilumya	PA	

Immunological Agents – Interleukin (IL)-1 Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
anakinra	Kineret	PA	

Immunological Agents – Selective T-Cell Costimulation Blocker			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
abatacept auto-injection, prefilled syringe	Orencia	PA	
abatacept vial	Orencia	PA	MB

Immunological Agents – Interleukin (IL)-12/23 Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ustekinumab 130 mg/26 mL vial	Stelara	PA	MB
ustekinumab 45 mg/0.5 mL prefilled syringe, 90 mg/mL prefilled syringe, 45 mg/0.5 mL vial	Stelara PD	PA	
ustekinumab-aauz prefilled syringe	Otulfi	PA	
ustekinumab-aauz vial	Otulfi	PA	MB
ustekinumab-aekn prefilled syringe	Selarsdi	PA	
ustekinumab-aekn vial	Selarsdi	PA	MB
ustekinumab-aekn,		PA	

Immunological Agents – Interleukin (IL)-12/23 Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
unbranded prefilled syringe			
ustekinumab-kfce 130 mg/26 mL vial	Yesintek	PA	MB
ustekinumab-kfce prefilled syringe, 45 mg/0.5 mL vial	Yesintek	PA	
ustekinumab-stba prefilled syringe	Steqeyma	PA	
ustekinumab-stba vial	Steqeyma	PA	MB
ustekinumab-ttwe prefilled syringe	Pyzchiva	PA	
ustekinumab-ttwe vial	Pyzchiva	PA	MB
ustekinumab-ttwe, unbranded prefilled syringe		PA	
ustekinumab-ttwe, unbranded vial		PA	MB

Immunological Agents – Topical Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
calcipotriene cream, ointment		PA - > 60 grams/30 days	A90
calcipotriene foam	Sorilux	PA	A90
calcipotriene scalp solution			A90
calcitriol ointment	Vectical	PA	A90

Immunological Agents – Tyrosine Kinase 2 (TYK2) Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
deucravacitinib	Sotyktu	PA	

Immunological Agents – Interleukin (IL)-36 Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
spesolimab-sbzo	Spevigo	PA	

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Acute graft versus host disease prophylaxis – Orencia
- Acute lymphoblastic leukemia – Jylamvo, Xatmep
- Adult onset Still's disease (AOSD) – Ilaris
- Adrenocortical insufficiency – Alkindi
- Alopecia areata, severe – Litfulo, Olumiant
- Ankylosing spondylitis – Abrilada, Amjevita, Avsola, Bimzelx, Cimzia, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Rinvoq, Simlandi, Simponi, Simponi Aria, Taltz, unbranded adalimumab generics, unbranded infliximab, Xeljanz, Yuflyma, Yusimry
- Atopic dermatitis, moderate-to-severe – Adbry, Cibinqo, Ebglyss, Rinvoq
- Crohn’s disease, moderate-to-severe – Abrilada, Amjevita, Avsola, Cimzia, Cyltezo, Entyvio, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Omvoh, Otulfi, Pyzchiva, Remicade, Renflexis, Rinvoq, Selarsdi, Simlandi, Skyrizi, Stelara, Steqeyma, unbranded adalimumab generics, unbranded infliximab, unbranded ustekinumab generics, Yesintek, Yuflyma, Yusimry
- Crohn’s disease (including fistulizing disease), moderate-to-severe – Avsola, Inflectra, Remicade, Renflexis, unbranded infliximab
- Cytokine release syndrome – Actemra, Tofidence, Tyenne
- Deficiency of interleukin-1 Receptor Antagonist (DIRA) – Arcalyst, Kineret
- Duchenne muscular dystrophy (DMD) – Agamree, deflazacort
- Enthesitis-related arthritis – Cosentyx
- Eosinophilic esophagitis – Eohilia
- Familial cold autoinflammatory syndrome – Arcalyst, Ilaris
- Familial mediterranean fever (FMF) – Ilaris
- Generalized pustular psoriasis – Spevigo
- Giant cell arteritis – Actemra, Tofidence, Tyenne
- Gout flares – Ilaris
- Hidradenitis suppurativa, moderate-to-severe – Abrilada, Amjevita, Bimzelx, Cosentyx auto-injection, prefilled syringe, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Simlandi, unbranded adalimumab generics, Yuflyma, Yusimry
- Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD)– Ilaris
- Immunoglobulin A nephropathy (IgAN) – Tarpeyo
- Inflammatory, allergic, or immunological disorders – dexamethasone tablet pack, prednisolone ODT, prednisolone oral solution, Rayos
- Lupus nephritis – Lupkynis
- Muckle-Wells syndrome – Arcalyst, Ilaris
- Multicentric Castleman's disease – Sylvant

- Multiple myeloma – Hemady
- Mycosis fungoides – Jylamvo
- Neonatal-onset multisystem inflammatory disease – Kineret
- Non-infectious uveitis – Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Simlandi, unbranded adalimumab generics, Yuflyma, Yusimry
- Non-radiographic axial spondyloarthritis – Bimzelx, Cimzia, Cosentyx, Rinvoq, Taltz
- Oral ulcers associated with Behçet's disease – Otezla
- Osteoarthritis pain of the knee – Zilretta
- Plaque psoriasis – calcipotriene cream, ointment, calcipotriene foam, calcitriol ointment, Otezla
- Plaque psoriasis, moderate-to-severe – Abrilada, Amjevita, Avsola, Bimzelx, Cimzia, Cosentyx auto-injection, prefilled syringe, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Ilumya, Inflectra, Otulfi, Otrexup, Pyzchiva, Rasuvo, Remicade, Renflexis, Selarsdi, Siliq, Simlandi, Skyrizi, Sotyktu, Stelara, Steqeyma, Taltz, Tremfya, unbranded adalimumab generics, unbranded infliximab, unbranded ustekinumab generics, Yesintek, Yuflyma, Yusimry
- Polyarticular juvenile idiopathic arthritis – Otrexup, Rasuvo, Xatmep
- Polyarticular juvenile idiopathic arthritis, moderate-to-severe – Abrilada, Amjevita, Actemra, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Kevzara, Orencia, Rinvoq, Rinvoq LQ, Simlandi, Simponi Aria, Tofidence, Tyenne, unbranded adalimumab generics, Xeljanz, Yuflyma, Yusimry
- Polymyalgia rheumatica – Kevzara
- Prevention of rejection of heart transplant – Myhibbin, Prograf granules, Sandimmune solution
- Prevention of rejection of kidney transplant – azathioprine 75 mg and 100 mg tablets, Envarsus XR, Myhibbin, Nulojix, Prograf granules, Sandimmune solution
- Prevention of rejection of liver transplant – Myhibbin, Prograf granules, Sandimmune solution
- Prevention of rejection of lung transplant – Prograf granules
- Psoriasis, severe – Jylamvo
- Psoriatic arthritis – Abrilada, Amjevita, Avsola, Bimzelx, Cimzia, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Orencia, Otezla, Otulfi, Pyzchiva, Remicade, Renflexis, Rinvoq, Rinvoq LQ, Selarsdi, Simlandi, Simponi, Simponi Aria, Skyrizi, Stelara, Steqeyma, Taltz, Tremfya, unbranded adalimumab generics, unbranded infliximab, unbranded ustekinumab generics, Xeljanz, Xeljanz XR, Yesintek, Yuflyma, Yusimry
- Recurrent pericarditis – Arcalyst
- Relapsed or refractory non-Hodgkin lymphoma – Jylamvo
- Rheumatoid arthritis – azathioprine 75 mg and 100 mg tablets, Jylamvo, Otrexup, Rasuvo
- Rheumatoid arthritis, moderate-to-severe – Abrilada, Amjevita, Actemra, Avsola, Cimzia, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Kevzara, Kineret, Olumiant, Orencia, Remicade, Renflexis, Rinvoq, Simlandi, Simponi, Simponi Aria, Tofidence, Tyenne, unbranded adalimumab generics, unbranded infliximab, Xeljanz, Xeljanz XR, Yuflyma, Yusimry
- Systemic juvenile idiopathic arthritis (sJIA) – Actemra, Ilaris, Tofidence, Tyenne
- Systemic sclerosis-associated interstitial lung disease – Actemra auto-injection, prefilled syringe
- Tumor necrosis factor receptor associated periodic syndrome – Ilaris
- Ulcerative colitis, moderate-to-severe – Abrilada, Amjevita, Avsola, Cyltezo, Entyvio, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Omvoh, Otulfi, Pyzchiva, Remicade, Renflexis, Rinvoq, Selarsdi, Simlandi, Simponi, Skyrizi, Stelara, Steqeyma, Tremfya, unbranded adalimumab generics, unbranded infliximab, unbranded ustekinumab generics, Xeljanz, Xeljanz XR, Yesintek, Yuflyma, Yusimry, Velsipity, Zeposia

Non-FDA-approved, for example:

- Acute gout – Kineret
- Acute lymphoblastic leukemia in adult members – Xatmep
- Adult onset Still's disease (AOSD) – Kineret
- Alopecia areata – Xeljanz, Xeljanz XR
- Behçet's disease (BD) – Avsola, Enbrel, Humira, Inflectra, Remicade, Renflexis, unbranded adalimumab generics, unbranded

infliximab
- Familial cold autoinflammatory syndrome – Kineret
- Fistulizing Crohn's disease – Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, unbranded ustekinumab generics, Yesintek
- Hidradenitis suppurativa – Xeljanz, Xeljanz XR
- Hidradenitis suppurativa, moderate-to-severe – Avsola, Inflectra, Kineret, Otulfi, Pyzchiva, Remicade, Renflexis, Selarsdi, Stelara, Steqeyma, unbranded infliximab, unbranded ustekinumab generics, Yesintek
- Hyperimmunoglobulin D syndrome (HIDS) – Kineret
- Lichen planus – Otezla
- Muckle-Wells syndrome – Kineret
- Mycosis fungoides – Xatmep
- Neurologic sarcoidosis – Avsola, Inflectra, Remicade, Renflexis, unbranded infliximab
- Pityriasis rubra pilaris (PRP) – Cosentyx auto-injection, prefilled syringe, Ilumya, Otulfi, Pyzchiva, Selarsdi, Siliq, Skyrizi, Stelara, Steqeyma, Taltz, Tremfya, unbranded ustekinumab generics, Yesintek
- Plaque psoriasis, moderate-to-severe – Xatmep, Xeljanz, Xeljanz XR
- Polymyalgia rheumatica (PMR) – Actemra, Kevzara, Tofidence, Tyenne
- Pulmonary sarcoidosis – Avsola, Humira, Inflectra, Remicade, Renflexis, unbranded adalimumab generics, unbranded infliximab
- Recurrent pericarditis – Kineret
- Relapsed or refractory non-Hodgkin lymphoma – Xatmep
- Rheumatoid arthritis – Xatmep
- Scleritis – Actemra, Avsola, Humira, Inflectra, Remicade, Renflexis, unbranded adalimumab generics, unbranded infliximab
- Synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome – Avsola, Cosentyx, Enbrel, Humira, Inflectra, Kineret, Otulfi, Pyzchiva, Remicade, Renflexis, Selarsdi, Stelara, Steqeyma, unbranded adalimumab generics, unbranded infliximab, unbranded ustekinumab generics, Yesintek
- Systemic juvenile idiopathic arthritis (sJIA) – Kineret
- Systemic sclerosis-associated interstitial lung disease – Tyenne auto-injection, prefilled syringe
- Takayasu arteritis – Avsola, Enbrel, Humira, Inflectra, Remicade, Renflexis, unbranded adalimumab generics, unbranded infliximab
- Uveitis – Actemra, Avsola, Inflectra, Remicade, Renflexis, unbranded infliximab

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested

medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Abrilada, Amjevita, Avsola, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Simlandi, Simponi, Simponi Aria, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for ankylosing spondylitis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to two or contraindication to all NSAIDs; **and**
  - for Avsola, Inflectra, Remicade, Renflexis, Simponi, Simponi Aria, and unbranded infliximab, both of the following:
    - clinical rationale for the use of the requested agent instead of Enbrel; **and**
    - clinical rationale for the use of the requested agent instead of Humira; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Inflecta, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Avsola, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Simlandi, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for Behçet's Disease (BD)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all topical corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, colchicine, cyclophosphamide, cyclosporine, methotrexate, Otezla; **and**
  - for infliximab agents, clinical rationale for use of the requested agent instead of Enbrel and Humira; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Avsola, Cimzia, Cyltezo, Enbrel, Entyvio, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Omvoh, Otulfi, Pyzchiva, Remicade, Renflexis, Selarsdi, Simlandi, Skyrizi, Stelara, Steqeyma, unbranded adalimumab generics, unbranded

infliximab, unbranded ustekinumab generics, Yesintek, Yuflyma, Yusimry, and Zymfentra for Crohn's disease

- Documentation of the following is required for moderate-to-severe Crohn's disease (see below for fistulizing Crohn's disease):
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - for Avsola, Cimzia, Inflectra, Remicade, Renflexis, and unbranded infliximab, clinical rationale for the use of the requested agent instead of Humira; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for Entyvio, inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for Crohn's disease; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Otulfi, Pyzchiva, Selarsdi, Steqeyma, unbranded ustekinumab generics, and Yesintek, one of the following:
    - clinical rationale for use of the requested agent instead of Stelara; **or**
    - medical records documenting an inadequate response or adverse reaction to Stelara; **and**
  - for Zymfentra, both of the following:
    - medical necessity for subcutaneous formulation instead of intravenous infliximab formulation; **and**
    - member is currently stable (at least 10 weeks of treatment) on an intravenous infliximab product; **and**
  - for Cimzia vial, clinical rationale for use instead of Cimzia prefilled syringe; **and**
  - for Omvoh 100 mg/mL and 200 mg/2 mL pen and syringe, clinical rationale for use of the requested formulation instead of the 300 mg dose pack; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Remicade, Pyzchiva, Selarsdi, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic.
- For Avsola, Inflectra, Remicade, Renflexis, and unbranded infliximab for fistulizing Crohn's disease, documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Bimzelx, Cosentyx auto-injection, prefilled syringe, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics for moderate-to-severe hidradenitis suppurativa

- Documentation of the following is required:
  - diagnosis of moderate-to-severe hidradenitis suppurativa (Hurley Stage II or Hurley Stage III disease); **and**
  - appropriate dosing; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Cosentyx, inadequate response, adverse reaction, or contraindication to Humira; **and**
  - for Bimzelx, inadequate response, adverse reaction, or contraindication to both of the following: Cosentyx, Humira; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent

generic.

Abrilada, Amjevita, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Kevzara, Orencia, Simlandi, Simponi Aria, unbranded adalimumab generics, Yuflyma, and Yusimry for moderate-to-severe PJIA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to all traditional DMARDs; **or**
    - inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for PJIA; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Simponi Aria, both of the following:
    - clinical rationale for the use of the requested agent instead of Enbrel; **and**
    - clinical rationale for the use of the requested agent instead of Humira; **and**
  - for Kevzara, inadequate response or adverse reaction to one or contraindication to both of the following: Enbrel, Humira; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic.

Abrilada, Amjevita, Avsola, Bimzelx, Cimzia, Cyltezo, Cosentyx auto-injection, prefilled syringe, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Ilumya, Inflectra, Otulfi, Pyzchiva, Remicade, Renflexis, Selarsdi, Siliq, Simlandi, Skyrizi, Stelara, Steqeyma, Taltz, Tremfya, unbranded adalimumab generics, unbranded infliximab, unbranded ustekinumab generics, Yesintek, Yuflyma, and Yusimry for moderate-to-severe plaque psoriasis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - one of the following:
    - inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for plaque psoriasis; **or**
    - inadequate response or adverse reaction to one or contraindication to all conventional therapies (topical agents, phototherapy, and systemic agents as defined in appendix below); **and**
  - for Avsola, Cimzia, Inflectra, Remicade, Renflexis, and unbranded infliximab, both of the following:
    - clinical rationale for the use of the requested agent instead of Enbrel; **and**
    - clinical rationale for the use of the requested agent instead of Humira; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Otulfi, Pyzchiva, Selarsdi, Steqeyma, unbranded ustekinumab generics, and Yesintek, one of the following:
    - clinical rationale for use of the requested agent instead of Stelara; **or**
    - medical records documenting an inadequate response or adverse reaction to Stelara; **and**
  - for Bimzelx, Cosentyx, Iluymya, Siliq, and Tremfya, both of the following:
    - inadequate response, adverse reaction, or contraindication to all of the following: Stelara, Skyrizi, Taltz; **and**
    - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for plaque psoriasis; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded

infliximab; **and**
- for Cimzia vial, clinical rationale for use instead of Cimzia prefilled syringe; **and**
- for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Pyzchiva, Remicade, Selarsdi, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic.

Abrilada, Amjevita, Actemra, Avsola, Cimzia, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Kevzara, Orencia, Remicade, Renflexis, Simlandi, Simponi, Simponi Aria, Tofidence, Tyenne, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for moderate-to-severe rheumatoid arthritis (RA)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to all traditional DMARDs; **or**
    - inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for RA; **and**
  - for Avsola, Cimzia, Inflectra, Remicade, Renflexis, Simponi, Simponi Aria, and unbranded infliximab, both of the following:
    - clinical rationale for the use of the requested agent instead of Enbrel; **and**
    - clinical rationale for the use of the requested agent instead of Humira; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for Actemra auto-injection, prefilled syringe, clinical rationale for use of the requested agent instead of Tyenne auto-injection, prefilled syringe; **and**
  - for Cimzia vial, clinical rationale for use instead of Cimzia prefilled syringe; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Avsola, Cyltezo, Entyvio, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Omvoh, Otulfi, Pyzchiva, Remicade, Renflexis, Selarsdi, Simlandi, Simponi, Skyrizi, Stelara, Steqeyma, Tremfya, unbranded adalimumab generics, unbranded infliximab, unbranded ustekinumab generics, Yesintek, Yuflyma, Yusimry, and Zymfentra for moderate-to-severe ulcerative colitis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - for Simponi, clinical rationale for use of the requested agent instead of Humira; **and**
  - for Entyvio and Tremfya, inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for ulcerative colitis; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Otulfi, Pyzchiva, Selarsdi, Steqeyma, unbranded ustekinumab generics, and Yesintek, one of the following:
    - clinical rationale for use of the requested agent instead of Stelara; **or**

    - medical records documenting an inadequate response or adverse reaction to Stelara; **and**
- for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
- for Omvoh 300 mg dose pack, clinical rationale for use of the requested formulation instead of the 100 mg/mL and 200 mg/2 mL pen and syringe; **and**
- for Tremfya, inadequate response, adverse reaction, or contraindication to all of the following: Stelara, Skyrizi, Omvoh; **and**
- for Zymfentra, both of the following:
    - medical necessity for subcutaneous formulation instead of intravenous infliximab formulation; **and**
    - member is currently stable (at least 10 weeks of treatment) on an intravenous infliximab product; **and**
- for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Pyzchiva, Remicade, Selarsdi, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic.

Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics for non-infectious uveitis

- Documentation of the following is required:
    - appropriate diagnosis; **and**
    - appropriate dosing; **and**
    - inadequate response or adverse reaction to one topical or systemic glucocorticoid, or contraindication to all topical and systemic glucocorticoids; **and**
    - inadequate response or adverse reaction to one or contraindication to all systemic immunosuppressive therapies (e.g., methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus, cyclophosphamide); **and**
    - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
        - clinical rationale for use of the requested agent instead of Humira; **or**
        - medical records documenting an inadequate response or adverse reaction to Humira; **and**
    - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic.

Abrilada, Amjevita, Avsola, Bimzelx, Cimzia, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Orencia, Otezla, Otulfi, Pyzchiva, Remicade, Renflexis, Selarsdi, Simlandi, Simponi, Simponi Aria, Skyrizi, Stelara, Steqeyma, Taltz, Tremfya, unbranded adalimumab generics, unbranded infliximab, unbranded ustekinumab generics, Yesintek, Yuflyma, and Yusimry for psoriatic arthritis

- Documentation of the following is required:
    - appropriate diagnosis; **and**
    - appropriate dosing; **and**
    - for Avsola, Cimzia, Inflectra, Remicade, Renflexis, Simponi, Simponi Aria, and unbranded infliximab, both of the following:
        - clinical rationale for the use of the requested agent instead of Enbrel; **and**
        - clinical rationale for the use of the requested agent instead of Humira; **and**
    - for Orencia, an inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for psoriatic arthritis; **and**
    - for Otezla, requested quantity is ≤ two tablets/day; **and**
    - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
    - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
        - clinical rationale for use of the requested agent instead of Humira; **or**

    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
- for Otulfi, Pyzchiva, Selarsdi, Steqeyma, unbranded ustekinumab generics, and Yesintek, one of the following:
    - clinical rationale for use of the requested agent instead of Stelara; **or**
    - medical records documenting an inadequate response or adverse reaction to Stelara; and
- for Cimzia vial, clinical rationale for use instead of Cimzia prefilled syringe; **and**
- for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Pyzchiva, Remicade, Selarsdi, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic.
- for Bimzelx, Cosentyx, and Tremfya, both of the following:
    - inadequate response, adverse reaction, or contraindication to all of the following: Stelara, Skyrizi, Taltz; **and**
    - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for psoriatic arthritis.

Abrilada, Amjevita, Avsola, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Simlandi, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for Pulmonary Sarcoidosis

- Documentation of the following is required:
    - appropriate diagnosis; **and**
    - inadequate response, adverse reaction, or contraindication to both of the following: systemic glucocorticoids, one traditional DMARD; **and**
    - for Avsola, Inflectra, Remicade, Renflexis, or unbranded infliximab, one of the following:
        - inadequate response, adverse reaction or contraindication to Humira; **or**
        - clinical rationale for use of the requested agent instead of Humira; **and**
    - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
        - clinical rationale for use of the requested agent instead of Humira; **or**
        - medical records documenting an inadequate response or adverse reaction to Humira; **and**
    - for Inflecta, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
    - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
    - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Avsola, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Otulfi, Pyzchiva, Remicade, Renflexis, Selarsdi, Simlandi, Stelara, Steqeyma, unbranded adalimumab generics, unbranded infliximab, unbranded ustekinumab generics, Yesintek, Yuflyma, and Yusimry for Synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome

- Documentation of the following is required:
    - appropriate diagnosis; **and**
    - inadequate response or adverse reaction to one or contraindication to all NSAIDs; **and**
    - inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids; **and**
    - for infliximab agents, clinical rationale for use of the requested agent instead of Enbrel and Humira; **and**
    - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
        - clinical rationale for use of the requested agent instead of Humira; **or**
        - medical records documenting an inadequate response or adverse reaction to Humira; **and**
    - for Otulfi, Pyzchiva, Selarsdi, Steqeyma, unbranded ustekinumab generics, and Yesintek, one of the following:

    - clinical rationale for use of the requested agent instead of Stelara; or
    - medical records documenting an inadequate response or adverse reaction to Stelara; and
  - for Inflecta, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Pyzchiva, Remicade, Selarsdi, Simlandi, and Yuflyma the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
  - for Cosentyx, clinical rationale for use of the requested agent instead of Stelara.

Abrilada, Actemra, Amjevita, Avsola, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Simlandi, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for scleritis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following:
    - ophthalmic, oral, or injectable glucocorticoids; **and**
    - oral or injectable immunosuppressive therapy; **and**
  - for Actemra, inadequate response, adverse reaction, or contraindication to Rituxan; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Inflecta, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Avsola, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Simlandi, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for Takayasu arteritis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: systemic glucocorticoids, one traditional DMARD; **and**
  - for Avsola, Inflectra, Remicade, Renflexis, or unbranded infliximab, one of the following:
    - inadequate response, adverse reaction, or contraindication to Humira and Enbrel; **or**
    - clinical rationale for use of the requested agent instead of Humira and Enbrel; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Inflecta, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction

to unbranded infliximab.

Actemra, Tofidence, and Tyenne for Polymyalgia Rheumatica (PMR)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids; **and**
    - inadequate response, adverse reaction or contraindication to methotrexate; **and**
  - for Actemra auto-injection, prefilled syringe, clinical rationale for use of the requested agent instead of Tyenne auto-injection, prefilled syringe.

Actemra, Tofidence, and Tyenne for cytokine release syndrome

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - concurrent therapy with CAR T-cell therapies (request must include anticipated date of administration); **and**
  - appropriate dosing**.**

Actemra, Tofidence, and Tyenne for giant cell arteritis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all systemic glucocorticoids; **and**
  - for Actemra auto-injection, prefilled syringe, clinical rationale for use of the requested agent instead of Tyenne auto-injection, prefilled syringe.

Actemra, Tofidence, and Tyenne for moderate-to-severe polyarticular juvenile idiopathic arthritis (PJIA)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to all traditional DMARDs; **or**
    - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents; **and**
  - for Actemra auto-injection, prefilled syringe, clinical rationale for use of the requested agent instead of Tyenne auto-injection, prefilled syringe.

Actemra, Tofidence, and Tyenne for systemic juvenile idiopathic arthritis (sJIA)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to all traditional DMARDs; **or**
    - inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for systemic juvenile idiopathic arthritis; **and**
  - for Actemra auto-injection, prefilled syringe, clinical rationale for use of the requested agent instead of Tyenne auto-injection, prefilled syringe.

Actemra and Tyenne for systemic sclerosis-associated interstitial lung disease

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: cyclophosphamide, mycophenolate; **and**
  - for Actemra auto-injection, prefilled syringe, clinical rationale for use of the requested agent instead of Tyenne auto-injection, prefilled syringe.

Actemra, Avsola, Inflectra, Remicade, Renflexis, and unbranded infliximab for uveitis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following:
    - ophthalmic, oral, or injectable glucocorticoids; **and**
    - oral or injectable immunosuppressive therapy; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to Humira; **or**
    - clinical rationale for use of the requested agent instead of Humira; **and**
  - for Inflecta, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Adbry and Ebglyss for moderate-to-severe atopic dermatitis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - prescriber is a specialist (i.e., allergist/immunologist or dermatologist) or consult notes from a specialist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - one of the following:
    - total body surface area (BSA) to be treated is ≥ 10%; **or**
    - inadequate response or adverse reaction to one other systemic immunomodulatory agent or contraindication to all other systemic immunomodulatory agents for the treatment of atopic dermatitis; **or**
    - both of the following:
      - inadequate response or adverse reaction to one or contraindication to both of the following: Eucrisa, topical tacrolimus; **and**
      - one of the following:
        - inadequate response or adverse reaction to one or contraindication to all superpotent or potent topical corticosteroids; **or**
        - treatment area is a sensitive area (facial/groin).

Agamree
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - genetically confirmed mutation in the dystrophin gene representative of DMD; **and**
  - member is ≥ two years of age; **and**
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - adverse reaction to prednisone that was not alleviated with at least a 25% dose reduction (~0.56 mg/kg/day); **and**
  - adverse reaction to deflazacort that was not alleviated with at least a 25% dose reduction (~0.675 mg/kg/day); **and**
  - requested dose ≤ 6 mg/kg/day or 300 mg/day.
- For recertification, documentation of the following is required:

- prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
- requested dose ≤ 6 mg/kg/day or 300 mg/day; **and**
- medical records to support improvement from baseline in steroid-specific side effects after treatment with the requested agent.

Alkindi

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is < 18 years of age; **and**
  - medical necessity for the requested formulation instead of hydrocortisone tablets.

Arcalyst and Ilaris for familial cold autoinflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate age (for Arcalyst member is ≥ 12 years of age, for Ilaris member is ≥ four years of age); **and**
  - appropriate dosing; **and**
  - one of the following:
    - evidence of symptoms indicative of the disease; **or**
    - confirmation of diagnosis through genetic testing; **and**
  - for Arcalyst, an inadequate response, adverse reaction, or contraindication to Ilaris.

Arcalyst and Kineret for Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - confirmation of diagnosis through genetic testing; **and**
  - appropriate dosing; **and**
  - for Arcalyst, an inadequate response, adverse reaction, or contraindication to Kineret.

Arcalyst for recurrent pericarditis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: aspirin, NSAIDs; **and**
  - inadequate response or adverse reaction to one or contraindication to all corticosteroids; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: colchicine, Kineret.

Avsola, Inflectra, Kineret, Otulfi, Pyzchiva, Remicade, Renflexis, Selarsdi, Stelara, Steqeyma, unbranded infliximab, unbranded ustekinumab generics, and Yesintek for moderate-to-severe hidradenitis suppurativa

- Documentation of the following is required:
  - diagnosis of moderate-to-severe hidradenitis suppurativa (Hurley Stage II or Hurley Stage III disease); **and**
  - inadequate response or adverse reaction to one or contraindication to all oral antibiotics; **and**
  - for Avsola, Inflectra, Kineret, Remicade, Renflexis, or unbranded infliximab, inadequate response, adverse reaction, or contraindication to Humira; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, unbranded ustekinumab generics, and Yesintek, inadequate response, adverse reaction, or contraindication to Humira; **and**

- for Otulfi, Pyzchiva, Selarsdi, Steqeyma, unbranded ustekinumab generics, and Yesintek, one of the following:
  - clinical rationale for use of the requested agent instead of Stelara; **or**
  - medical records documenting an inadequate response or adverse reaction to Stelara; and
- for brand name Pyzchiva, Remicade, and Selarsdi, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic.

Avsola, Inflectra, Remicade, Renflexis, and unbranded infliximab for Neurologic Sarcoidosis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

azathioprine 75 mg, 100 mg tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the use of the 75 mg or 100 mg tablets instead of the 50 mg tablets.

SmartPA: Claims for azathioprine 75 mg and 100 mg tablets will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent and the member has a history of MassHealth medical claims for organ transplant, complications of transplanted organs, or paid MassHealth pharmacy claims for sirolimus in the past 365 days.†

Bimzelx, Cosentyx, Rinvoq, Xeljanz and Xeljanz XR for ankylosing spondylitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to two or contraindication to all NSAIDs; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for ankylosing spondylitis; **and**
  - for Bimzelx, Cosentyx, and Rinvoq, inadequate response, adverse reaction, or contraindication to Taltz; **and**
  - for Rinvoq, inadequate response or adverse reaction to one or contraindication to both of the following: Xeljanz, Xeljanz XR; **and**
  - one of the following:
    - for Xeljanz, requested quantity is ≤ two tablets/day; **or**
    - for Rinvoq and Xeljanz XR, requested quantity is ≤ one tablet/day.

Bimzelx, Cosentyx, and Rinvoq for non-radiographic axial spondyloarthritis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to two or contraindication to all NSAIDs; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents; **and**
  - inadequate response, adverse reaction, or contraindication to Taltz; **and**
  - for Rinvoq, requested quantity is ≤ one tablet/day.

calcipotriene cream, ointment > 60 grams/30 days

- Documentation of the following is required:
  - diagnosis of plaque psoriasis; **and**
  - one of the following:
    - both of the following:
      - member is < 18 years of age; **and**
      - prescriber is a dermatologist or consult notes from a dermatologist are provided; **or**
    - member is ≥ 18 years of age; **and**
  - clinical rationale for the use of > 60 grams/30 days.

calcipotriene foam and calcitriol ointment

- Documentation of the following is required:
  - diagnosis of plaque psoriasis; **and**
  - one of the following:
    - for calcitriol ointment, one of the following:
      - member is ≥ two years of age; **or**
      - prescriber is a dermatologist or consult notes from a dermatologist are provided; **or**
    - for calcipotriene foam, member is ≥ four years of age; **and**
  - one of the following:
    - member has plaque psoriasis on areas at high risk for skin atrophy (e.g., face, intertriginous areas, genitals); **or**
    - inadequate response (within the last six months) or adverse reaction to one or contraindication to all topical corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: calcipotriene cream, ointment, and scalp solution; **and**
  - for calcipotriene foam, one of the following:
    - requested quantity is 60 grams; **or**
    - clinical rationale for the use of > 60 grams/30 days.

Cibinqo for moderate-to-severe atopic dermatitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - prescriber is a specialist (i.e., allergist/immunologist or dermatologist) or consult notes from a specialist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response or adverse reaction to one superpotent or potent topical corticosteroid, or contraindication to all superpotent or potent topical corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Eucrisa, topical tacrolimus; **and**
  - inadequate response, adverse reaction, or contraindication to Dupixent; **and**
  - requested quantity is ≤ one tablet/day; **and**
  - for the 200 mg tablet, inadequate response (defined as ≥ 12 weeks of therapy) to the 100 mg dose.

Cimzia and Taltz for ankylosing spondylitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to two or contraindication to all NSAIDs; **and**
  - for Cimzia, both of the following:
    - clinical rationale for the use of the requested agent instead of Enbrel; **and**
    - clinical rationale for the use of the requested agent instead of Humira; **and**
  - for Cimzia vial, clinical rationale for use instead of Cimzia prefilled syringe.

Cimzia and Taltz for non-radiographic axial spondyloarthritis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to two or contraindication to all NSAIDs; **and**
  - for Cimzia vial, clinical rationale for use instead of Cimzia prefilled syringe.

Cosentyx for Enthesitis-Related Arthritis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ four years and < 18 years of age; **and**
  - appropriate dosing.

Cosentyx auto-injection, prefilled syringe for psoriatic arthritis in pediatric members

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years and < 18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Enbrel, Humira; **and**
  - appropriate dosing.

Cosentyx auto-injection, prefilled syringe, Ilumya, Otulfi, Pyzchiva, Selarsdi, Siliq, Skyrizi, Stelara, Steqeyma, Taltz, Tremfya, unbranded ustekinumab generics, and Yesintek for Pityriasis rubra pilaris (PRP)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all topical corticosteroids; **and**
  - for Cosentyx, Ilumya, Siliq, Skyrizi, and Tremfya, clinical rationale for use of the requested agent instead of Stelara and Taltz; **and**
  - for Otulfi, Pyzchiva, Selarsdi, Steqeyma, unbranded ustekinumab generics, and Yesintek, one of the following:
    - clinical rationale for use of the requested agent instead of Stelara; **or**
    - medical records documenting an inadequate response or adverse reaction to Stelara; **and**
  - for brand name Pyzchiva and Selarsdi, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic.

deflazacort

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - genetically confirmed mutation in the dystrophin gene representative of DMD; **and**
  - member is ≥ two years of age; **and**
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - trial of prednisone and experienced significant weight gain [e.g., crossing two major percentiles and/or reaching the 98th percentile for body mass index (BMI) for age and gender] that was not alleviated with at least a 25% dose reduction (~0.56 mg/kg/day); **and**
  - appropriate dosing for weight (~0.9 mg/kg/day) (current dose and current weight must be provided); **and**
  - for suspension formulation, one of the following:

- medical necessity for use of the suspension formulation instead of the tablet formulation; **or**
- member is not utilizing other solid oral formulations.

- For recertification, documentation of the following is required:
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - appropriate dosing for weight (~0.9 mg/kg/day) (current dose and current weight must be provided); **and**
  - medical records to support improvement from baseline in steroid-specific side effects after treatment with the requested agent; **and**
  - for suspension formulation, one of the following:
    - continued medical necessity for use of the suspension formulation instead of the tablet formulation; **or**
    - member is not utilizing other solid oral formulations.

dexamethasone tablet pack

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested agent instead of other glucocorticoid formulations available without PA.

Envarsus XR

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to tacrolimus capsules.

SmartPA: Claims for Envarsus XR will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days of therapy out of the last 120 days.†

Eohilia

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (i.e., allergist, hematologist, immunologist, gastroenterologist, etc.) or consult notes from specialist are provided; **and**
  - member is ≥ 11 years of age; **and**
  - inadequate response (defined as ≥ 60 days of therapy) or adverse reaction to one or contraindication to all proton pump inhibitors; **and**
  - inadequate response (defined as ≥ 30 days of therapy), adverse reaction, or contraindication to fluticasone propionate inhalation aerosol; **and**
  - appropriate dosing; **and**
  - requested duration does not exceed 12 weeks.

Hemady, prednisolone 10 mg/5 mL oral solution, prednisolone 20 mg/5 mL oral solution, prednisolone orally disintegrating tablet, and prednisolone tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested agent instead of other glucocorticoid formulations available without PA.

Ilaris for familial Mediterranean fever (FMF), Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD), or Tumor necrosis factor receptor associated periodic syndrome (TRAPS)

- Documentation of the following is required:
  - an appropriate diagnosis; **and**

- appropriate dosing; **and**
- one of the following:
  - evidence of symptoms indicative of the disease; **or**
  - confirmation of diagnosis through genetic testing; **and**
- for diagnosis of FMF, an inadequate response, adverse reaction, or contraindication to colchicine.

Ilaris for Adult Onset Still's Disease (AOSD) and sJIA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all corticosteroids; **and**
  - inadequate response, adverse reaction, or contraindication to Kineret; **and**
  - appropriate dosing.

Ilaris for gout flares

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: colchicine, corticosteroids, NSAIDs; **and**
  - appropriate dosing.

Jylamvo for acute lymphoblastic leukemia, mycosis fungoides, relapsed or refractory non-Hodgkin lymphoma, RA, or severe psoriasis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to methotrexate tablet; **or**
    - medical necessity for methotrexate oral solution as noted by one of the following:
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
      - use of dose that is not optimal to obtain from tablet formulation; **or**
      - member utilizes tube feeding (G-tube/J-tube).

Kevzara for Polymyalgia Rheumatica (PMR)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids; **and**
  - inadequate response, adverse reaction, or contraindication to methotrexate; **and**
  - appropriate dosing.

Kineret for acute gout

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: colchicine, NSAIDs, oral or intraarticular glucocorticoids.

Kineret for Adult-Onset Still’s Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA)

- Documentation of the following is required:
  - diagnosis of one of the following:
    - AOSD; **or**
    - SJIA; **and**
  - inadequate response or adverse reaction to one or contraindication to all corticosteroids; **and**
  - requested dose is 1 to 2 mg/kg once daily (maximum initial dose of 100 mg); if no response, dose may be titrated up to 4 mg/kg once daily (maximum dose of 200 mg).

Kineret for familial cold autoinflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS)
- Documentation of the following is required:
  - diagnosis of one of the following:
    - FCAS; **or**
    - MWS; **and**
  - requested dose is 1 mg/kg/day subcutaneously (maximum, 100 mg).

Kineret for Hyperimmunoglobulin D Syndrome (HIDS)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all NSAIDs; **and**
  - inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids.

Kineret for neonatal-onset multisystem inflammatory disease (NOMID)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing.

Kineret for moderate-to-severe RA
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all traditional DMARDs; **and**
  - inadequate response or adverse reaction to one or contraindication to all biologic DMARDs that are FDA-approved for RA.

Kineret for recurrent pericarditis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: aspirin, NSAIDs; **and**
  - inadequate response or adverse reaction to one corticosteroid, or contraindication to all corticosteroids; **and**
  - inadequate response, adverse reaction, or contraindication to colchicine; **and**
  - requested dose is 100 mg subcutaneously once daily.

Litfulo and Olumiant for severe alopecia areata
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - prescriber is a dermatologist or consult notes from a dermatologist are provided; **and**
  - one of the following:
    - for Litfulo, member is ≥ 12 years of age; **or**

    - for Olumiant, member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all topical corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to all intralesional corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Xeljanz, Xeljanz XR; **and**
  - requested quantity is ≤ one unit/day.

Lupkynis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - member is receiving low-dose oral corticosteroids in combination with one of the following immunosuppressant agents: azathioprine, mycophenolic acid analog; **and**
  - member will not be receiving cyclophosphamide or biologics as maintenance immunosuppressive therapy; **and**
  - appropriate dosing.

Myhibbin
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to mycophenolate mofetil suspension [Cellcept]; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to mycophenolate mofetil capsules or tablets; **or**
    - medical necessity for the use of a suspension formulation as noted by one of the following:
      - member is < 13 years of age; **or**
      - use of dose that is not optimal to obtain from capsule or tablet formulation; **or**
      - member utilizes tube feeding (J-tube, G-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow.
- For recertification, documentation of continued medical necessity for the requested formulation is required.

Nulojix
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age.

Olumiant, Rinvoq, Xeljanz, and Xeljanz XR for moderate-to-severe RA
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for RA; **and**
  - for Olumiant and Rinvoq, inadequate response or adverse reaction to one or contraindication to both of the following: Xeljanz, Xeljanz XR; **and**
  - one of the following:
    - for Xeljanz, requested quantity is ≤ two tablets/day; **or**
    - for Olumiant, Rinvoq, and Xeljanz XR, requested quantity is ≤ one tablet/day.

Orencia for Acute Graft Versus Host Disease (aGVHD) prophylaxis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**

- requested agent will be used in combination with both a calcineurin inhibitor and methotrexate; **and**
- appropriate dosing.

Otezla for Lichen Planus

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one high-potency or super-high-potency topical corticosteroid or contraindication to all high-potency or super-high-potency topical corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to all intralesional corticosteroids; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: phototherapy, acitretin, cyclosporine, dapsone, hydroxychloroquine, hydroxyzine, methotrexate, metronidazole, mycophenolate mofetil, sulfasalazine, systemic glucocorticoids.

Otezla for plaque psoriasis (all severity levels)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all conventional therapies (topical agents, phototherapy, and systemic agents as defined in appendix below); **and**
  - for Otezla 20 mg tablet and 10-20 mg 28-day starter kit, both of the following:
    - member is ≥ six years of age; **and**
    - member weight is ≥ 20 kg and < 50 kg; **and**
  - requested quantity is ≤ two tablets/day.

Otezla for oral ulcers associated with Behçet's disease

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - requested quantity is ≤ two tablets/day.

Otrexup and Rasuvo for moderate-to-severe plaque psoriasis in adults or RA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to oral methotrexate; **and**
  - for Otrexup, inadequate response or adverse reaction to Rasuvo; **and**
  - medical necessity for prefilled methotrexate injector as noted by one of the following:
    - physical disability; **or**
    - visual impairment; **or**
    - cognitive impairment.

Otrexup and Rasuvo for moderate-to-severe plaque psoriasis in pediatrics or PJIA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for Otrexup, inadequate response or adverse reaction to Rasuvo; **and**
  - medical necessity for prefilled methotrexate injector as noted by one of the following:
    - physical disability; **or**
    - visual impairment; **or**
    - cognitive impairment.

Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, unbranded ustekinumab generics, and Yesintek for fistulizing Crohn's disease

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents; **and**
  - appropriate dosing; and
  - for Otulfi, Pyzchiva, Selarsdi, Steqeyma, unbranded ustekinumab generics, and Yesintek, one of the following:
    - clinical rationale for use of the requested agent instead of Stelara; **or**
    - medical records documenting an inadequate response or adverse reaction to Stelara; **and**
  - for brand name Pyzchiva and Selarsdi, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic.

Prograf granules

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to tacrolimus capsules; **or**
    - medical necessity for the use of a granule formulation as noted by one of the following:
      - member is < 13 years of age; **or**
      - use of dose that is not optimal to obtain from capsule formulation; **or**
      - member utilizes tube feeding (J-tube, G-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow.
- For recertification, documentation of continued medical necessity for the requested formulation is required.

Rayos

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the delayed-release formulation instead of other glucocorticoid formulations available without PA.

Rinvoq for Crohn's disease

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for Crohn's disease; **and**
  - requested quantity is ≤ one tablet/day.

Rinvoq for moderate-to-severe atopic dermatitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., allergist/immunologist or dermatologist), or consult notes from a specialist office are provided; **and**
  - member is ≥ 12 years of age; **and**
  - for members ≥ 12 years and < 18 years of age, weight is ≥ 40 kg; **and**
  - inadequate response or adverse reaction to one superpotent or potent topical corticosteroid, or contraindication to all superpotent and potent topical corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Eucrisa, topical tacrolimus; **and**
  - inadequate response, adverse reaction, or contraindication to Dupixent; **and**
  - appropriate dosing; **and**

- requested quantity is ≤ one tablet/day.

Rinvoq, Rinvoq LQ, and Xeljanz for moderate-to-severe PJIA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents; **and**
  - for Rinvoq and Rinvoq LQ, an inadequate response or adverse reaction to one or contraindication to both of the following: Xeljanz, Xeljanz XR; **and**
  - for Rinvoq LQ, medical necessity for the use of the oral solution as noted by one of the following:
    - member is < 13 years of age; **or**
    - use of dose that is not optimal to obtain from tablet formulation; **or**
    - member utilizes tube feeding (J-tube, G-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **and**
  - one of the following:
    - for Rinvoq LQ, requested quantity is ≤ 12 mL/day; **or**
    - for Rinvoq, requested quantity is ≤ one tablet/day; **or**
    - for Xeljanz solution, requested quantity is ≤ 20 mL/day; **or**
    - for Xeljanz tablets, requested quantity is ≤ two tablets/day.

Rinvoq, Rinvoq LQ, Xeljanz, and Xeljanz XR for psoriatic arthritis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all traditional DMARDs; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for psoriatic arthritis; **and**
  - for Rinvoq and Rinvoq LQ, an inadequate response or adverse reaction to one or contraindication to both of the following: Xeljanz, Xeljanz XR; **and**
  - for Rinvoq LQ, medical necessity for the use of the oral solution as noted by one of the following:
    - member is < 13 years of age; **or**
    - use of dose that is not optimal to obtain from tablet formulation; **or**
    - member utilizes tube feeding (J-tube, G-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **and**
  - one of the following:
    - for Xeljanz, requested quantity is ≤ two tablets/day; **or**
    - for Rinvoq or Xeljanz XR, requested quantity is ≤ one tablet/day; **or**
    - for Rinvoq LQ, requested quantity is ≤ 12 mL/day.

Rinvoq, Xeljanz, and Xeljanz XR for ulcerative colitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for ulcerative colitis; **and**
  - for Rinvoq, inadequate response or adverse reaction to one or contraindication to both of the following: Xeljanz, Xeljanz XR; **and**
  - one of the following:

- for Xeljanz, requested quantity is ≤ two tablets/day; **or**
- for Rinvoq or Xeljanz XR, requested quantity is ≤ one tablet/day.

Sandimmune solution
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to cyclosporine capsules; **or**
    - medical necessity for the use of a solution formulation as noted by one of the following:
      - member is < 13 years of age; **or**
      - use of dose that is not optimal to obtain from capsule formulation; **or**
      - member utilizes tube feeding (J-tube, G-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow.
- For recertification, documentation of continued medical necessity for the requested formulation is required.

Sotyktu for moderate-to-severe plaque psoriasis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - requested quantity is ≤ one tablet/day; **and**
  - inadequate response or adverse reaction to one of the following or contraindication to both of the following: one biologic DMARD that is FDA-approved for plaque psoriasis, Otezla.

Spevigo for generalized pustular psoriasis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - both of the following:
      - member is ≥ 12 years of age; **and**
      - member's current weight is ≥ 40 kg; **or**
    - member is ≥ 18 years of age; **and**
  - for Spevigo prefilled syringe, one of the following:
    - inadequate response or adverse reaction to one or contraindication to all of the following: Enbrel, Humira, infliximab, Stelara, Taltz; **or**
    - documentation of positive response to treatment for an acute pustular psoriasis flare using Spevigo vial; **and**
  - appropriate dosing.

Sylvant
- Documentation of the following is required:
  - diagnosis of multicentric Castleman's disease (MCD); **and**
  - member is ≥ 18 years of age; **and**
  - member is HIV negative and HHV-8 negative; **and**
  - member's current weight; **and**
  - results from hematological laboratory tests at baseline showing all of the following:
    - absolute neutrophil count ≥ 1.0×10^9/L; **and**
    - platelet count ≥75×10^9/L; **and**
    - hemoglobin <17 g/dL.

Tarpeyo

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - prescriber is a nephrologist or consult notes from a nephrologist are provided; **and**
  - one of the following:
    - both of the following:
      - inadequate response (defined as ≥ 90 days of therapy) to the maximally tolerated dose of an ACE inhibitor or ARB; **and**
      - medical records documenting intolerance to an ACE inhibitor or ARB at a dose above the maximally tolerated dose; **or**
    - inadequate response (defined as ≥ 90 days of therapy) to the maximum FDA-approved dose of an ACE inhibitor or ARB; **and**
  - medical records documenting one of the following despite treatment with a maximally tolerated dose of an ACE inhibitor or ARB for ≥ 90 days:
    - urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g; **or**
    - proteinuria >1.0 g/day; **and**
  - medical necessity for the delayed-release formulation instead of other glucocorticoid formulations available without PA.

Velsipity and Zeposia for moderate-to-severe ulcerative colitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or consult notes from a gastroenterology office are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for ulcerative colitis; **and**
  - inadequate response, adverse reaction, or contraindication to Entyvio; **and**
  - appropriate dosing; **and**
  - requested quantity is ≤ one capsule/day.

Xatmep for acute lymphoblastic leukemia in members < 18 years or PJIA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is < 18 years of age; **and**
  - appropriate dosing; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to methotrexate tablets; **or**
    - medical necessity for methotrexate oral solution as noted by one of the following:
      - member is < 13 years of age; **or**
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
      - requested dose cannot be obtained from tablet formulation; **or**
      - member utilizes tube feeding (G-tube/J-tube).

Xatmep for acute lymphoblastic leukemia in members ≥ 18 years, moderate-to-severe plaque psoriasis, relapsed or refractory non-Hodgkin lymphoma, or RA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to methotrexate injection; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to methotrexate tablets; **or**
    - medical necessity for methotrexate oral solution as noted by one of the following:

- member is < 13 years of age; **or**
- member has a swallowing disorder or condition affecting ability to swallow; **or**
- requested dose cannot be obtained from tablet formulation; **or**
- member utilizes tube feeding (G-tube/J-tube).

Xeljanz and Xeljanz XR for Alopecia Areata

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a dermatologist or consult notes from a dermatologist are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to all topical corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to all intralesional corticosteroids
  - one of the following:
    - for Xeljanz, requested quantity is ≤ two tablets/day; **or**
    - for Xeljanz XR, requested quantity is ≤ one tablet/day; **or**
    - for Xeljanz solution, requested quantity is ≤ 20 mL/day; **and**
  - for Xeljanz solution, medical necessity for the use of a solution formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age; **or**
    - requested dose is < 5 mg.

Xeljanz and Xeljanz XR for Hidradenitis Suppurativa (HS)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to Humira; **and**
  - for Xeljanz solution, medical necessity for the use of a solution formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age; **or**
    - requested dose is < 5 mg; **and**
  - one of the following:
    - for Xeljanz, requested quantity is ≤ two tablets/day; **or**
    - for Xeljanz XR, requested quantity is ≤ one tablet/day; **or**
    - for Xeljanz solution, requested quantity is ≤ 20 mL/day.

Xeljanz and Xeljanz XR for moderate-to-severe plaque psoriasis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to all conventional therapies (topical agents, phototherapy, and systemic agents as defined in appendix below); **and**
    - inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for plaque psoriasis; **and**
  - for Xeljanz solution, medical necessity for the use of a solution formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age; **or**
    - requested dose is < 5 mg; **and**
  - one of the following:

- for Xeljanz, requested quantity is ≤ two tablets/day; **or**
- for Xeljanz XR, requested quantity is ≤ one tablet/day; **or**
- for Xeljanz solution, requested quantity is ≤ 20 mL/day.

Xeljanz solution for off-label indications

- Documentation of the following is required:
  - PA criteria for Xeljanz or Xeljanz XR must be met, depending on indication; **and**
  - medical necessity for the use of a solution formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age; **or**
    - requested dose is < 5 mg; **and**
  - requested quantity is ≤ 20 mL/day.

Zilretta

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two different intra-articular corticosteroid injection preparations or contraindication to all other intra-articular corticosteroid injection preparations; **and**
  - appropriate dosing.

Appendix:

Conventional Therapies for Plaque Psoriasis		
Phototherapy	**Topical Agents**	**Systemic Agents**
ultraviolet A and topical psoralens (topical PUVA)	emollients	*Traditional DMARDs:*
ultraviolet A and oral psoralens (systemic PUVA)	keratolytics	methotrexate
narrow band UV-B (NUVB)	corticosteroids	sulfasalazine
	calcipotriene	cyclosporine
	tazarotene	tacrolimus
		acitretin
		mycophenolate mofetil
		azathioprine
		hydroxyurea
		leflunomide
		6-thioguanine

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 6 - Nutrients, Vitamins, and Vitamin Analogs

Drug Category: Vitamin supplementation and management

Medication Class/Individual Agents: Vitamins and Nutrients

I. Prior-Authorization Requirements

Nutrients, Vitamins, and Vitamin Analogs – Vitamins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ascorbic acid	vitamin C		*, M90
calcium replacement			*, M90
cyanocobalamin	vitamin B-12		o, M90
cyanocobalamin nasal spray	Nascobal	PA	
ergocalciferol capsule			M90
folic acid			*, M90
multivitamin injection	Infuvite		
multivitamin-Dekas Essential	Dekas Essential	PA	M90
multivitamins			*, M90
multivitamins / minerals / coenzyme Q10-Dekas Plus	Dekas Plus	PA	M90
multivitamins / minerals / folic acid / coenzyme Q10-Dekas Bariatric	Dekas Bariatric	PA	M90
multivitamins / minerals / folic acid / coenzyme Q10-Dekas Plus	Dekas Plus	PA	M90
multivitamins / zinc gummy	Adek Gummies	PA	M90
niacin	vitamin B-3		*, M90
niacinamide			*, M90
pediatric multivitamins			*, M90
prenatal vitamins			*, M90
pyridoxine	vitamin B-6		*, M90
retinol	vitamin A		*, M90
riboflavin	vitamin B-2		*, M90
thiamine	vitamin B-1		*, M90
vitamin A injection	Aquasol A		
vitamin B complex			*, M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Vitamin D and Vitamin D Analogs:

- In patients with stage 3-5 CKD not on dialysis with intact parathyroid hormone (PTH) progressively rising or persistently above the upper normal limit of the assay, it is suggested to evaluate for hyperphosphatemia, hypocalcemia, high phosphate intake, and vitamin D deficiency.[1]
- In adults with stage 3-5 CKD not on dialysis, it is suggested to not routinely use calcitriol and vitamin D analogs. It is reasonable to reserve the use of calcitriol and vitamin D analogs for adults with CKD G4–G5 with severe and progressive hyperparathyroidism. The use in children may be considered to maintain serum calcium levels in the age-appropriate normal range.[1]
- Excessive administration of vitamin D compounds may lead to over suppression of parathyroid hormone (PTH), hypercalcemia, hypercalciuria, hyperphosphatemia, and adynamic bone disease.[4]

calcifediol:

- FDA-approved for the treatment of secondary hyperparathyroidism in adults with stage 3 or 4 CKD and serum total 25-hydoxyvitamin D levels less than 30

Nutrients, Vitamins, and Vitamin Analogs – Vitamins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
vitamin D			*, M90
vitamin E, oral			*, M90
vitamins, multiple			*, M90
vitamins, multiple / minerals			*, M90
vitamins, pediatric			*, M90
vitamins, prenatal			*, M90

Nutrients, Vitamins, and Vitamin Analogs – Vitamin D Analogs			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
calcifediol	Rayaldee	PA	
calcitriol capsule			M90
calcitriol injection			MB
calcitriol solution	Rocaltrol	PA	M90
doxercalciferol capsule		PA	M90
doxercalciferol injection	Hectorol		MB
paricalcitol capsule	Zemplar	PA	M90
paricalcitol injection	Zemplar		MB

Nutrients, Vitamins, and Vitamin Analogs – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
glucose products		PA - ≥ 21 years	A90
magnesium injection			MB
magnesium salts			*, A90
potassium bicarbonate			A90
potassium chloride extended-release capsule			A90
potassium chloride extended-release tablet	K-Tab		# , A90
potassium chloride injection			
potassium chloride oral solution			A90
potassium chloride powder for oral solution	Pokonza	PA	
potassium chloride	Klor-Con		# , A90

Clinical Notes

ng/mL.

cyanocobalamin (generic Nascobal):

- FDA-approved for the maintenance of normal hematologic status in pernicious anemia in patients in remission following intramuscular vitamin B-12 therapy with no nervous system involvement.
- FDA-approved as a supplement for various other vitamin B-12 deficiencies.

doxercalciferol:

- FDA-approved for the treatment of secondary hyperparathyroidism in adults with stage 3 or 4 CKD or with CKD and on dialysis.

paricalcitol:

- FDA-approved for the treatment of secondary hyperparathyroidism in adults and children 10 years or older with stage 3 or 4 CKD or stage 5 CKD and on dialysis.

potassium chloride powder for oral solution[2,3]:

- FDA-approved for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient.
- The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis requires careful attention to acid-base balance; volume status; electrolytes, including magnesium, sodium, chloride, phosphate, and calcium; electrocardiograms; and the clinical status of the patient. Correct volume status, acid-base balance, and electrolyte deficits as appropriate.
- Administration of oral potassium salts rarely causes serious hyperkalemia in persons with normal potassium excretion. Serious hyperkalemia is characterized by electrocardiographic changes, and potentially muscle paralysis or cardiovascular collapse in the most severe cases.
- For members who have difficulty swallowing capsules or tablets, some potassium chloride capsules may be opened and sprinkled on soft food and some potassium chloride tablets may be split in half or dissolved in water. See specific product information for further information on food and liquids compatible with capsule or tablet contents.

[1] Kidney Disease Improving Global Outcomes. KDIGO Clinical Practice Guideline Update for the Diagnosis,

Nutrients, Vitamins, and Vitamin Analogs – Not Otherwise Classified				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
powder packet, extended-release tablet				Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) [guideline on the Internet]. Kidney international supplements, 2017 [cited 2025 June 13]. Available from: https://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL-Update.pdf. [2] Lexicomp Online Database [database on the Internet]. Hudson (OH): Lexicomp Inc.; 2024 [cited 2025 June 13]. Available from: http://online.lexi.com. Subscription required to view. [3] Pokonza [package insert]. Hazlet (NJ): Carwin Pharmaceutical Associates, LLC; 2024 Mar. [4] Zemplar [package insert on the internet]. North Chicago (IL): AbbVie, Inc.; 2016 Oct [cited 2025 June 13]. Available from: www.zemplar.com.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
o	PA status depends on the drug's formulation.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Secondary hyperparathyroidism in chronic kidney disease (CKD)
- Short bowel syndrome
- Vitamin deficiency

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Adek Gummies, Dekas Bariatric, Dekas Essential, and Dekas Plus

- Documentation of the following is required:
  - appropriate diagnosis (e.g., cystic fibrosis, short gut syndrome, malabsorption syndrome).

SmartPA: Claims for Adek Gummies, Dekas Bariatric, Dekas Essential, and Dekas Plus will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent within the last 90 days, or if the member has a history of MassHealth medical claims for cystic fibrosis, malabsorption syndrome, or short gut syndrome.†

calcitriol solution

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age.

cyanocobalamin (generic Nascobal)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all other comparable cyanocobalamin and vitamin B12 preparations available without prior authorization.

doxercalciferol capsule and paricalcitol capsule

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate age (for doxercalciferol capsule member is ≥ 18 years of age, for paricalcitol capsule member is ≥ ten years of age); **and**
  - inadequate response (defined as ≥ 90 days of therapy), adverse reaction, or contraindication to both of the following: Vitamin D, calcitriol; **and**
  - for doxercalciferol, inadequate response (defined as ≥ 90 days of therapy), adverse reaction, or contraindication to paricalcitol.

glucose products for members ≥ 21 years of age

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested agent above age limit.

Pokonza

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: potassium bicarbonate, potassium chloride oral solution; **and**
  - for members ≥ 13 years of age, inadequate response, adverse reaction, or contraindication to both of the following: potassium chloride extended-release capsule, potassium chloride extended-release tablet; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to potassium chloride 20 mEq powder packet at an equivalent requested dose; **or**
    - requested dose cannot be achieved without using Pokonza.
- For recertification, documentation that the member meets the criteria above is required.

Rayaldee

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - total 25-hydroxyvitamin D level is < 30 ng/mL; **and**
  - inadequate response (defined as ≥ 90 days of therapy), adverse reaction, or contraindication to all of the following: vitamin D, calcitriol, paricalcitol; **and**
  - appropriate dosing.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 7 - Muscle Relaxants - Skeletal

Drug Category: Musculoskeletal

Medication Class/Individual Agents: Muscle Relaxants - Skeletal

I. Prior-Authorization Requirements

Muscle Relaxants - Skeletal			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
baclofen 15 mg tablet		PA	
baclofen 5 mg, 10 mg, 20 mg tablet			A90
baclofen granules	Lyvispah	PA	
baclofen injection	Gablofen		#
baclofen intrathecal injection	Lioresal		
baclofen oral solution		PA	A90
baclofen suspension	Fleqsuvy	PA	A90
carisoprodol	Soma	PA	
carisoprodol / aspirin		PA	
carisoprodol / aspirin / codeine		PA	
chlorzoxazone 250 mg, 375 mg, 750 mg		PA	A90
chlorzoxazone 500 mg		PA - < 18 years	# , A90
cyclobenzaprine 5 mg, 10 mg		PA - < 15 years	A90
cyclobenzaprine 7.5 mg		PA	A90
cyclobenzaprine extended-release	Amrix	PA	A90
dantrolene capsule	Dantrium		# , A90
dantrolene injection solution	Dantrium		MB
dantrolene injection suspension	Ryanodex		MB
metaxalone		PA	A90
methocarbamol injection	Robaxin	PA - < 16 years	#
methocarbamol tablet		PA - < 16 years	A90
orphenadrine		PA - < 18 years	A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Precautions:

- All agents within this class may cause drowsiness and dizziness. Members should be advised of this and to avoid alcohol and other CNS depressants.
- anticholinergic effects - baclofen, cyclobenzaprine, orphenadrine, tizanidine
- cyclobenzaprine - structurally related to tricyclic antidepressants (TCAs); consider potential for similar adverse effects and drug interactions as with TCAs.
- tizanidine - an alpha$_2$ agonist structurally related to clonidine; may cause hypotension; hepatocellular injury reported – monitor LFTs.

Urine discoloration

- orange or red-purple: chlorzoxazone
- brown, black, or green: methocarbamol

Carisoprodol and carisoprodol-containing products

Please see the following link to find out more information regarding carisoprodol products (e.g., Letter to Prescribers) https://www.mass.gov/doc/carisoprodol-letter/download

Muscle Relaxants - Skeletal			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
orphenadrine / aspirin / caffeine		PA	A90
tizanidine capsule	Zanaflex	PA	A90
tizanidine tablet	Zanaflex		# , A90

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- spastic conditions
- adjunctive treatment to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal disorders.

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested

medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

baclofen oral solution, baclofen suspension, and Lyvispah
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - medical necessity for the requested formulation as noted by one of the following:
      - member is < 13 years of age; **or**
      - requested dose is not available in the tablet formulation; **or**
      - swallowing disorder or condition affecting ability to swallow; **or**
    - inadequate response or adverse reaction to baclofen tablets; **and**
  - for Lyvispah, one of the following:
    - requested quantity is ≤ four units/day; **or**
    - both of the following:
      - medical necessity for exceeding four units/day; **and**
      - requested dose is consolidated.

baclofen 15 mg tablet
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for requested agent instead of baclofen tablets available without PA.

carisoprodol and carisoprodol-containing products
- Documentation of all of the following is required:
  - medical records documenting an inadequate response, adverse reaction, or contraindication to all of the following: baclofen, chlorzoxazone, cyclobenzaprine, dantrolene, metaxalone, methocarbamol, orphenadrine, tizanidine; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - requested agent is being used for an acute condition; **or**
    - clinical rationale for the use of carisoprodol for the treatment of a chronic condition.

Spastic Conditions

Brand-name products (Dantrium, Zanaflex tablets) and tizanidine capsules
- Documentation of the following is required:
  - diagnosis of a spastic condition; **and**
  - for brand name Dantrium or Zanaflex, the prescriber must provide documentation of an inadequate response, adverse reaction, or contraindication to dantrolene, baclofen, and tizanidine tablets; **and**
  - for a brand name drug with an A-rated generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to a generic equivalent of the requested product; **and**
  - for tizanidine capsules, both of the following:
    - inadequate response, adverse reaction, or contraindication to both of the following: baclofen, tizanidine tablets; **and**
    - medical necessity for capsule formulation (2 mg and 4 mg) or for dose (6 mg).

Musculoskeletal Conditions

chlorzoxazone 250 mg, 375 mg, 750 mg, cyclobenzaprine 7.5 mg, cyclobenzaprine extended-release, metaxalone, and orphenadrine/aspirin/caffeine

- Documentation of the following is required:
  - diagnosis of musculoskeletal condition; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: cyclobenzaprine immediate-release, orphenadrine, methocarbamol, chlorzoxazone 500 mg; **and**
  - one of the following:
    - member is ≥ 18 years of age; **or**
    - inadequate response, adverse reaction, or contraindication to acetaminophen; **and**
    - inadequate response or adverse reaction to two NSAIDS or contraindication to all NSAIDS; **and**
  - for orphenadrine/aspirin/caffeine, medical necessity for the combination product instead of the commercially available separate agents; **and**
  - for a brand name drug (with or without an A-rated generic) the prescriber must provide medical records documenting an inadequate response or adverse reaction to a generic equivalent of the requested drug.

Please note: requests for cyclobenzaprine extended-release require medical records of a trial with cyclobenzaprine immediate-release. Chlorzoxazone 250 mg, 375 mg, and 750 mg requests require medical records of a trial with chlorzoxazone 500 mg.

SmartPA: Claims for metaxalone will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for a musculoskeletal disorder and paid MassHealth pharmacy claims for the following drugs: cyclobenzaprine immediate-release, orphenadrine, methocarbamol, and chlorzoxazone for members ≥ 18 years of age.†

chlorzoxazone 500 mg < 18 years of age cyclobenzaprine 5 mg, 10 mg < 15 years of age, methocarbamol < 16 years of age, and orphenadrine < 18 years of age:

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to acetaminophen; **and**
  - inadequate response or adverse reaction to two or contraindication to all NSAIDs.

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 8 - Opioids and Analgesics

Drug Category: Pain and Inflammation

Medication Class/Individual Agents: Opioids and Analgesics

I. Prior-Authorization Requirements

Opioids and Analgesics – Short-Acting Opioids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acetaminophen / codeine		PA - < 12 years and PA > 4 g/day acetaminophen and PA > 360 mg/day codeine	
benzhydrocodone / acetaminophen	Apadaz	PA	
buprenorphine injection		PA	
butorphanol nasal spray		PA	
celecoxib / tramadol	Seglentis	PA	
codeine		PA - < 12 years and PA > 360 mg/day	
dihydrocodeine / acetaminophen / caffeine		PA	
fentanyl buccal tablet	Fentora	PA	
fentanyl injection			
fentanyl transmucosal system		PA	
hydrocodone / acetaminophen		PA - > 120 mg/day hydrocodone and PA > 4 g/day acetaminophen	
hydrocodone 5 mg, 10 mg / ibuprofen		PA	
hydrocodone 7.5 mg / ibuprofen		PA - > 120 mg/day hydrocodone and PA > 3.2 g/day ibuprofen	
hydromorphone injection, solution, tablet	Dilaudid	PA - > 24 mg/day	#
hydromorphone suppository		PA	
meperidine	Demerol	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Please note: PA will be required if it is determined that the member is stable on opioid dependence therapy (≥ 60 days of therapy within the last 90 days of an oral opioid dependence agent, or ≥ 56 days of Brixadi or Sublocade in the last 84 days) for any long-acting opioid agent, any short-acting opioid agent > 7 days supply, and any short-acting opioid agent if there is ≥ 7 days of a short-acting opioid agent in the last 30 days.

Please note: Opioids and Analgesics that require PA are listed within this therapeutic class table. Managed Care Organizations (MCOs) may have different high dose thresholds and quantity limits.

Acetaminophen Hepatotoxicity:

- Acetaminophen has been associated with severe hepatotoxicity following acute and chronic ingestion.
- Maximum recommended dose of acetaminophen for adults is four grams/day.
- Be sure to consider and ask about all potential sources of acetaminophen (e.g., OTC, combination analgesics) when determining daily acetaminophen dose.

Opioids and Analgesics – Short-Acting Opioids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
morphine immediate-release		PA - > 120 mg/day	
morphine infusion	Infumorph		
morphine suppositories			
morphine, injection-Astramorph-PF	Astramorph-PF	PA - > 120 mg/day	
morphine, injection-Duramorph	Duramorph	PA - > 120 mg/day	
oxycodone / acetaminophen		PA - > 80 mg/day oxycodone and PA > 4 g/day acetaminophen	
oxycodone / acetaminophen 300 mg		PA	
oxycodone / acetaminophen-Percocet	Percocet	PA - > 80 mg/day oxycodone and PA > 4 g/day acetaminophen	#
oxycodone / aspirin		PA - > 80 mg/day oxycodone and PA > 4 g/day aspirin	
oxycodone immediate-release-Roxicodone	Roxicodone	PA - > 80 mg/day	#
oxycodone immediate-release-Roxybond	Roxybond	PA	
oxymorphone immediate-release		PA	
sufentanil injection			
tramadol / acetaminophen		PA - < 12 years and PA > 400 mg/day tramadol and PA > 4 g/day acetaminophen	
tramadol 25 mg, 100 mg		PA	
tramadol 50 mg		PA - < 12 years and PA > 400 mg/day	
tramadol solution	Qdolo	PA	

Opioids and Analgesics – Long-Acting Opioids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
buprenorphine	Belbuca	PA	

Clinical Notes

- Risk may increase with concurrent alcohol use, underlying liver disease, and/or the fasting state.
- **PA is required for any acetaminophen-containing product that exceeds four grams/day.**

Aspirin Dose Limit:

- The maximum recommended dose of aspirin for adults is four grams/day.
- **PA is required for any aspirin-containing product that exceeds four grams/day.**

Ibuprofen Dose Limit:

- The maximum recommended dose of ibuprofen for adults is 3.2 grams/day.
- **PA is required for any ibuprofen-containing product that exceeds 3.2 grams/day.**

Concomitant Opioid and Benzodiazepine Initiative (COBI)

PA is required for members who are newly starting opioid therapy and are stable on benzodiazepine therapy for ≥ 15 days supply within the past 45 days. Members can receive up to a combined total of 14 days supply of one or more opioid(s) within the past 45-day period without PA within dose limits.

High-Dose Opioid and Analgesic Dose Limit:

- **PA is required for certain high-dose opioids and analgesics if used at doses exceeding the established limits. The accumulated high dose threshold is 120 mg of morphine or morphine milligram equivalent (MME) per day for an individual agent, and 180 MME per day for the entire regimen. All buprenorphine formulations are excluded from the opioid accumulator.**
- Please refer to the High-Dose section of this table for individual agents and their respective high-dose thresholds.

Duplicate Opioid Therapy:

- Standard practice in chronic pain management includes a long-acting opioid for chronic pain and a short-acting opioid for acute/breakthrough pain as needed.
- **PA is required for ≥ two long-acting opioids for > two months.**
- **PA is required for ≥ two short-acting opioids for > two months.**

Allergy:

- True systemic opioid allergy, such as a generalized rash, or angioedema, is unusual. A local, itchy wheal

Opioids and Analgesics – Long-Acting Opioids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
buccal film			
buprenorphine transdermal	Butrans	PA - > 20 mcg/hr and PA > 4 patches/28 days	BP
fentanyl 12, 25, 50 mcg/hr transdermal system		PA - > 50 mcg/hr and PA > 10 patches/30 days	
fentanyl 37.5, 62.5, 87.5 mcg/hr transdermal system		PA	
fentanyl 75, 100 mcg/hr transdermal system		PA	
hydrocodone extended-release capsule		PA	
hydrocodone extended-release tablet	Hysingla ER	PA	
hydromorphone extended-release		PA	
levorphanol tablet		PA	
methadone injection		PA	
methadone oral	Methadose	PA	
methadone oral		PA	
morphine controlled-release tablet	MS Contin	PA - > 120 mg/day	#
morphine extended-release capsule		PA	
oxycodone extended-release tablet	Oxycontin	PA	BP
oxymorphone extended-release		PA	
tramadol extended -release capsule	Conzip	PA	
tramadol extended -release tablet		PA	

Opioids and Analgesics – Other Analgesics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acetaminophen		PA - > 4 g/day	*, A90
clonidine injection	Duraclon		#
pentazocine / naloxone		PA	
suzetrigine	Journavx PD	PA - < 18 years	

Clinical Notes

formation at the site of narcotic injection, generalized pruritus (no rash), or flushing may occur, and is due to histamine release.

Renal Dysfunction:

- Accumulation of certain opioids in members with significant renal dysfunction can lead to excess sedation, respiratory depression, delirium, myoclonus, or seizures.
  - avoid use: meperidine, tapentadol (severe impairment), tramadol (severe impairment)
  - cautious use: acetaminophen, codeine, hydrocodone, morphine, oxycodone

Constipation:

- Common adverse effect with chronic opioid use; prescribe laxative +/- stool softener with opioid.

Hydrocodone and oxycodone in combination with acetaminophen:

- Generically available solution formulations continue to be available without PA within dose limits.
- Select generic tablet formulations continue to be available without PA within dose limits. These include the following products.

Hydrocodone Strength	Acetaminophen Strength
2.5 mg	325 mg
5 mg	325 mg and 300 mg
7.5 mg	325 mg and 300 mg
10 mg	325 mg and 300 mg

Oxycodone Strength	Acetaminophen Strength
5 mg	325 mg
7.5 mg	325 mg
10 mg	325 mg

Opioid First-Fill Seven-Day Supply Restriction:

- In general, members who have not filled an opioid prescription recently (defined as no history of a paid MassHealth pharmacy claim for an opioid in the past 90 days) or who are naïve to opioids will be limited to a seven-day supply for their first fill.
- In general, seven-day supply opioid restrictions do not apply to members who already take opioids.

Opioids and Analgesics – Other Analgesics				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	• Certain exemptions may apply to seven-day supply opioid restrictions. Please note: In general, members that are residents of nursing homes or chronic care facilities, enrolled in hospice, or with a current diagnosis of cancer or sickle cell disease may be considered on a case-by-case basis for an exemption from select opioid-related requirements (e.g., COBI, high dose criteria documentation, opioid first-fill seven-day supply restriction). Please click on the link below to see the Opioid and Pain Initiative. MassHealth Pharmacy Initiatives and Clinical Information For additional information about Opioids (e.g., Letters to Prescribers), go to the following link. https://www.mass.gov/lists/opioids-and-controlled-substances-information
		and PA > 29 units/60 days		

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- acute pain
- chronic pain

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, frequency, and formulation.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply, depending upon the member's condition, requested medication, and Duplicate Therapy, High-Dose, High-Dose Short-Acting Monotherapy, and Quantity Limit restrictions (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.
- If MassHealth pharmacy claims history of required trials is not available, medical records documenting such trials may be required.

Please note: PA will be required if it is determined that the member is stable on opioid dependence therapy (≥ 60 days of therapy within the last 90 days of an oral opioid dependence agent, or ≥ 56 days of Sublocade in the last 84 days) for any long-acting opioid agent, any short-acting opioid agent > seven days supply, and any short-acting opioid agent if there is ≥ seven days of a short-acting opioid agent in the last 30 days.

Belbuca

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - adverse reaction or contraindication to morphine sulfate extended-release that cannot be expected or managed as a part of opioid therapy; **or**
    - medical necessity for buccal formulation; **or**
    - prescriber wants to avoid using a full opioid agonist; **or**
    - treatment plan to microdose buprenorphine with the intent to taper off full agonist opioid therapy (including opioid taper plan, buprenorphine dosing, and tapering schedule); **and**
  - requested dose is ≤ 1,800 mcg/day.

benzhydrocodone/acetaminophen, dihydrocodeine/acetaminophen/caffeine, hydrocodone 5 mg, 10 mg/ibuprofen, oxycodone/acetaminophen 300 mg

Please refer to table in Section I. Prior-Authorization Requirements: Clinical Notes above for hydrocodone/acetaminophen and oxycodone/acetaminophen strengths available without PA within dose limits.

- For strengths and formulations that require PA, documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to all of the following:
    - codeine/acetaminophen; **and**

- hydrocodone/acetaminophen; **and**
- hydrocodone/ibuprofen; **and**
- oxycodone/acetaminophen.

buprenorphine injection

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale why oral pain medications cannot be used; **and**
  - adverse reaction or contraindication to both of the following: buprenorphine transdermal, fentanyl transdermal.

butorphanol nasal spray

- Documentation of the following is required for the diagnosis of acute pain:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ two canisters/30 days; **and**
  - medical records documenting one of the following:
    - adverse reaction or contraindication to all other generic short-acting opioids: codeine, hydromorphone, morphine, and oxycodone; **or**
    - both of the following:
      - medical necessity for nasal spray formulation; **and**
      - adverse reaction or contraindication to both of the following: morphine immediate-release solution, oxycodone immediate-release solution.
- Documentation of the following is required for the treatment of acute migraine:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to two or contraindication to all triptans; **and**
  - requested quantity is ≤ two canisters/30 days; **and**
  - one of the following:
    - medical records documenting an inadequate response, adverse reaction to one additional triptan; **or**
    - medical records documenting an inadequate response, adverse reaction, or contraindication to one agent from a different anti-migraine medication class.
- Documentation of the following is required for requests noting the member is tapering off butorphanol nasal spray:
  - indication for the treatment of acute migraine; **and**
  - medical records documenting the member is on chronic butorphanol; **and**
  - requested quantity is ≤ two canisters/30 days; **and**
  - treatment plan including taper period for discontinuation.

codeine products for members < 12 years of age

- Documentation of one of the following is required:
  - CYP2D6 genotyping confirms member is not an ultra-rapid CYP2D6 metabolizer; **or**
  - member has previously utilized a codeine-containing product without adverse effect that prevents repeat use.

fentanyl buccal tablet

- Documentation of the following is required:
  - indication of breakthrough cancer pain; **and**
  - adverse reaction or contraindication to all of the following:
    - fentanyl transmucosal system (requires PA - see criteria below); **and**
    - hydromorphone immediate-release; **and**
    - morphine immediate-release; **and**

- oxycodone immediate-release; **and**
- member is maintained on a long-acting opioid regimen; **and**
- prescriber is an oncologist or pain specialist.

fentanyl 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr transdermal system
- Documentation of the following is required:
  - clinical rationale why two patches cannot be combined to obtain the equivalent strength requested.

fentanyl transmucosal system
- Documentation of the following is required:
  - indication of breakthrough cancer pain; **and**
  - adverse reaction or contraindication to all of the following:
    - hydromorphone immediate-release; **and**
    - morphine immediate-release; **and**
    - oxycodone immediate-release; **and**
  - member is maintained on a long-acting opioid regimen; **and**
  - prescriber is an oncologist or pain specialist.

hydrocodone extended-release capsule, hydrocodone extended-release tablet, hydromorphone extended-release, oxymorphone extended-release
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - adverse reaction or contraindication to all of the following that cannot be expected or managed as a part of opioid therapy:
    - fentanyl transdermal; **and**
    - morphine extended-release; **and**
    - oxycodone extended-release tablet (requires PA - see criteria below).

hydromorphone suppository
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation instead of solution or tablet formulation; **and**
  - inadequate response, adverse reaction, or contraindication to morphine suppositories.

Journavx (> 29 units/60 days)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member ≥ 18 years of age; **and**
  - medical necessity for another 14-day course of Journavx therapy.

SmartPA: Claims for Journavx will usually process at the pharmacy if the current claim and the current claim plus history is ≤ 29 units within 60 days and if the member is not < 18 years of age.†

levorphanol tablet
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - adverse reaction or contraindication to all of the following that cannot be expected or managed as a part of opioid therapy:
    - fentanyl transdermal; **and**
    - morphine extended-release; **and**

- oxycodone extended-release tablet (requires PA - see criteria below); **and**
- clinical rationale for use of the requested agent instead of all other long-acting opioids.

meperidine
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - allergy to morphine; **and**
  - member has not used morphine derivatives since documented date of morphine allergy.

methadone injection
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for use instead of oral formulations of methadone.

methadone tablet
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is not opioid naïve; **and**
  - baseline ECG showing normal QTc interval; **and**
  - one of the following:
    - adverse reaction or contraindication to both of the following: morphine sulfate extended-release, fentanyl transdermal; **or**
    - clinical rationale for the use of methadone instead of other long-acting opioids.

morphine extended-release capsule
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to morphine extended-release tablets; **and**
  - medical necessity for once daily dosing.

oxycodone extended-release tablet
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - adverse reaction or contraindication to one of the following: fentanyl transdermal, morphine sulfate extended-release.

oxymorphone immediate-release
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - adverse reaction or contraindication to all of the following:
    - hydromorphone immediate-release; **and**
    - morphine immediate-release; **and**
    - oxycodone immediate-release.

pentazocine/naloxone
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - adverse reaction or contraindication to all of the following:
    - one nonsteroidal anti-inflammatory drug (NSAID); **and**
    - hydromorphone immediate-release; **and**

- morphine immediate-release; **and**
- oxycodone immediate-release; **and**
- tramadol; **and**

- requested dose is ≤ 600 mg/day of pentazocine.

Roxybond
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for use instead of oxycodone immediate-release tablets available without PA.

Seglentis
- Documentation of the following is required:
  - diagnosis of management of acute pain; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents.

tramadol 25 mg
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an adverse reaction or contraindication to both of the following: tramadol 50 mg tablet, tramadol/acetaminophen tablet.

tramadol 100 mg
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the use of the 100 mg tablets instead of the 50 mg tablets; **and**
  - medical records documenting an inadequate response or adverse reaction to tramadol 50 mg tablet (two 50 mg tablets).

tramadol extended-release capsule, tablet
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to tramadol immediate-release; **and**
  - medical necessity for use of an extended-release formulation.

tramadol solution
- Documentation of the following is required:
  - diagnosis of moderate to severe pain; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - medical necessity for the oral solution formulation; **or**
    - medical records documenting inadequate response or adverse reaction to tramadol immediate-release tablets that are available without prior authorization.

tramadol products for members < 12 years of age
- Documentation of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - one of the following:
    - CYP2D6 genotyping confirms member is not an ultra-rapid CYP2D6 metabolizer; **or**
    - member has previously utilized a tramadol-containing product without adverse effect that prevents repeat use.

In addition to individual drug PA criteria above, some opioids are subject to additional concomitant opioid and benzodiazepine polypharmacy, duplicate therapy, concurrent therapy with opioid dependence agents, high-dose, high-dose short-acting monotherapy, and quantity limit restrictions.

Concomitant Opioid and Benzodiazepine Polypharmacy (pharmacy claims for ≥ 15 days supply for one or more opioid(s) [new to therapy] and one or more benzodiazepine(s) [clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations are not included] for ≥ 15 days supply within the past 45-day period.

- If PA is required for concomitant opioid and benzodiazepine polypharmacy, documentation of the following is required
  - individual drug PA criteria must be met first where applicable; **and**
  - appropriate diagnosis for the opioid; **and**
  - appropriate diagnosis for the benzodiazepine; **and**
  - one of the following:
    - member is currently stable on chronic opioid; **or**
    - member's treatment is currently managed by palliative care; **or**
    - member is currently in hospice or is transitioning to hospice; **or**
    - member is currently being treated for sickle cell disease or cancer pain; **or**
    - inadequate response or adverse reaction to three non-opioid therapies (e.g., prescription NSAIDs, topical analgesics, physical therapy); **or**
    - clinical rationale for the use of opioids instead of non-opioid alternatives; **or**
    - treatment plan to taper off opioid therapy; **or**
    - treatment plan to taper off or taper down from benzodiazepine therapy; **or**
    - clinical rationale for the concomitant use of opioids and benzodiazepines; **and**
  - member will be co-prescribed naloxone.

Duplicate Therapy and Concurrent Therapy with Opioid Dependence Agents

The following opioids require PA if there is concurrent use of two long-acting or two short-acting opioids for at least 60 days out of any 180-day period. In addition, PA will be required if it is determined that the member is stable on opioid dependence therapy, for any long-acting opioid agent, any short-acting opioid agent > seven days supply, and any short-acting opioid agent if there is ≥ seven days of a short-acting opioid agent in the last 30 days.

Long-acting	Short-acting
Belbuca (buprenorphine buccal film)	acetaminophen/codeine
Butrans (buprenorphine transdermal)	Apadaz (benzhydrocodone/acetaminophen)
Conzip (tramadol extended-release capsule)	buprenorphine injection
fentanyl transdermal system	butalbital/aspirin/caffeine/codeine
hydrocodone extended-release capsule	butorphanol nasal spray
hydromorphone extended-release	carisoprodol/aspirin/codeine
Hysingla ER (hydrocodone extended-release tablet)	codeine
levorphanol tablet	Demerol (meperidine)
Methadose (methadone oral)	dihydrocodeine/acetaminophen/caffeine
morphine extended-release capsule	Dilaudid (hydromorphone)
MS Contin (morphine controlled-release)	fentanyl buccal tablet, fentanyl transmucosal system
Oxycontin (oxycodone extended-release tablet)	hydrocodone/acetaminophen
oxymorphone extended-release	hydrocodone/ibuprofen

tramadol extended-release tablet	MSIR (morphine immediate-release)
	oxycodone/aspirin
	oxycodone immediate-release
	oxymorphone immediate-release
	Percocet (oxycodone/acetaminophen)
	pentazocine/naloxone
	Seglentis (celecoxib/tramadol)
	tramadol/acetaminophen
	tramadol
	tramadol solution

- If PA is required for duplicate therapy, documentation of the following is required:
  - appropriate diagnosis; **and**
  - individual drug PA criteria must be met first where applicable; **and**
  - clinical rationale for not maximizing opioid monotherapy.

- If PA is required for concurrent therapy with opioid dependence agents, documentation of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - clinical rationale why concurrent therapy with buprenorphine is clinically appropriate.

High-Dose

The following opioids and analgesics require PA for high-dose if used at doses exceeding the following limits.
The accumulated high dose threshold is 120 mg of morphine or morphine equivalent (MME) per day for an individual agent, and 180 MME per day for the entire regimen. All buprenorphine formulations are excluded from the opioid accumulator.

Long-acting		Short-acting	
Belbuca (buprenorphine buccal film)	> 1,800 mcg/day	acetaminophen products	> 4 grams/day
Butrans (buprenorphine transdermal system)	> 20 mcg/hr	acetaminophen with codeine products	> 4 grams acetaminophen/day > 360 mg codeine/day
Conzip (tramadol extended-release capsule)	> 300 mg/day	Apadaz (benzhydrocodone/acetaminophen)	> 65.28 mg benzhydrocodone/day > 4 grams acetaminophen/day
fentanyl transdermal system	> 50 mcg/hr	codeine products	> 360 mg/day
hydrocodone extended-release capsule	> 80 mg/day	Dilaudid (hydromorphone)	> 24 mg/day
hydromorphone extended-release	> 24 mg/day	hydrocodone/acetaminophen	> 120 mg hydrocodone/day > 4 grams acetaminophen/day
Hysingla ER (hydrocodone extended-release tablet)	> 80 mg/day	hydrocodone/ibuprofen	> 120 mg hydrocodone/day > 3.2 grams ibuprofen/day
levorphanol tablet	> 4 mg/day	morphine immediate-release	> 120 mg/day
Methadose (methadone oral)	> 25 mg/day	oxycodone/acetaminophen	> 80 mg oxycodone/day > 4 grams acetaminophen/day
morphine extended-release capsule	> 120 mg/day	oxycodone/aspirin	> 80 mg oxycodone/day > 4 grams aspirin/day

MS Contin (morphine controlled-release)	> 120 mg/day	oxycodone immediate-release	> 80 mg/day
Oxycontin (oxycodone extended-release tablet)	> 80 mg/day	oxymorphone immediate-release	> 40 mg/day
oxymorphone extended-release	> 40 mg/day	Seglentis (celecoxib/tramadol)	> 400 mg tramadol/day
tramadol extended-release tablet	> 300 mg/day	tramadol/acetaminophen	> 400 mg tramadol/day > 4 grams acetaminophen/day
		tramadol	> 400 mg/day
		tramadol solution	> 400 mg/day

- If exceeding four grams/day of an acetaminophen- or aspirin-containing product, or 3.2 grams/day of an ibuprofen-containing product, documentation of the following is required:
  - appropriate diagnosis; **and**
  - individual drug PA criteria must be met first, where applicable; **and**
  - clinical rationale for utilizing greater than four grams of acetaminophen or aspirin, or greater than 3.2 grams of ibuprofen per day.

- If exceeding the above high-dose limits for other agents, documentation of the following is required:
  - appropriate diagnosis; **and**
  - individual drug PA criteria must be met first, where applicable; **and**
  - member is co-prescribed naloxone or has naloxone filled within the previous year and is unused; **and**
  - one of the following:
    - diagnosis of sickle cell disease; **or**
    - diagnosis of active cancer pain; **or**
    - member's pain control is currently managed by palliative care; **or**
    - member is currently in hospice or is transitioning to hospice; **or**
    - one of the following:
      - all of the following:
        - medical records documenting treatment plan, including clinical rationale for high-dose and titration of medication up to current dose; **and**
        - pain consult from a pain specialist supporting the high-dose of opioid requested (Please note, up to three one-month provisional approvals may be allowed to accommodate pain consult scheduling and completion. If requesting a provisional approval to obtain a pain consult, include the specialist contact information and anticipated date of consult); **and**
        - signed and dated patient-prescriber agreement for opioid use; **or**
      - both of the following:
        - medical records documenting treatment plan to initiate a taper of the requested medication within the next 90 days; **and**
        - signed and dated patient-prescriber agreement for opioid use.

High-Dose, Short-Acting Monotherapy

The following opioids and analgesics require PA for monotherapy if used at doses exceeding the limits listed below.

Short-acting	
acetaminophen with codeine products	> 4 grams acetaminophen/day > 360 mg codeine/day
Apadaz (benzhydrocodone/acetaminophen)	> 65.28 mg benzhydrocodone/day > 4 grams acetaminophen/day

codeine products	> 360 mg/day
Dilaudid (hydromorphone)	> 24 mg/day
hydrocodone/acetaminophen	> 120 mg hydrocodone/day > 4 grams acetaminophen/day
hydrocodone/ibuprofen	> 120 mg hydrocodone/day > 3.2 grams ibuprofen/day
morphine immediate-release	> 120 mg/day
oxycodone/acetaminophen	> 80 mg oxycodone/day > 4 grams acetaminophen/day
oxycodone/aspirin	> 80 mg oxycodone/day > 4 grams aspirin/day
oxycodone immediate-release	> 80 mg/day
oxymorphone immediate-release	> 40 mg/day
Seglentis (celecoxib/tramadol)	> 400 mg tramadol/day
tramadol/acetaminophen	> 400 mg tramadol/day > 4 grams acetaminophen/day
tramadol	> 400 mg/day
tramadol solution	> 400 mg/day

- If exceeding the above high-dose limits and using as monotherapy, documentation of the following is required:
  - individual drug PA criteria must be met first, where applicable; **and**
  - medical records documenting treatment plan, including clinical rationale for high-dose and titration of medication up to current dose; **and**
  - pain consult from a pain specialist supporting the high-dose of opioid requested (Please note, up to three one-month provisional approvals may be allowed to accommodate pain consult scheduling and completion. If requesting a provisional approval to obtain a pain consult, include the specialist contact information and anticipated date of consult); **and**
  - clinical rationale for not utilizing a long-acting agent in a member requiring high-dose, short-acting opioid therapy for the treatment of chronic pain; **and**
  - signed and dated patient-prescriber agreement for opioid use; **and**
  - member is co-prescribed naloxone or has naloxone filled within the previous year and is unused.

Quantity Limits

The following opioids require PA if used at the quantities listed below.

Long-acting	
Belbuca (buprenorphine buccal film)	> 2 films/day
Butrans (buprenorphine transdermal system)	> 4 patches/28 days
Conzip (tramadol extended-release capsule)	> 1 unit/day
fentanyl transdermal system	> 10 patches/30 days
fentanyl 37.5, 62.5, 87.5 mcg/hr transdermal system	> 10 patches/30 days
hydrocodone extended-release capsule	> 2 units/day
hydromorphone extended-release	> 1 unit/day
Hysingla ER (hydrocodone extended-release tablet)	> 1 unit/day
levorphanol tablet	> 2 units/day

morphine extended-release capsule	> 1 unit/day
Oxycontin (oxycodone extended-release tablet)	> 3 units/day
oxymorphone extended-release	> 2 units/day
tramadol extended-release tablet	> 1 unit/day

- If exceeding the above quantity limits, documentation of the following is required:
  - appropriate diagnosis; **and**
  - individual drug PA criteria must be met first, where applicable; **and**
  - requested dose cannot be obtained within the established quantity limits.

MassHealth Evaluation Criteria
Table 9 - Growth Hormones and Increlex

Drug Category: Endocrine and Metabolic Agents

Medication Class/Individual Agents: Pituitary Agents

I. Prior-Authorization Requirements

Growth Hormones			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
lonapegsomatropin-tcgd	Skytrofa PD	PA	
somapacitan-beco	Sogroya PD	PA	
somatrogon-ghla	Ngenla	PA	
somatropin-Genotropin	Genotropin PD	PA	
somatropin-Humatrope	Humatrope	PA	
somatropin-Norditropin	Norditropin	PA	
somatropin-Nutropin AQ	Nutropin AQ	PA	
somatropin-Omnitrope	Omnitrope	PA	
somatropin-Saizen	Saizen	PA	
somatropin-Serostim	Serostim	PA	
somatropin-Zomacton	Zomacton	PA	

Recombinant Human Insulin-Like Growth Factor I			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
mecasermin	Increlex	PA	

Growth Hormone Secretagogue Receptor Agonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
macimorelin	Macrilen		MB

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Contraindications:

- active malignancy
- growth promotion in children with fused epiphyses
- acute critical illness due to complications following open-heart surgery or abdominal surgery

Warnings:

- Dosage and schedule should be individualized.
- Injection sites should be rotated to avoid lipoatrophy.

insulin-like growth factor-1 (IGF-1) or insulin-like growth factor binding protein-3 (IGFBP-3):

Values more than 2 standard deviations (SD) below the mean for IGF-1, also known as somatomedin C, or IGFBP-3 may suggest an abnormality in the growth hormone axis, but results of these tests can depend on transient issues such as poor nutrition or psychosocial deprivation. These tests, therefore, cannot be used as the sole determinant of a growth hormone deficiency diagnosis.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Growth hormone deficiency in children – Genotropin, Humatrope, Ngenla, Norditropin, Nutropin AQ, Omnitrope, Saizen, Skytrofa, Sogroya, Zomacton
- Growth hormone gene deletion with the development of neutralizing antibodies to growth hormone – Increlex
- Growth failure in children associated with chronic renal insufficiency before renal transplant – Nutropin AQ
- Growth failure in children associated with Noonan Syndrome – Norditropin
- Growth failure in children associated with Prader-Willi Syndrome – Genotropin, Omnitrope
- Growth failure in children associated with Turner Syndrome – Genotropin, Humatrope, Norditropin, Nutropin AQ
- Growth failure in children born small for gestational age – Genotropin, Humatrope, Norditropin, Omnitrope
- Growth hormone deficiency in adults – Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Sogroya
- HIV/AIDS-associated wasting or cachexia – Serostim
- Primary insulin-like growth factor (IGF)-1 deficiency – Increlex

non-FDA-approved, for example:

- Growth failure in children associated with chronic renal failure post-transplant (growth hormone agents)
- Short stature secondary to sickle cell disease (growth hormone agents)
- Silver-Russell Syndrome (growth hormone agents)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate

and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Pediatric - Growth hormone (GH) deficiency or panhypopituitarism (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - short stature or growth failure, documented by one of the following:
    - pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
    - growth velocity below the tenth percentile for age and gender as defined by one of the following:
      - age two to less than four years: < 5.5 cm/year; **or**
      - age four to less than six years: < 5 cm/year; **or**
      - age six years to puberty: < 4.5 cm/year (biologic females) or < 4 cm/year (biologic males); **or**
    - height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**
  - prescriber is an endocrinologist or consult notes from an endocrinology office are provided; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Ngenla, clinical rationale for use of the requested agent instead of Skytrofa and Sogroya; **and**
  - one of the following:
    - results of two abnormal GH stimulation tests; **or**
    - results of one abnormal stimulation test and one abnormal IGF-1 or IGFBP-3 level; **or**
    - results of one abnormal test (IGF-1, IGFBP-3, or GH stimulation test); **and**
      - one of the following:
        - abnormal pituitary imaging; **or**
        - deficiency of at least three other pituitary hormones (TSH, ACTH, LH, FSH, or AVP/ADH); **or**
        - appropriate current medication claims suggesting deficiency of at least three other pituitary hormones (levothyroxine, hydrocortisone or other glucocorticoid, testosterone or estrogen/progesterone, or desmopressin).
- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Pediatric - Hypoglycemia due to GH deficiency (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - test results indicating GH deficiency (at least one abnormal GH stimulation test is required); **and**
  - hypoglycemia symptoms and low glucose level; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Ngenla, clinical rationale for use of the requested agent instead of Skytrofa and Sogroya.

Pediatric - Noonan, Prader-Willi, or Turner Syndrome (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - short stature or growth failure, documented by one of the following:
    - pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
    - growth velocity below the tenth percentile for age and gender as defined by one of the following:
      - age two to less than four years: < 5.5 cm/year; **or**
      - age four to less than six years: < 5 cm/year; **or**
      - age six years to puberty: < 4.5 cm/year (biologic females) or < 4 cm/year (biologic males); **or**
    - height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**

- one of the following:
  - rationale for why genetic testing cannot be provided as noted by one of the following:
    - member is new to prescriber and current prescriber has no means of obtaining labs used for diagnosis; **or**
    - diagnosis made many years ago; **or**
  - genetic testing confirming diagnosis; **and**
- for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
- for Ngenla, clinical rationale for use of the requested agent instead of Skytrofa and Sogroya.

- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Pediatric - Chronic renal failure up to time of renal transplantation (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - short stature or growth failure, documented by one of the following:
    - pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
    - growth velocity below the tenth percentile for age and gender as defined by one of the following:
      - age two to less than four years: < 5.5 cm/year; **or**
      - age four to less than six years: < 5 cm/year; **or**
      - age six years to puberty: < 4.5 cm/year (biologic females) or < 4 cm/year (biologic males); **or**
    - height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**
  - one of the following:
    - other CRF-associated etiologies have been excluded; **or**
    - member is under care of a renal specialist; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Ngenla, clinical rationale for use of the requested agent instead of Skytrofa or Sogroya.
- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Pediatric - Chronic renal failure post-transplant (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - short stature or growth failure, documented by one of the following:
    - pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
    - growth velocity below the tenth percentile for age and gender as defined by one of the following:
      - age two to less than four years: < 5.5 cm/year; **or**
      - age four to less than six years: < 5 cm/year; **or**
      - age six to puberty: < 4.5 cm/year (biologic females) or < 4 cm/year (biologic males); **or**
    - height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**
  - one of the following:
    - other CRF-associated etiologies have been excluded; **or**
    - member is under the care of a renal specialist; **and**
  - growth has been monitored for at least one year post-transplant, without catch-up growth documented as height continually less than -2 standard deviations below mean or below third percentile from time of transplant to current request; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Ngenla, clinical rationale for use of the requested agent instead of Skytrofa and Sogroya.

- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Pediatric - Small for gestational age (SGA)/Intrauterine growth restriction (IUGR) with failed catch-up growth between age two - four (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - short stature or growth failure, documented by one of the following:
    - pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
    - growth velocity below the tenth percentile for age and gender as defined by one of the following:
      - age two to less than four years: < 5.5 cm/year; **or**
      - age four to less than six years: < 5 cm/year; **or**
      - age six years to puberty: < 4.5 cm/year (biologic females) or < 4 cm/year (biologic males); **or**
    - height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**
  - diagnosis of SGA/IUGR (birth weight or length less than -2 standard deviations below mean or below third percentile for gestational age); **and**
  - catch-up growth not achieved between the ages of two to four, as indicated by both of the following:
    - at least one height measurement less than -2 standard deviations below mean or below third percentile between age two to four years; **and**
    - member does not have evidence of consistent catch-up growth (defined as: from age two to current age [or age four, whichever is less], no consecutive years with height measurements greater than -2 standard deviations below mean or greater than third percentile); **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Ngenla, clinical rationale for use of the requested agent instead of Skytrofa and Sogroya.
- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Primary IGFD and Growth hormone gene deletion with the development of neutralizing antibodies to growth hormone (Increlex)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - appropriate dosing; **and**
  - prescriber is a pediatric endocrinologist or other growth disorder specialist or consult notes are provided; **and**
  - height standard deviation score ≤ -3; **and**
  - basal IGF-1 standard deviation score ≤ -3; **and**
  - normal or elevated growth hormone level; **and**
  - member has an open epiphysis; **and**
  - other forms of secondary IGF-1 deficiency have been ruled out (i.e., growth hormone deficiency, malnutrition, hypothyroidism, use of chronic pharmacologic doses of anti-inflammatory steroids).
- For recertification, documentation of the following is required:
  - response to therapy; **and**
  - open epiphyses.

Pediatric - Short stature secondary to sickle cell disease (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - short stature or growth failure, documented by one of the following:

    - pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
    - height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**
  - growth velocity below the tenth percentile for age and gender as defined by one of the following:
    - age two to less than four years: < 5.5 cm/year; **or**
    - age four to less than six years: < 5 cm/year; **or**
    - age six years to puberty: < 4.5 cm/year (biologic females) or < 4 cm/year (biologic males); **and**
  - one abnormal test (GH stimulation, IGF-1, or IGFBP-3 test); **and**
  - prescriber is an endocrinologist or consult notes from an endocrinology office are provided; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Ngenla, clinical rationale for use of the requested agent instead of Skytrofa and Sogroya.
- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Pediatric - Silver-Russell Syndrome (growth hormone agents)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - short stature or growth failure, documented by one of the following:
    - pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
    - growth velocity below the tenth percentile for age and gender as defined by one of the following:
      - age two to less than four years: < 5.5 cm/year; **or**
      - age four to less than six years: < 5 cm/year; **or**
      - age six years to puberty: < 4.5 cm/year (biologic females) or < 4 cm/year (biologic males); **or**
    - height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**
  - one of the following:
    - rationale for why genetic testing cannot be provided as noted by one of the following:
      - member is new to prescriber and current prescriber has no means of obtaining labs used for diagnosis; **or**
      - diagnosis made many years ago; **or**
    - genetic testing confirming diagnosis; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Ngenla, clinical rationale for use of the requested agent instead of Skytrofa and Sogroya.
- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Adult - GH deficiency or panhypopituitarism (growth hormone agents)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an endocrinologist or consult notes from an endocrinology office are provided; **and**
  - at least one symptom consistent with GH deficiency; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Ngenla, the prescriber provides clinial rationale for use of the requested agent instead of Sogroya; **and**
  - one of the following:
    - results of two abnormal GH stimulation tests; **or**
    - results of one abnormal stimulation test and one abnormal IGF-1 or IGFBP-3 level; **or**
    - results of one abnormal test (IGF-1, IGFBP-3, or GH stimulation test); **and**
      - one of the following:

        - abnormal pituitary imaging; **or**
        - deficiency of at least three other pituitary hormones (TSH, ACTH, LH, FSH, or AVP/ADH); **or**
        - appropriate current medication claims suggesting deficiency of at least three other pituitary hormones (levothyroxine, hydrocortisone or other glucocorticoid, testosterone or estrogen/progesterone, or desmopressin).
- For recertification, documentation of the following is required:
  - IGF-1 or IGFBP-3 level within lab-specific reference range; **and**
  - for isolated or idiopathic adult GHD, positive response regarding documented GH complication.

Adult - HIV/AIDS-associated wasting or cachexia (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is receiving concurrent antiretroviral therapy; **and**
  - evidence of wasting, as indicated by one of the following (with or without chronic fever, weakness, or diarrhea):
    - an involuntary loss of at least 10% of body weight within one year; **or**
    - an involuntary loss of at least 7.5% of body weight within six months; **or**
    - a reduction in lean body mass (measured via bioelectrical impedance assay or BIA); **or**
    - BMI < 20 kg/m^2; **and**
  - member has had a trial of an FDA-approved appetite stimulant (i.e., dronabinol or megestrol acetate) prior to initiation of GH therapy if the etiology of wasting or cachexia is decreased caloric intake; **and**
  - one of the following:
    - other causes of weight loss have been ruled out (i.e., gastrointestinal tract opportunistic infections, decrease in food intake due to oral, pharyngeal, esophageal lesions or candidiasis, gonadal dysfunction, adverse effects due to medications, or psychosocial factors); **or**
    - member is under the care of an infectious disease specialist; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Ngenla, the prescriber provides clinical rationale for use of the requested agent instead of Sogroya.

Adult - Short-bowel syndrome (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis (in members receiving specialized nutritional support); **and**
  - intended duration of therapy; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Ngenla, the prescriber provides clinical rationale for use of the requested agent instead of Sogroya.

MassHealth Evaluation Criteria
Table 10 - Dermatologic Agents - Acne and Rosacea

Drug Category: Dermatological Agents

Medication Class/Individual Agents: Anti-acne and Rosacea Agents

I. Prior-Authorization Requirements

Dermatologic Agents: Acne and Rosacea – Retinoids (Oral)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
acitretin			A90	*Contraindicated in Pregnancy:* • Isotretinoin and acitretin • Isotretinoin – prescribers must comply with the manufacturer's iPLEDGE program (see manufacturer's product information for full details) *Retinoids and Photosensitivity Reactions*: • Minimize exposure to ultraviolet light or sunlight. Quinolones, sulfonamides, thiazide diuretics, and phenothiazines are some other drugs which may also increase sensitivity to the sun.
isotretinoin		PA - ≥ 21 years	A90	
isotretinoin micronized	Absorica LD	PA	A90	
isotretinoin-Absorica	Absorica	PA	BP, A90	

Dermatologic Agents: Acne and Rosacea – Combination Products

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
adapalene 0.1% / benzoyl peroxide 2.5%	Epiduo	PA	A90	*Prior Authorizations:* • Select generic, select brand name, combination topical acne products, and convenience delivery systems (e.g., foams, kits, pads, pledgets) require prior authorization.
adapalene 0.3% / benzoyl peroxide 2.5%	Epiduo Forte	PA	A90	
benzoyl peroxide / erythromycin	Benzamycin	PA	A90	
clindamycin / adapalene / benzoyl peroxide	Cabtreo	PA		
clindamycin / benzoyl peroxide gel	Onexton	PA	A90	
clindamycin / benzoyl peroxide-Acanya	Acanya	PA	A90	
clindamycin / tretinoin-Veltin	Veltin	PA	A90	
clindamycin / tretinoin-Ziana	Ziana	PA	A90	
clindamycin 1% / benzoyl peroxide 5%		PA	A90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
clindamycin 1.2% / benzoyl peroxide 5%		PA	A90
tretinoin / benzoyl peroxide	Twyneo	PA	

Dermatologic Agents: Acne and Rosacea – Retinoids (Topical)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
adapalene	Differin	PA	A90	*Prior Authorizations:* • Select generic, select brand name, combination topical acne products, and convenience delivery systems (e.g., foams, kits, pads, pledgets) require prior authorization. • Prior authorization is also required for generic topical retinoid products for members ≥ 21 years of age. *Contraindicated in Pregnancy:* • Tazarotene *Retinoids and Photosensitivity Reactions*: • Minimize exposure to ultraviolet light or sunlight. Quinolones, sulfonamides, thiazide diuretics, and phenothiazines are some other drugs which may also increase sensitivity to the sun.
tazarotene cream, gel		PA	A90	
tazarotene foam	Fabior	PA	BP	
tazarotene lotion	Arazlo	PA		
tretinoin 0.05% gel	Atralin	PA	BP, A90	
tretinoin 0.05% lotion	Altreno	PA - ≥ 21 years		
tretinoin microspheres	Retin-A Micro	PA	BP, A90	
tretinoin-Avita	Avita	PA - ≥ 21 years	# , A90	
tretinoin-Retin-A	Retin-A	PA - ≥ 21 years	BP, A90	
trifarotene	Aklief	PA		

Dermatologic Agents: Acne and Rosacea – Antibiotics (Topical)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
clindamycin foam	Evoclin	PA	A90	*Prior Authorizations:* • Select generic, select brand name, combination topical acne products, and convenience delivery systems (e.g., foams, kits, pads, pledgets) require prior authorization. • Prior authorization is also required for generic sulfacetamide 10% lotion agents for members ≥ 21 years of age. *Topical Antibiotics:* • Used in moderate-severe acne (Types 2 and 3) as part of a combination therapy. • Also possesses anti-inflammatory activity. • Long-term use is discouraged due to increased emergence of *P. acnes* resistance. • Combination therapy with another topical medication decreases resistance emergence.
clindamycin gel, solution			A90	
clindamycin gel-Clindagel	Clindagel		BP	
clindamycin lotion	Cleocin T		# , A90	
clindamycin pledgets			A90	
erythromycin / ethanol pads, pledgets		PA	A90	
erythromycin gel	Erygel		# , A90	
erythromycin solution			A90	
metronidazole 0.75% cream	Metrocream		A90	
metronidazole 0.75% gel			A90	
metronidazole 1% cream	Noritate			
metronidazole 1%	Metrogel	PA	A90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
gel				• Sulfacetamide products are used for mild inflammatory acne. These products are contraindicated in sulfonamide allergic patients.
metronidazole lotion	Metrolotion	PA	A90	
sulfacetamide 10% lotion	Klaron	PA - ≥ 21 years	# , A90	

Dermatologic Agents: Acne and Rosacea – Benzoyl Peroxide Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
benzoyl peroxide			*, A90	*Prior Authorizations:* • Select generic, select brand name, combination topical acne products, and convenience delivery systems (e.g., foams, kits, pads, pledgets) require prior authorization. *Benzoyl Peroxide Products:* • Often used alone for noninflammatory, mainly comedonal acne (Type 1). • Used as an adjunctive therapy for mild-moderate inflammatory acne (Type 2) with a retinoid. • Used as an adjunctive therapy for moderate-severe acne (Type 3 to 4) with a retinoid, topical and/or oral antibiotic. • Demonstrates antibacterial activity and some comedolytic activity. • A trial of two to three months is usually required to establish efficacy or treatment failure of any topical product. • High incidence of local irritation is evident with most topical treatments.
benzoyl peroxide 9.8% foam		PA	A90	
benzoyl peroxide-Epsolay	Epsolay	PA		

Dermatologic Agents: Acne and Rosacea – Agents Not Otherwise Classified

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
azelaic acid foam	Finacea	PA	BP	*Prior Authorizations:* • Select generic, select brand name, combination topical acne products, and convenience delivery systems (e.g., foams, kits, pads, pledgets) require prior authorization. *Azelaic Acid Products:* • Exhibits antimicrobial activity and has comedolytic properties
azelaic acid gel	Finacea	PA	A90	
brimonidine 0.33% topical gel	Mirvaso	PA	A90	
clascoterone	Winlevi	PA		
dapsone gel		PA	A90	
ivermectin cream	Soolantra	PA	A90	
oxymetazoline cream	Rhofade	PA		

Dermatologic Agents: Acne and Rosacea – Salicylic Acid Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
salicylic acid			o, A90	*Salicylic acid products:* • Topical salicylic acid products may be used for the treatment of acne vulgaris, psoriasis, removal of warts, or other hyperkeratotic skin disorders.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
o	PA status depends on the drug's formulation.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Acne vulgaris – adapalene, Aklief, Altreno, Arazlo, Avita, benzoyl peroxide, clindamycin, dapsone, erythromycin, sulfacetamide, salicylic acid, tazarotene cream and foam, tretinoin, tretinoin 0.05% gel, tretinoin microspheres, Winlevi
- Keratosis pilaris – azelaic acid, dapsone
- Nodulocystic acne (severe), recalcitrant – Absorica LD, isotretinoin, isotretinoin (generic Absorica)
- Psoriasis – acitretin, tazarotene cream, salicylic acid
- Rosacea – azelaic acid gel, brimonidine topical gel, Finacea foam, ivermectin cream, metronidazole, Rhofade, tazarotene cream

Non-FDA-approved, for example:

- cutaneous warts – adapalene, Aklief, Altreno, Arazlo, tazarotene cream and foam, tretinoin, tretinoin 0.05% gel, tretinoin microspheres
- folliculitis/pseudofolliculitis – adapalene, Aklief, Altreno, Arazlo, benzoyl peroxide, clindamycin, tazarotene cream and foam, tretinoin, tretinoin 0.05% gel, tretinoin microspheres
- keratosis pilaris – adapalene 0.1% cream, tretinoin 0.05% cream
- perioral/periorificial dermatitis – erythromycin, metronidazole

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month,

per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

adapalene, tretinoin 0.05% gel, and tretinoin microspheres
- Documentation of all of the following is required for a diagnosis of acne, cutaneous warts, folliculitis/pseudofolliculitis:
  - appropriate diagnosis (e.g., acne grade II or greater, cutaneous warts, folliculitis/pseudofolliculitis); **and**
  - medical records documenting an adverse reaction or inadequate response to a topical tretinoin agent.
- Documentation of all of the following is required for a diagnosis of rosacea:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following:
    - benzoyl peroxide with a concurrent topical antibiotic; **and**
    - topical metronidazole.
- Documentation of the following is required for adapalene 0.1% cream for a diagnosis of keratosis pilaris:
  - appropriate diagnosis.

Aklief
- Documentation of all of the following is required for a diagnosis of acne, cutaneous warts, folliculitis/pseudofolliculitis:
  - appropriate diagnosis (e.g., acne grade II or greater, cutaneous warts, folliculitis/pseudofolliculitis); **and**
  - medical records documenting an adverse reaction or inadequate response to a topical tretinoin agent.

Altreno for members ≥ 21 years of age
- Documentation of the following is required for a diagnosis of acne, cutaneous warts, folliculitis/pseudofolliculitis:
  - appropriate diagnosis (e.g., acne grade II or greater, cutaneous warts, folliculitis/pseudofolliculitis).
- Documentation of all of the following is required for a diagnosis of rosacea:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following:
    - benzoyl peroxide with a concurrent topical antibiotic; **and**
    - topical metronidazole.

Arazlo
- Documentation of all of the following is required for a diagnosis of acne, cutaneous warts, folliculitis/pseudofolliculitis:
  - appropriate diagnosis (e.g., acne grade II or greater, cutaneous warts, folliculitis/pseudofolliculitis); **and**
  - medical records documenting inadequate response or adverse reaction to a topical tretinoin agent; **and**
  - medical records documenting inadequate response or an adverse reaction to a topical tazarotene agent.

azelaic acid gel
- Documentation of all of the following is required for a diagnosis of acne, cutaneous warts, folliculitis/pseudofolliculitis:
  - appropriate diagnosis (e.g., acne grade II or greater); **and**
  - inadequate response, adverse reaction, or contraindication to benzoyl peroxide with a concurrent topical antibiotic.
- Documentation of all of the following is required for a diagnosis of rosacea:

- appropriate diagnosis; **and**
- inadequate response, adverse reaction, or contraindication to topical metronidazole.

- Documentation of all of the following is required for a diagnosis of keratosis pilaris:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: benzoyl peroxide, salicylic acid, urea, topical retinoid.

Brand-name benzoyl peroxide and clindamycin products

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., acne grade II or greater, folliculitis/pseudofolliculitis, hidradenitis suppurativa, rosacea); **and**
  - medical records documenting an inadequate response or adverse reaction to at least two clinically appropriate generic products with the same active ingredient.

brimonidine topical gel, 0.33%

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., rosacea); **and**
  - inadequate response, adverse reaction, or contraindication to one topical metronidazole agent and azelaic acid agent.

Combination products

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., acne grade II or greater, folliculitis/pseudofolliculitis, hidradenitis suppurativa, rosacea); **and**
  - medical necessity for the combination product instead of the commercially available separate agents.

dapsone gel

- Documentation of all of the following is required for a diagnosis of acne:
  - appropriate diagnosis (e.g., acne grade II or greater); **and**
  - medical records documenting inadequate response, adverse reaction, or contraindication to a benzoyl peroxide agent used in combination with a topical antibiotic agent; **and**
  - medical records documenting inadequate response or adverse reaction to one or contraindication to all other FDA-approved alternatives: oral tetracycline (i.e., tetracycline, doxycycline, minocycline), sulfacetamide 10% lotion, topical adapalene, topical azelaic acid, topical tretinoin.
- Documentation of all of the following is required for a diagnosis of keratosis pilaris:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: benzoyl peroxide, salicylic acid, urea, topical retinoid.

Fabior

- Documentation of the following is required:
  - appropriate diagnosis (e.g., acne grade II or greater, cutaneous warts, folliculitis/pseudofolliculitis, rosacea).

Finacea 15% foam

- Documentation of the following is required:
  - appropriate diagnosis (e.g., acne grade II or greater, rosacea).

Generic single-entity sulfacetamide agents for members ≥ 21 years of age

- Documentation of the following is required:
  - appropriate diagnosis (e.g., acne grade II or greater, rosacea).

Generic topical retinoids (excludes adapalene, tretinoin 0.05% gel, and tretinoin microspheres) for members ≥ 21 years of age

- Documentation of the following is required for a diagnosis of acne:
  - appropriate diagnosis (e.g., acne grade II or greater).
- Documentation of the following is required for a diagnosis of cutaneous warts, or folliculitis/pseudofolliculitis:
  - appropriate diagnosis.
- Documentation of all of the following is required for a diagnosis of rosacea:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following:
    - benzoyl peroxide with a concurrent topical antibiotic; **and**
    - topical metronidazole.
- Documentation of the following is required for tretinoin 0.05% cream for a diagnosis of keratosis pilaris:
  - appropriate diagnosis.

isotretinoin for members ≥ 21 years of age (excludes generic Absorica and Absorica LD)

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., treatment-resistant acne grade II or greater, unresponsive to conventional therapy); **and**
  - inadequate response or adverse reaction to a topical retinoid used in combination with a topical/oral antibiotic with or without benzoyl peroxide.

isotretinoin (generic Absorica) and Absorica LD for all ages

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., treatment-resistant acne grade II or greater, unresponsive to conventional therapy); **and**
  - inadequate response or adverse reaction to a topical retinoid used in combination with a topical/oral antibiotic with or without benzoyl peroxide; **and**
  - medical records documenting an inadequate response or adverse reaction to an oral isotretinoin agent available without PA for members < 21 years of age; **and**
  - for Absorica LD, medical records documenting an inadequate response or adverse reaction to isotretinoin (generic Absorica).

ivermectin cream

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., rosacea); **and**
  - inadequate response, adverse reaction, or contraindication to a topical metronidazole agent.

metronidazole 0.75% lotion and metronidazole 1% gel

- Documentation of the following is required for a diagnosis of perioral/periorificial dermatitis, rosacea:
  - appropriate diagnosis; **and**
  - medical records documenting inadequate response to one of the following: metronidazole 0.75% gel or metronidazole 0.75% cream.

Rhofade

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., rosacea); **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: topical metronidazole, azelaic acid, topical brimonidine.

tazarotene cream, gel

- Documentation of all of the following is required for a diagnosis of acne, cutaneous warts, folliculitis/pseudofolliculitis:
  - appropriate diagnosis (e.g., acne grade II or greater, cutaneous warts, folliculitis/pseudofolliculitis); **and**

    - medical records documenting an inadequate response or adverse reaction to a topical tretinoin agent.
- Documentation of all of the following is required for a diagnosis of psoriasis:
    - appropriate diagnosis; **and**
    - inadequate response, adverse reaction, or contraindication to a topical corticosteroid agent.
- Documentation of all of the following is required for a diagnosis of rosacea:
    - appropriate diagnosis; **and**
    - inadequate response, adverse reaction, or contraindication to all of the following:
        - benzoyl peroxide with a concurrent topical antibiotic; **and**
        - topical metronidazole.

Unique formulations (i.e., foams, kits, pads, pledgets, excludes Fabior and Finacea Foam)

- Documentation of all of the following is required:
    - appropriate diagnosis (e.g., acne grade II or greater, cutaneous warts, folliculitis/pseudofolliculitis, hidradenitis suppurativa, keratosis pilaris, perioral/periorificial dermatitis, rosacea, etc.); **and**
    - medical records documenting an inadequate response or adverse reaction to at least **two** clinically appropriate products with the same active ingredient; **and**
    - medical necessity for the requested formulation.

Winlevi

- Documentation of all of the following is required:
    - appropriate diagnosis (e.g., acne grade II or greater); **and**
    - medical records documenting inadequate response, adverse reaction, or contraindication to a benzoyl peroxide agent used in combination with a topical antibiotic agent; **and**
    - medical records documenting inadequate response or adverse reaction to one or contraindication to all other FDA-approved alternatives: oral tetracycline (i.e., tetracycline, doxycycline, minocycline), sulfacetamide 10% lotion, topical adapalene, topical azelaic acid, topical tretinoin.

MassHealth Evaluation Criteria
Table 11 - Nonsteroidal Anti-Inflammatory Drugs

Drug Category: Pain and inflammation

Medication Class/Individual Agents: Nonsteroidal Anti-Inflammatory Drugs (NSAIDS)

I. Prior-Authorization Requirements

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Phenylacetic Acid Derivatives			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
diclofenac / misoprostol	Arthrotec	PA - < 60 years	# , A90
diclofenac 1% gel			*, A90
diclofenac 18 mg, 35 mg capsule		PA	A90
diclofenac 25 mg capsule		PA	A90
diclofenac extended-release			A90
diclofenac potassium 25 mg tablet		PA	A90
diclofenac potassium 50 mg tablet			A90
diclofenac powder for solution		PA	A90
diclofenac sodium tablet			A90
diclofenac topical patch		PA	A90
diclofenac topical solution	Pennsaid		# , A90

Nonsteroidal Anti-Inflammatory Drugs – COX-2 (Highly Selective) NSAIDs			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
celecoxib	Celebrex		# , A90
celecoxib oral solution	Elyxyb	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Risk factors for NSAID-related GI toxicity:

- Member is ≥ 60 years of age, history of gastric or duodenal ulcer, history of gastrointestinal (GI) bleed, perforation or obstruction, concurrent use of anticoagulants, aspirin (including low doses for cardiovascular prophylaxis), corticosteroids, high daily NSAID doses.

To avoid or minimize GI toxicity:

- Lowest effective dose should be prescribed for the shortest possible duration.
- GI toxicity may be lower with ibuprofen, naproxen, ketoprofen, diclofenac, and higher with indomethacin, flurbiprofen, and piroxicam.

If risk factors are present for NSAID-related GI toxicity as above, consider:

- Etodolac, nabumetone and meloxicam, all of which are preferential COX-2 inhibitors; however, with higher doses of etodolac and nabumetone, preferential inhibition of COX-2 is diminished.
- Highly selective COX-2 inhibitor (see table below).
- An antisecretory agent (PPI or misoprostol) with a non-selective NSAID.

Risk factors for NSAID-related renal toxicity:

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Propionic Acid Derivatives			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fenoprofen capsule	Nalfon	PA	A90
fenoprofen tablet		PA	A90
flurbiprofen			A90
ibuprofen			*, A90
ibuprofen / famotidine	Duexis	PA - < 60 years	# , A90
ketoprofen			A90
ketoprofen extended-release		PA	A90
ketorolac nasal spray		PA	
ketorolac tablets and injection		PA - > 20 units/30 days	
naproxen / esomeprazole	Vimovo	PA - <60 years	# , A90
naproxen capsule, tablet			*, A90
naproxen controlled-release	Naprelan CR	PA	A90
naproxen enteric coated			A90
naproxen suspension		PA - ≥ 13 years	A90
oxaprozin	Daypro		# , A90

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Enolic Acid Derivatives			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
meloxicam capsule		PA	A90
meloxicam tablet			A90
piroxicam	Feldene		# , A90

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Acetic Acid Derivatives			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
etodolac			A90
etodolac extended-release		PA	A90
indomethacin 25 mg, 50 mg			A90
indomethacin			A90

Clinical Notes

- Preexisting renal disease, severe CHF, liver disease, or diuretic use

Ankylosing Spondylitis (AS)/Osteoarthritis(OA)/Rheumatoid Arthritis (RA) Dosing for celecoxib:

- Celecoxib: AS: 200 mg once daily or 100 mg twice daily, up to 400 mg/day; OA: 200 mg once daily or 100 mg twice daily; RA: 100-200 mg twice daily

Sulfonamide Allergy:

- Celecoxib is a sulfonamide derivative. The labeling for celecoxib states that use is contraindicated in sulfonamide-allergic patients.

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Acetic Acid Derivatives			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
extended-release			
indomethacin suppository		PA	
indomethacin suspension		PA	
nabumetone 1000 mg	Relafen DS	PA	
nabumetone 500 mg, 750 mg			A90
sulindac			A90
tolmetin		PA	A90

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Anthranilic Acid Derivatives			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
meclofenamate		PA	A90
mefenamic acid			A90

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Salicylic Acid Derivative			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
diflunisal			A90
salsalate		PA	A90

#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved:

- Acute pain
- Ankylosing spondylitis
- Familial adenomatous polyposis (FAP)
- Juvenile rheumatoid arthritis
- Mild-to-moderate pain

- Moderate to moderately severe pain
- Osteoarthritis
- Primary dysmenorrhea
- Rheumatoid arthritis

Non-FDA-approved:

- Cutaneous mastocytosis
- Mast cell activiation
- Migraine

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

diclofenac/misoprostol for members < 60 years of age

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction with concurrent therapy of diclofenac (minimum of 50 mg twice daily) and misoprostol (minimum of 200 mcg twice daily).

diclofenac potassium 25 capsule, diclofenac potassium 25 mg tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to an oral diclofenac product available without PA; **and**
  - inadequate response or adverse reaction to two other different NSAIDs.

diclofenac powder for solution

- Documentation of the following is required:
  - diagnosis of migraine; **and**

- one of the following:
  - medical records documenting an inadequate response or adverse reaction to three different NSAIDs, one of which must be diclofenac sodium; **or**
  - for members with a swallowing disorder or condition affecting the ability to swallow tablets, an inadequate response or adverse reaction to both of the following: ibuprofen suspension, naproxen suspension.

diclofenac topical patch
- Documentation of the following is required:
  - diagnosis of acute pain (caused by minor strains, sprains, and contusions) or osteoarthritis; **and**
  - inadequate response or adverse reaction to diclofenac 1% gel.

Elyxyb
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to celecoxib capsules; **or**
    - medical necessity for the use of the solution formulation as noted by one of the following:
      - requested dose is not available in the capsule formulation; **or**
      - member utilizes tube feeding (G-tube/J-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
      - member is < 13 years of age.

etodolac ER, ketoprofen ER, naproxen CR
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for an extended-release formulation instead of the immediate-release equivalent.

fenoprofen, meclofenamate, salsalate, tolmetin
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to three different oral NSAIDs.

ibuprofen/famotidine for members < 60 years of age
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction with concurrent therapy of ibuprofen (minimum of 800 mg three times daily) and famotidine (minimum of 20 mg three times daily).

indomethacin suppository
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to ibuprofen suppositories; **and**
  - medical necessity for the requested formulation as noted by nausea/vomiting with oral formulations.

indomethacin suspension for all ages, and naproxen suspension for members ≥ 13 years of age
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to ibuprofen suspension; **and**

- medical necessity for the use of the solution formulation as noted by one of the following:
  - requested dose is not available in the capsule formulation; **or**
  - member utilizes tube feeding (G-tube/J-tube); **or**
  - member has a swallowing disorder or condition affecting ability to swallow; **or**
  - for indomethacin suspension, member is <13 years of age.

ketorolac (tablets and injection) > 20 units/30 days
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to three different NSAIDs; **and**
  - clinical rationale for exceeding FDA-approved dosing/duration.

ketorolac nasal spray
- Documentation of the following is required for a diagnosis of moderate to moderately severe pain:
  - appropriate diagnosis; **and**
  - one of the following:
    - both of the following:
      - inadequate response or adverse reaction to two different NSAIDs; **and**
      - medical records documenting an inadequate response or adverse reaction to one of the following: ketorolac tablets, ketorolac injection; **or**
    - medical necessity for a non-oral NSAID formulation; **and**
  - requested quantity is ≤ five bottles/30 days.
- Documentation of the following is required for treatment of migraine:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to sumatriptan tablets; **or**
    - member has nausea and vomiting with migraines, is unable to take oral medications, and prescriber provides medical records documenting an inadequate response or adverse reaction to sumatriptan nasal spray; **or**
    - medical records documenting an inadequate response or adverse reaction to ketorolac injection or ketorolac tablet; **and**
  - requested quantity is ≤ five bottles/30 days.

meloxicam capsule
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to meloxicam tablet; **and**
  - inadequate response or adverse reaction to two other different NSAIDs; **and**
  - requested quantity is ≤ one unit/day.

naproxen/esomeprazole for members < 60 years of age
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction with concurrent therapy of naproxen (minimum of 375 mg twice daily) and omeprazole (minimum of 20 mg twice daily).

Relafen DS
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to an equivalent dose of nabumetone 500 mg or 750

mg; **and**

- inadequate response or adverse reaction to two other different NSAIDs.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 12 - Antihistamines

Drug Category: Cough/Cold/Allergy

Medication Class/Individual Agents: Antihistamines

I. Prior-Authorization Requirements

First Generation (Nonselective) Antihistamines – Ethanolamines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
carbinoxamine 4 mg/5 mL solution, 6 mg tablet		PA	A90
carbinoxamine 4 mg tablet			A90
carbinoxamine extended-release	Karbinal ER	PA	A90
clemastine syrup		PA	A90
clemastine tablet			A90
dimenhydrinate injection			
diphenhydramine	Benadryl		# , *, A90

Second Generation (Peripherally Selective) Antihistamines – Piperidines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
desloratadine / pseudoephedrine	Clarinex-D	PA	
desloratadine orally disintegrating tablet		PA	M90
desloratadine tablet	Clarinex	PA	M90
fexofenadine / pseudoephedrine			*, A90
fexofenadine tablet			*, M90
loratadine / pseudoephedrine			*, A90
loratadine solution			*, A90
loratadine tablet			*, M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

OTC

- Some of the former prescription antihistamines are now available over-the-counter (OTC).

Combinations of antihistamines and decongestants (for example, chlorpheniramine/pseudoephedrine) may be payable under MassHealth, but may not be listed in the antihistamine table. Please refer to the OTC drug list.

Second Generation (Peripherally Selective) Antihistamines – Nasal Preparations			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
azelastine 0.15% nasal spray		PA	A90
azelastine 137 mcg nasal spray			A90
olopatadine nasal spray	Patanase	PA	A90

First Generation (Nonselective) Antihistamines – Piperazines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
hydroxyzine hydrochloride			A90
hydroxyzine pamoate	Vistaril		# , A90

First Generation (Nonselective) Antihistamines – Alkylamines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
chlorpheniramine			*, A90
dexchlorpheniramine solution		PA	A90

First Generation (Nonselective) Antihistamines – Phenothiazine			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
promethazine			A90

First Generation (Nonselective) Antihistamines – Piperidines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cyproheptadine			A90

Second Generation (Peripherally Selective) Antihistamines – Piperazines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cetirizine / pseudoephedrine			*, A90
cetirizine syrup			*, A90

Second Generation (Peripherally Selective) Antihistamines – Piperazines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cetirizine tablet			*, M90
levocetirizine solution		PA	A90
levocetirizine tablet			# , M90

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- perennial or seasonal allergic rhinitis: oral/intranasal antihistamines
- chronic idiopathic urticaria: oral antihistamines only
- vasomotor (i.e., non-allergic) rhinitis: oral/intranasal agents

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.

- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

azelastine 0.15% (generic Astepro) and olopatadine (generic Patanase) nasal sprays

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to two or contraindication to all of the following: an intranasal corticosteroid, azelastine 137 mcg nasal spray, azelastine/fluticasone propionate; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction or contraindication to azelastine 137 mcg nasal spray.
- For quantities greater than one bottle/30 days, in addition to the above criteria, documentation must be provided regarding an inadequate clinical response at the manufacturer's recommended doses.

SmartPA: Claims for one bottle/30 days of azelastine 0.15% nasal spray and olopatadine nasal spray will usually process at the pharmacy without a PA request if the member has MassHealth medical claims for allergic rhinitis or non-allergic rhinitis and a history of paid pharmacy claims for ≥ 14 days out of the last 180 days of one intranasal corticosteroid and azelastine 137 mcg nasal spray.

carbinoxamine 6 mg tablet, carbinoxamine extended-release, and carbinoxamine solution

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to one or contraindication to all intranasal corticosteroid agents; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to two or contraindication to all nonselective antihistamines available without prior authorization; **and**
  - for carbinoxamine extended-release suspension and carbinoxamine solution, medical necessity for use of requested agent as noted by one of the following:
    - member utilizes tube feeding (G-tube, J tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age; **and**
  - for carbinoxamine extended-release suspension, inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to carbinoxamine immediate-release solution; **and**
  - for carbinoxamine 6 mg tablet, inadequate response or adverse reaction to carbinoxamine 4 mg tablet.

Clarinex-D

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to one or contraindication to all intranasal corticosteroid agents (if the diagnosis is chronic idiopathic urticaria, a trial with an intranasal corticosteroid is not required); **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to two or contraindication to all of the following: cetirizine/pseudoephedrine, fexofenadine/pseudoephedrine, loratadine/pseudoephedrine.

SmartPA: Claims for Clarinex-D will usually process at the pharmacy without a PA request if the member has MassHealth medical claims for allergic rhinitis or chronic idiopathic urticaria and a history of paid pharmacy claims for ≥ 14 days out of the last 180 days of loratadine/pseudoephedrine, cetirizine/pseudoephedrine, **and** an intranasal corticosteroid.

clemastine syrup and dexchlorpheniramine solution

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medically necessity for use of requested agent as noted by one of the following:
    - member utilizes tube feeding (G-tube, J tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow;**or**

    - member is < 13 years of age; **and**
- inadequate response (defined as ≥ 14 days of therapy) or adverse reaction or contraindication to both of the following: cetirizine syrup, loratadine solution.

desloratadine tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to one or contraindication to all of the following: cetirizine, fexofenadine, levocetirizine, and loratadine.

SmartPA: Claims for desloratadine tablets will usually process at the pharmacy without a PA request if the member has MassHealth medical claims for allergic rhinitis or chronic idiopathic urticaria and a history of paid pharmacy claims for ≥ 14 days out of the last 180 days for one of the following: loratadine tablets or liquid, cetirizine tablets or liquid, fexofenadine tablet, or levocetirizine tablet.

desloratadine ODT and levocetirizine solution

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for use of requested agent as noted by one of the following:
    - member utilizes tube feeding (G-tube, J tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction or contraindication to both of the following: cetirizine syrup, loratadine solution.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 13 - Lipid-Lowering Agents

Drug Category: Cardiovascular

Medication Class/Individual Agents: Lipid-Lowering Agent

I. Prior-Authorization Requirements

Lipid-Lowering Agents – Statins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amlodipine / atorvastatin	Caduet	PA	M90
atorvastatin 10 mg, 20 mg, 40 mg tablet	Lipitor	PA - > 1.5 units/day	# , M90
atorvastatin 80 mg tablet	Lipitor	PA - > 1 unit/day	# , M90
atorvastatin suspension	Atorvaliq	PA	
fluvastatin		PA	M90
fluvastatin extended-release	Lescol XL	PA	M90
lovastatin 10 mg, 20 mg		PA - > 1.5 units/day	M90
lovastatin 40 mg		PA - > 2 units/day	M90
lovastatin extended-release	Altoprev	PA	
pitavastatin calcium	Livalo	PA	M90
pitavastatin magnesium	Zypitamag	PA	
pravastatin 10 mg, 20 mg, 40 mg		PA - > 1.5 units/day	M90
pravastatin 80 mg		PA - > 1 unit/day	M90
rosuvastatin 40 mg	Crestor	PA - > 1 unit/day	# , M90
rosuvastatin 5 mg, 10 mg, 20 mg	Crestor	PA - > 1.5 units/day	# , M90
rosuvastatin sprinkle capsule	Ezallor	PA	
simvastatin 5 mg, 10 mg, 20 mg, 40 mg	Zocor	PA - > 1.5 units/day	# , M90
simvastatin 80 mg		PA - > 1 unit/day	M90
simvastatin oral suspension	Flolipid	PA	

Lipid-Lowering Agents – Bile Acid Sequestrants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cholestyramine /			M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Available treatment guidelines for the management of hyperlipidemia include:

- The National Cholesterol Education Program (NCEP) Adult Treatment Program (ATP) III guideline (2004)[1]
- The American College of Cardiology and American Heart Association Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults (2013)[2]
- The American College of Cardiology and American Heart Association Guideline on the Management of Blood Cholesterol Adults (2019)[3]

1. Grundy SM, Cleeman JI, Merz NB, Brewer Jr B, Clark LT, Hunninghake DB, et al. Implications of recent clinical trials for the National Cholesterol Education Program Adult

Lipid-Lowering Agents – Bile Acid Sequestrants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aspartame			
cholestyramine / sucrose			M90
colesevelam	Welchol		# , M90
colestipol	Colestid		# , M90

Lipid-Lowering Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bempedoic acid	Nexletol	PA	
bempedoic acid / ezetimibe	Nexlizet	PA	
evinacumab-dgnb	Evkeeza	PA	MB
icosapent ethyl		PA	M90
inclisiran	Leqvio	PA	
lomitapide	Juxtapid	PA	
omega-3 acid ethyl esters	Lovaza		# , M90

Lipid-Lowering Agents – Fibric Acids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fenofibrate 40 mg, 120 mg tablet	Fenoglide	PA	M90
fenofibrate 43 mg, 67 mg, 130 mg, 134 mg, 200 mg capsule			M90
fenofibrate 48 mg, 145 mg tablet	Tricor		# , M90
fenofibrate 50 mg, 150 mg capsule	Lipofen		M90
fenofibrate 54 mg, 160 mg tablet			M90
fenofibrate 90 mg capsule		PA	M90
fenofibric acid	Trilipix		# , M90
fenofibric acid tablet			M90
gemfibrozil	Lopid		# , M90

Lipid-Lowering Agents – PCSK9 Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alirocumab	Praluent	PA	
evolocumab	Repatha	PA	

Clinical Notes

Treatment Panel III Guidelines. Circulation. 2004;110:227-39.

2.Stone NJ, Robinson J, Lichtenstein AH, Bairey Merz CN, Blum CB, Eckel RH, Goldberg AC, Gordon D, Levy D, Lloyd-Jones DM, McBride P, Schwartz JS, Shero ST, Smith SC Jr, Watson K, Wilson PWF. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;00:000–000. DOI: 10.1161/01.cir.0000437738.63853.7a

3. Grundy SM, Stone NJ, Bailey AL, Beam C, Birtcher KK, Blumenthal RS et al. AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: Executive Summary. Circulation. 2018 Nov 10:CIR0000000000000624.

Lipid-Lowering Agents – Nicotinic Acids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
niacin	vitamin B-3		*, M90
niacin extended-release tablet			M90
niacinamide			*, M90

Lipid-Lowering Agents – Cholesterol Absorption Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ezetimibe	Zetia		# , M90
ezetimibe / simvastatin	Vytorin	PA - > 1 unit/day	# , M90

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

Evkeeza

FDA-approved, for example:

- homozygous familial hypercholesterolemia (HoFH)

fenofibrate

FDA-approved, for example:

- hypercholesterolemia
- hypertriglyceridemia
- mixed dyslipidemias

icosapent ethyl

FDA-approved, for example:

- cardiovascular risk reduction (with established cardiovascular disease or diabetes mellitus and risk factors for cardiovascular disease)
- hypertriglyceridemia (not inclusive of those with established cardiovascular disease or diabetes mellitus and cardiovascular risk factors)

Juxtapid

FDA-approved, for example:

- HoFH

Leqvio

FDA-approved, for example:

- hypercholesterolemia in a member with clinical atherosclerotic cardiovascular disease in combination with a statin
- heterozygous familial hypercholesterolemia (HeFH) in combination with a statin

Nexletol, Nexlizet

FDA-approved, for example:

- atherosclerotic cardiovascular disease
- HeFH

Praluent, Repatha

FDA-approved, for example:

- HeFH in combination with a statin
- HoFH in combination with a statin
- hypercholesterolemia in a member with clinical atherosclerotic cardiovascular disease in combination with a statin
- primary hyperlipidemia

Statins

FDA-approved, for example:

- hypercholesterolemia

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Table 1. Statin Quantity Limits

1 unit/day	1.5 units/day	2 units/day
Altoprev 60 mg	Altoprev 20 mg, 40 mg	fluvastatin 40 mg
amlodipine/atorvastatin	atorvastatin 10 mg, 20 mg, 40 mg	lovastatin 40 mg

atorvastatin 80 mg	fluvastatin 20 mg	
Ezallor	pitavastatin calcium 1 mg, 2 mg	
ezetimibe/simvastatin	lovastatin 10 mg, 20 mg	
fluvastatin extended-release 80 mg	pravastatin 10 mg, 20 mg, 40 mg	
pitavastatin calcium 4 mg	rosuvastatin 5 mg, 10 mg, 20 mg	
pravastatin 80 mg	simvastatin 5 mg, 10 mg, 20 mg, 40 mg	
rosuvastatin 40 mg	Zypitamag 1 mg, 2 mg	
simvastatin 80 mg		
Zypitamag 4 mg		

amlodipine/atorvastatin

- Documentation of the following is required:
  - diagnosis of one of the following:
    - heterozygous familial hypercholesterolemia; **or**
    - homozygous familial hypercholesterolemia; **or**
    - hypercholesterolemia in a member with a previous history of any cardiovascular event; **or**
    - hypertriglyceridemia; **or**
    - primary dysbetaliproteinemia; **or**
    - primary hyperlipidemia; **or**
    - primary prevention of cardiovascular events; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents; **and**
  - one of the following:
    - requested quantity is ≤ one tablet/day; **or**
    - medical necessity for exceeding the quantity limits; **or**
    - for requests above the maximum FDA-approved dose, inadequate response (defined as ≥ the last 3 months) to atorvastatin 80 mg daily.

SmartPA: Claims for amlodipine/atorvastatin at a quantity of ≤ one unit/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for 90 days out of the last 120 days or has a history of paid MassHealth pharmacy claims for rosuvastatin at a dose of at least 20 mg or atorvastatin at a dose of at least 40 mg for at least 90 days in all claims history.†

Altoprev, fluvastatin, fluvastatin extended-release, pitavastatin calcium, and Zypitamag

- Documentation of the following is required:
  - diagnosis of one of the following:
    - heterozygous familial hypercholesterolemia; **or**
    - homozygous familial hypercholesterolemia; **or**
    - hypercholesterolemia in a member with a previous history of any cardiovascular event; **or**
    - hypertriglyceridemia; **or**
    - primary dysbetaliproteinemia; **or**
    - primary hyperlipidemia; **or**
    - primary prevention of cardiovascular events; **and**
  - one of the following:
    - inadequate response (defined as ≥ the last 3 months) or adverse reaction to one or contraindication to all high-intensity statins; **or**
    - clinical rationale for not using a high-intensity statin; **and**

- one of the following:
  - request is within quantity limits; **or**
  - medical necessity for exceeding the quantity limits; **or**
  - for requests above the maximum FDA-approved dose, inadequate response (defined as ≥ the last 3 months) to atorvastatin 80 mg daily.

SmartPA: Claims for Altoprev (60 mg), fluvastatin extended-release (80 mg), pitavastatin calcium (4 mg), or Zypitamag (4 mg) at a quantity of ≤ one unit/day, Altoprev (20 mg, 40 mg), fluvastatin (20 mg), pitavastatin calcium (1 mg, 2 mg), or Zypitamag (1 mg, 2 mg) at a quantity of ≤ 1.5 units/day, and fluvastatin (40 mg) at a quantity of ≤ 2 units/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for 90 days out of the last 120 days or has a history of paid MassHealth pharmacy claims for rosuvastatin at a dose of at least 20 mg or atorvastatin at a dose of at least 40 mg for at least 90 days in all claims history.†

Atorvaliq

- Documentation of the following is required:
  - diagnosis of one of the following:
    - heterozygous familial hypercholesterolemia; **or**
    - homozygous familial hypercholesterolemia; **or**
    - hypercholesterolemia in a member with a previous history of any cardiovascular event; **or**
    - hypertriglyceridemia; **or**
    - primary dysbetaliproteinemia; **or**
    - primary hyperlipidemia; **or**
    - primary prevention of cardiovascular events; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member is < 13 years of age; **or**
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets); **and**
  - appropriate dosing; **and**
  - clinical rationale for the use of the requested agent instead of Ezallor.

*Recertification of the requested agent will be contingent upon continued medical necessity for the requested formulation instead of tablets.

atorvastatin, ezetimibe/simvastatin, lovastatin, pravastatin, rosuvastatin, and simvastatin over quantity limits

- Documentation of the following is required:
  - diagnosis of one of the following:
    - heterozygous familial hypercholesterolemia; **or**
    - homozygous familial hypercholesterolemia; **or**
    - hypercholesterolemia in a member with a previous history of any cardiovascular event; **or**
    - hypertriglyceridemia; **or**
    - primary dysbetaliproteinemia; **or**
    - primary hyperlipidemia; **or**
    - primary prevention of cardiovascular events; **and**
  - medical necessity for exceeding the quantity limits.

Evkeeza

- Documentation of the following is required:
  - diagnosis of homozygous familial hypercholesterolemia confirmed by one of the following:
    - both of the following:

        - baseline LDL-C ≥ 400 mg/dL; **and**
        - current LDL-C ≥ 100 mg/dL; **or**
    - one of the following:
        - member had evidence of xanthoma before 10 years of age; **or**
        - evidence of HeFH in both parents; **or**
    - laboratory test confirming genetic mutation associated with HoFH including low density lipoprotein receptor (LDLR) mutations, PCSK9 mutations and familial defective apoB mutations; **and**
- member is ≥ five years of age; **and**
- prescriber is a specialist (e.g., cardiologist, vascular neurologist, lipid-lowering specialist, endocrinologist) or consultation notes from a specialist regarding the use of the agent are provided; **and**
- one of the following:
    - agent to be used as add-on therapy with a high-intensity statin, ezetimibe, and PCSK9 inhibitor; **or**
    - contraindication or other compelling clinical rationale for omitting one or more of the following standard lipid-lowering therapies: statin, ezetimibe, PCSK9 inhibitor; **and**
- member's current weight; **and**
- appropriate dosing.

*Recertification of the requested agent will be contingent upon MassHealth pharmacy claims history or additional documentation addressing adherence to the entire lipid-lowering regimen, as well as updated information regarding the member's current weight, and positive response to therapy, including decrease in LDL-C laboratory values from baseline.

Ezallor

- Documentation of the following is required:
    - diagnosis of one of the following:
        - heterozygous familial hypercholesterolemia; **or**
        - homozygous familial hypercholesterolemia; **or**
        - hypercholesterolemia in a member with a previous history of any cardiovascular event; **or**
        - hypertriglyceridemia; **or**
        - primary dysbetaliproteinemia; **or**
        - primary hyperlipidemia; **or**
        - primary prevention of cardiovascular events; **and**
    - medical necessity for the requested formulation as noted by one of the following:
        - member is < 13 years of age; **or**
        - member utilizes tube feeding (G-tube/J-tube); **or**
        - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed (e.g., solutions,suspensions, films, or dispersible tablets); **and**
    - appropriate dosing; **and**
    - requested quantity is ≤ one sprinkle capsule/day.

*Recertification of the requested agent will be contingent upon continued medical necessity for the requested formulation instead of tablets.

fenofibrate 90 mg capsule and 40 mg, 120 mg tablet

- Documentation of the following is required:
    - diagnosis of one of the following:
        - hypertriglyceridemia; **or**
        - hypercholesterolemia; **or**
        - mixed dyslipidemia; **and**
    - medical records documenting an inadequate response or adverse reaction to a therapeutically equivalent fenofibrate formulation available without PA; **and**

- one of the following:
  - requested quantity is ≤ one unit/day; **or**
  - medical necessity for exceeding the quantity limits.

Flolipid

- Documentation of the following is required:
  - diagnosis of one of the following:
    - heterozygous familial hypercholesterolemia; **or**
    - homozygous familial hypercholesterolemia; **or**
    - hypercholesterolemia in a member with a previous history of any cardiovascular event; **or**
    - hypertriglyceridemia; **or**
    - primary dysbetaliproteinemia; **or**
    - primary hyperlipidemia; **or**
    - primary prevention of cardiovascular events; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member is < 13 years of age; **or**
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed (e.g., solutions,suspensions, films, or dispersible tablets); **and**
  - appropriate dosing.

*Recertification of the requested agent will be contingent upon continued medical necessity for the requested formulation instead of tablets.

icosapent ethyl for cardiovascular risk reduction (with established cardiovascular disease or diabetes mellitus and risk factors for cardiovascular disease)

- Documentation of the following is required:
  - diagnosis of cardiovascular risk reduction with one of the following;
    - member has established cardiovascular disease (e.g., prior MI, hospitalization for high-risk NSTE-ACS cerebrovascular or carotid disease: prior ischemic stroke, carotid artery disease, PAD); **or**
    - member has diabetes mellitus with at least one risk factor for CVD (e.g., age [women ≥ 65 years, men ≥ 55 years], smoker, HTN, low HDL-C [≤ 40 mg/dL for men and ≤ 50 mg/dL for women], renal dysfunction [CrCl >30 and < 60 mL/min], retinopathy, micro- or macroalbuminuria), high-sensitivity C-reactive protein (hs-CRP) > 3.0 mg/dL, or ankle-brachial index < 0.9 without symptoms of intermittent claudication; **and**
  - triglyceride level ≥ 135 mg/dL; **and**
  - one of the following:
    - agent to be used in combination with a statin; **or**
    - clinical rationale why member cannot take a statin; **and**
  - one of the following:
    - for icosapent ethyl one gram capsule, requested quantity is ≤ four capsules/day; **or**
    - for icosapent ethyl 0.5 gram capsule, requested quantity is ≤ eight capsules/day; **or**
    - medical necessity for exceeding the quantity limits.

SmartPA: Claims for icosapent ethyl one gram capsule at a quantity of ≤ four units/day will usually process at the pharmacy without a PA request if the member has history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

SmartPA: Claims for icosapent ethyl 0.5 gram capsule at a quantity of ≤ eight units/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for for at least 90 days out of the last 120 days.†

icosapent ethyl for hypertriglyceridemia (not inclusive of those with established cardiovascular disease or diabetes mellitus and cardiovascular risk factors)

- Documentation of the following is required:
  - diagnosis of hypertriglyceridemia (not inclusive of those with established cardiovascular disease or diabetes mellitus and cardiovascular risk factors); **and**
  - triglyceride level ≥ 500 mg/dL; **and**
  - inadequate response (defined as ≥ the last 3 months), adverse reaction, or contraindication to a fibric acid derivative (i.e., fenofibrate or gemfibrozil); **and**
  - one of the following:
    - for icosapent ethyl one gram capsule, requested quantity is ≤ four capsules/day; **or**
    - for icosapent ethyl 0.5 gram capsule, requested quantity is ≤ eight capsules/day; **or**
    - medical necessity for exceeding the quantity limits.

SmartPA: Claims for icosapent ethyl one gram capsule at a quantity of ≤ four units/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

SmartPA: Claims for icosapent ethyl 0.5 gram capsule at a quantity of ≤ eight units/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

Juxtapid

- Documentation of the following is required:
  - diagnosis of homozygous familial hypercholesterolemia confirmed by one of the following:
    - both of the following:
      - baseline LDL-C ≥ 400 mg/dL; **and**
      - current LDL-C ≥ 100 mg/dL; **or**
    - one of the following:
      - member had evidence of xanthoma before 10 years of age; **or**
      - evidence of HeFH in both parents; **or**
    - laboratory test confirming genetic mutation associated with HoFH including low density lipoprotein receptor (LDLR) mutations, PCSK9 mutations and familial defective apoB mutations; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., cardiologist, vascular neurologist, lipid-lowering specialist, endocrinologist) or consultation notes from a specialist regarding the use of the agent are provided; **and**
  - one of the following:
    - inadequate response (defined as ≥ the last 3 months) or adverse reaction to one or contraindication to all high intensity statins; **or**
    - clinical rationale for not using a high intensity statin; **and**
  - one of the following:
    - agent to be used as add-on therapy with a high intensity statin; **or**
    - contraindication to statin therapy; **and**
  - inadequate response (defined as ≥ the last 3 months) or adverse reaction to one additional non-statin lipid-lowering agent or contraindication to all other non-statin lipid-lowering agents.

Leqvio

- Documentation of the following is required*:
  - diagnosis of hypercholesterolemia with one of the following:
    - for members with a diagnosis of heterozygous familial hypercholesterolemia, current LDL-C is ≥ 70 mg/dL; **or**
    - for members without a previous history of a cardiovascular event (with or without HeFH or HoFH), both of the following:

        - one of the following:
            - member has Type 2 diabetes; **or**
            - member has ≥ 20% 10-year risk of a cardiovascular event (Framingham Risk Score for Cardiovascular Disease or equivalent); **and**
        - current LDL-C is ≥ 55mg/dL; **and**
    - for members with a previous history of a cardiovascular event, current LDL-C is ≥ 55 mg/dL; **and**
- member is ≥ 18 years of age; **and**
- appropriate dosing; **and**
- prescriber is a specialist (e.g., cardiologist, endocrinologist, lipid-lowering specialist, vascular neurologist) or consultation notes from a specialist regarding the use of the agent are provided; **and**
- inadequate response (defined as ≥ the last 3 months)** or adverse reaction to one or contraindication to both of the following: Praluent, Repatha; **and**
- one of the following:
    - inadequate response (defined as ≥ the last 3 months) to a high intensity statin in combination with ezetimibe; **or**
    - adverse reaction or contraindication to ezetimibe and inadequate response (defined as ≥ the last 3 months) to high intensity statin monotherapy; **or**
    - adverse reaction to one high intensity statin or contraindication to all high intensity statins.

*Recertification of the requested agent will be contingent upon MassHealth pharmacy claims history or additional documentation addressing adherence to the entire lipid-lowering regimen, as well as positive response to therapy, including decrease in LDL-C laboratory values from baseline.

**Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to these agents.

Nexletol and Nexlizet

- Documentation of the following is required:
    - diagnosis of hypercholesterolemia with one of the following:
        - for members with a diagnosis of heterozygous familial hypercholesterolemia, current LDL-C is ≥ 70 mg/dL; **or**
        - for members without a previous history of a cardiovascular event (with or without HeFH or HoFH), both of the following:
            - one of the following:
                - member is female sex assigned at birth > 65 years of age or male sex assigned at birth > 65 years of age and has Type 1 or Type 2 diabetes; **or**
                - Reynolds risk score > 30% or SCORE risk score > 7.5% over 10 years; **or**
                - coronary artery calcium score > 400 Agatston units; **and**
            - current LDL-C is ≥ 55 mg/dL; **and**
        - for members with a previous history of a cardiovascular event, current LDL-C is ≥ 55 mg/dL; **and**
    - member is ≥ 18 years of age; **and**
    - one of the following:
        - inadequate response (defined as ≥ the last 3 months) to a high intensity statin in combination with ezetimibe; **or**
        - adverse reaction or contraindication to ezetimibe and inadequate response (defined as ≥ the last 3 months) to high intensity statin monotherapy; **or**
        - adverse reaction to one high intensity statin or contraindication to all high intensity statins; **and**
    - requested quantity is ≤ one tablet/day.

Praluent

- Documentation of the following is required:
    - diagnosis of hypercholesterolemia with one of the following:
        - for members with a diagnosis of heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia,

current LDL-C is ≥ 70 mg/dL; **or**
    - for members with a previous history of a cardiovascular event, current LDL-C is ≥ 55 mg/dL; **or**
    - for members with primary hyperlipidemia without a history of a cardiovascular event and/or heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia, baseline LDL-C is ≥ 190 mg/dL, and current LDL-C is ≥ 70 mg/dL; **and**
- one of the following:
    - member has a diagnosis of HeFH and is ≥ 8 years of age; **or**
    - member is ≥ 18 years of age; **and**
- appropriate dosing; **and**
- requested quantity is two pens or syringes/28 days; **and**
- one of the following:
    - inadequate response (defined as ≥ the last 3 months) to a high intensity statin in combination with ezetimibe; **or**
    - adverse reaction or contraindication to ezetimibe and inadequate response (defined as ≥ the last 3 months) to high intensity statin monotherapy; **or**
    - adverse reaction to one high intensity statin or contraindication to all high intensity statins; **or**
    - inadequate response (defined as ≥ the last 3 months) to a statin at the maximally tolerated dose in a member that needs > 25% LDL-C lowering.

Repatha

- Documentation of the following is required:
    - one of the following:
        - diagnosis of heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia and member is ≥ 10 years of age; **or**
        - member is ≥ 18 years of age; **and**
    - diagnosis of hypercholesterolemia with one of the following:
        - for members with a diagnosis of heterozygous or homozygous familial hypercholesterolemia, current LDL-C is ≥ 70 mg/dL; **or**
        - for members with a previous history of a cardiovascular event, current LDL-C is ≥ 55 mg/dL; **or**
        - for members with primary hyperlipidemia without a history of a cardiovascular event and/or heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia, baseline LDL-C is ≥ 190 mg/dL, and current LDL-C is ≥ 70 mg/dL; **and**
    - one of the following:
        - inadequate response (defined as ≥ the last 3 months) to a high intensity statin in combination with ezetimibe; **or**
        - adverse reaction or contraindication to ezetimibe and inadequate response (defined as ≥ the last 3 months) to high intensity statin monotherapy; **or**
        - adverse reaction to one high intensity statin or contraindication to all high intensity statins; **or**
        - inadequate response (defined as ≥ the last 3 months) to a statin at the maximally tolerated dose in a member that needs > 25% LDL-C lowering; **and**
    - appropriate dosing; **and**
    - requested quantity is two autoinjectors or syringes/28 days or one to two on-body infusor systems/28 days.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 14 - Headache Therapy

Drug Category: Pain and Inflammation

Medication Class/Individual Agents: Butalbitals, CGRP Inhibitors, Ergot Alkaloids, and Serotonin Receptor Agents

I. Prior-Authorization Requirements

Headache Therapy – Calcitonin Gene-Related Peptide (CGRP) Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
atogepant	Qulipta PD	PA	
eptinezumab-jjmr	Vyepti	PA	MB
erenumab-aooe	Aimovig	PA	
fremanezumab-vfrm for migraine prophylaxis	Ajovy PD	PA	
galcanezumab-gnlm	Emgality PD	PA	
rimegepant	Nurtec PD	PA	
ubrogepant	Ubrelvy PD	PA	
zavegepant	Zavzpret	PA	

Headache Therapy – Serotonin Receptor Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
almotriptan		PA	A90
eletriptan	Relpax	PA	A90
frovatriptan	Frova	PA	BP, A90
lasmiditan	Reyvow	PA	
naratriptan		PA - > 18 units/30 days	A90
rizatriptan orally disintegrating tablet	Maxalt MLT	PA - > 18 units/30 days	# , A90
rizatriptan tablet	Maxalt	PA - > 18 units/30 days	# , A90
sumatriptan / naproxen		PA	A90
sumatriptan 10 mg nasal spray	Tosymra	PA	
sumatriptan 5 mg, 20 mg nasal spray	Imitrex	PA - > 18 units/30 days and PA < 6 years	# , A90
sumatriptan injection-Imitrex	Imitrex	PA	
sumatriptan injection-	Zembrace	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Contraindications to Triptans:

- history, presence, symptoms, or signs of ischemic heart disease (e.g., angina, MI, stroke, TIA), coronary artery vasospasm, or other significant underlying cardiovascular disease
- uncontrolled hypertension
- concurrent use or use within 24 hours of ergotamine-containing products or ergot-type medications (e.g., dihydroergotamine, methysergide)
- concurrent use with MAO inhibitor therapy or within two weeks of MAO inhibitor discontinuation
- use within 24 hours of treatment with another triptan
- management of hemiplegic or basilar migraine
- hypersensitivity to the product or any of its ingredients

Do not exceed the maximum recommended dose per 24-hour period.

Orally Disintegrating Tablets:

- Place tablet on tongue, where it will be dissolved and swallowed with saliva.
- Inform phenylketonurics that tablets contain phenylalanine.

Migraine prophylaxis (e.g., amitriptyline, propranolol,

Headache Therapy – Serotonin Receptor Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
Zembrace			
sumatriptan tablet	Imitrex	PA - > 18 units/30 days	# , A90
zolmitriptan nasal spray	Zomig	PA	A90
zolmitriptan orally disintegrating tablet		PA	A90
zolmitriptan tablet	Zomig	PA - > 18 units/30 days	# , A90

Headache Therapy – Ergot Alkaloids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dihydroergotamine injection		PA	
dihydroergotamine nasal spray	Migranal	PA	A90
ergotamine / caffeine suppository		PA	A90

Headache Therapy – Butalbital-Containing Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
butalbital / aspirin / caffeine / codeine		PA	
butalbital / aspirin / caffeine capsule		PA - < 18 years and PA > 20 units/30 days	
butalbital / aspirin / caffeine tablet		PA	
butalbital 50 mg / acetaminophen 300 mg		PA	
butalbital 50 mg / acetaminophen 300 mg / caffeine 40 mg		PA	
butalbital 50 mg / acetaminophen 300 mg / caffeine 40 mg / codeine 30 mg		PA	
butalbital 50 mg / acetaminophen 325 mg		PA	
butalbital 50 mg / acetaminophen 325 mg / caffeine 40 mg / codeine		PA - < 18 years and PA > 20 units/30 days	

Clinical Notes

timolol) may be considered for the following conditions:

- migraine occurs ≥ twice monthly and produces disability lasting ≥ three days per month
- contraindication to, or failure of, acute treatments
- abortive medications are used > twice per week
- other severe migraine conditions

Headache Therapy – Butalbital-Containing Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
30 mg			
butalbital 50 mg / acetaminophen 325 mg / caffeine 40 mg capsule		PA	
butalbital 50 mg / acetaminophen 325 mg / caffeine 40 mg tablet		PA - < 18 years and PA > 20 units/30 days	

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- acute treatment of migraine (all triptans, dihydroergotamine injection, dihydroergotamine nasal spray, ergotamine/caffeine suppository, Nurtec, Reyvow, Ubrelvy, Zavzpret)
- cluster headache (dihydroergotamine injection, sumatriptan injection)
- chronic tension-type headache (butalbital agents)
- episodic cluster headache (Emgality)
- migraine prophylaxis (Aimovig, Ajovy, Emgality, Nurtec, Qulipta, Vyepti)
- vascular headache (ergotamine/caffeine suppository)

Triptans are NOT intended for prophylactic therapy of migraines.

Non-FDA-approved, for example:

- cluster headache (all triptans except sumatriptan injection, dihydroergotamine nasal spray, ergotamine/caffeine suppository, Reyvow)
- cyclic vomiting syndrome (sumatriptan 5 mg, 20 mg nasal spray, sumatriptan injection)
- migraine headache (butalbital agents)
- vascular headache (all triptans, dihydroergotamine injection, dihydroergotamine nasal spray, Reyvow)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Aimovig, Ajovy, Emgality

- Documentation of all of the following is required for migraine prophylaxis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - migraine frequency ≥ four days per month; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: atenolol, metoprolol, nadolol, propranolol, timolol; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: topiramate, tricyclic antidepressant, valproic acid, venlafaxine.
- Documentation of the following is required for Emgality for cluster headache:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing.
- Documentation of the following is required for recertification of Emgality for cluster headache:
  - the member is still actively having a cluster headache; **and**
  - the member has been initiated on prophylactic therapy for the cluster headache; **or**
  - clinical rationale why prophylactic therapy is not appropriate.

almotriptan (≤ 18 units/30 days), eletriptan (≤ 18 units/30 days), and frovatriptan (≤ 18 units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - for almotriptan, member is ≥ 12 years of age; **or**
    - for eletriptan or frovatriptan, member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: naratriptan, rizatriptan tablets or orally disintegrating tablets (ODTs), sumatriptan tablets, zolmitriptan tablets.

SmartPA: Claims for ≤ 18 units/30 days of almotriptan tablets will usually process at the pharmacy without a PA request if there is a history of paid MassHealth pharmacy claims for at least two different oral triptan agents available without PA within quantity limits (naratriptan, sumatriptan tablets, rizatriptan ODTs or tablets, zolmitriptan tablets) and the member is ≥ 12 years of age.†

SmartPA: Claims for ≤ 18 units/30 days of eletriptan or frovatriptan, will usually process at the pharmacy without a PA request if there is a history of paid MassHealth pharmacy claims for at least two different oral triptan agents available without PA within quantity limits (naratriptan, sumatriptan tablets, rizatriptan ODTs or tablets, zolmitriptan tablets) and the member is ≥ 18 years of age.†

almotriptan (> 18 units/30 days), eletriptan (> 18 units/30 days), and frovatriptan (> 18 units/30 days)
- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

Brand name Imitrex 5 mg, 20 mg nasal spray, Imitrex tablet, Maxalt MLT and tablet, and Zomig tablet (≤ 18 units/30 days)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to the generic equivalent of the requested agent; **and**
  - inadequate response or adverse reaction to all other triptans available without PA.

Brand name Imitrex 5 mg, 20 mg nasal spray, Imitrex tablet, Maxalt MLT and tablet, and Zomig tablet (> 18 units/30 days)
- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg capsule (≤ 20 units/30 days)
Please refer to additional criteria if request is for members < 18 years of age and/or for quantities exceeding 20 units/30 days.
- Documentation of the following is required for a diagnosis of chronic tension-type headache:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg tablets.
- Documentation of the following is required for a diagnosis of migraine headache:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg tablets; **and**
  - inadequate response or adverse reaction to two or contraindication to all triptans; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: NSAIDs, acetaminophen, aspirin, acetaminophen/caffeine, acetaminophen/aspirin/caffeine, and ergot alkaloid; **and**
  - inadequate response or adverse reaction to one or contraindication to all oral CGRP inhibitors.

butalbital 50 mg/aspirin 325 mg/caffeine 40 mg tablet (≤ 20 units/30 days)
- Documentation of the following is required for a diagnosis of chronic tension-type headache:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction or contraindication to butalbital 50 mg/aspirin 325 mg/caffeine 40 mg capsule.

butalbital-containing agents (formulations that require PA for all quantities, excluding butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg capsule and butalbital/aspirin/caffeine tablet) (≤ 20 units/30 days)
Please refer to additional criteria if request is for members < 18 years of age and/or for quantities exceeding 20 units/30 days.
- Documentation of the following is required for a diagnosis of chronic tension-type headache:

- appropriate diagnosis; **and**
- medical necessity for the requested formulation instead of formulations available without PA within quantity limits.

- Documentation of the following is required for a diagnosis of migraine headache:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all triptans; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: NSAIDs, acetaminophen, aspirin, acetaminophen/caffeine, acetaminophen/aspirin/caffeine, and ergot alkaloid; **and**
  - inadequate response or adverse reaction to one or contraindication to all oral CGRP inhibitors.

butalbital-containing agents exceeding quantity limits (> 20 units/30 days)

For all requests, individual drug PA criteria must be met first where applicable.

- Documentation of the following is required for a diagnosis of tension headache:
  - appropriate diagnosis; **and**
  - headache frequency; **and**
  - current prophylactic regimen; **and**
  - prescriber is a neurologist or consult notes from a neurologist are provided; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: NSAIDs, acetaminophen, aspirin, acetaminophen/caffeine, and acetaminophen/aspirin/caffeine.
- Documentation of the following is required for a diagnosis of migraine headache:
  - appropriate diagnosis; **and**
  - headache frequency; **and**
  - current prophylactic regimen; **and**
  - prescriber is a neurologist or consult notes from a neurologist are provided; **and**
  - inadequate response or adverse reaction to two or contraindication to all triptans; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: NSAIDs, acetaminophen, aspirin, acetaminophen/caffeine, acetaminophen/aspirin/caffeine, and ergot alkaloid; **and**
  - inadequate response or adverse reaction to one or contraindication to all oral CGRP inhibitors.

butalbital-containing agents for members < 18 years of age

For all requests, individual drug PA criteria must be met first where applicable.

- Documentation of the following is required for a diagnosis of tension headache:
  - appropriate diagnosis; **and**
  - headache frequency; **and**
  - current prophylactic regimen if member experiences more than four headaches per month or headaches that last longer than 12 hours; **and**
  - prescriber is a neurologist or consult notes from a neurologist are provided that support the use of a butalbital-containing agent; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: NSAIDs, acetaminophen, aspirin, acetaminophen/caffeine, acetaminophen/aspirin/caffeine.
- Documentation of the following is required for a diagnosis of migraine headache:
  - appropriate diagnosis; **and**
  - headache frequency; **and**
  - current prophylactic regimen if member experiences more than four headaches per month or headaches that last longer than 12 hours; **and**
  - prescriber is a neurologist or consult notes from a neurologist are provided that support the use of a butalbital-containing agent; **and**
  - inadequate response or adverse reaction to two or contraindication to all triptans; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: NSAIDs, acetaminophen, aspirin,

acetaminophen/caffeine, acetaminophen/aspirin/caffeine.

codeine-containing products for members < 12 years of age

For all requests, individual drug PA criteria and/or butalbital-containing agents age restriction criteria must be met first where applicable.

- Documentation of one of the following is required:
  - CYP2D6 genotyping confirms member is not an ultra-rapid CYP2D6 metabolizer; **or**
  - member has previously utilized a codeine-containing product without adverse effect that prevents repeat use.

dihydroergotamine injection

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - cluster headache; **or**
    - nausea or vomiting with migraine; **and**
  - inadequate response, adverse reaction, or contraindication to sumatriptan injection.

dihydroergotamine nasal spray (generic Migranal) (≤ 8 units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: sumatriptan nasal spray, zolmitriptan nasal spray.

dihydroergotamine nasal spray (generic Migranal) (> 8 units/30 days)

- Documentation of the following is required:
  - for all requests, individual drug PA criteria must be met first where applicable; **and**
  - headache frequency; **and**
  - neurology consultation should be provided if headache frequency is > 15 headaches/30 days; **and**
  - member is currently on a prophylactic regimen.

ergotamine/caffeine suppository

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation as noted by nausea or vomiting with migraine; **and**
  - inadequate response, adverse reaction, or contraindication to sumatriptan nasal spray; **and**
  - requested quantity is ≤ 18 suppositories/30 days.

naratriptan, rizatriptan ODT and tablet, sumatriptan 5 mg, 20 mg nasal spray, sumatriptan tablet, and zolmitriptan tablet (> 18 units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for sumatriptan 5 mg, 20 mg nasal spray in members < 6 years of age, individual PA criteria must be met first; **and**
  - requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

Nurtec

- Documentation of the following is required for a diagnosis of acute treatment of migraine:
  - appropriate diagnosis; **and**

- member is ≥ 18 years of age; **and**
- inadequate response or adverse drug reaction to two or contraindication to all oral triptans; **and**
- requested quantity is ≤ 16 units/30 days.

- Documentation of all of the following is required for a diagnosis of migraine prophylaxis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - migraine frequency ≥ four days per month; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Aimovig, Ajovy, Emgality; **and**
  - requested quantity is ≤ 16 units/30 days.

Ubrelvy (≤ 16 units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse drug reaction to two or contraindication to all oral triptans.
- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency and prophylactic regimen.

Qulipta

- Documentation of all of the following is required for a diagnosis of migraine prophylaxis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - migraine frequency ≥ four days per month; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: atenolol, metoprolol, nadolol, propranolol, timolol; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Botox, topiramate, tricyclic antidepressant, valproic acid, venlafaxine; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Aimovig, Ajovy, Emgality; **and**
  - requested quantity is ≤ one unit/day.

Reyvow (≤ eight units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two different triptan agents or contraindication to all oral triptans; **and**
  - prescriber is a neurologist or consult from a neurologist is provided.

Reyvow (> eight units/30 days)

- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

sumatriptan injection (≤ 18 injections/30 days)

- Documentation of the following is required for a diagnosis of acute treatment of migraine, cluster headache, vascular headache:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - cluster headache; **or**

    - nausea or vomiting with migraine.
- Documentation of the following is required for a diagnosis of acute treatment of cyclic vomiting syndrome:
    - appropriate diagnosis.

sumatriptan injection (> 18 injections/30 days) and zolmitriptan nasal spray (> 18 units/30 days)
- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

sumatriptan/naproxen (≤ 18 units/30 days)
- Documentation of the following is required:
    - appropriate diagnosis; **and**
    - inadequate response or adverse reaction to two of the following: naratriptan, sumatriptan tablets, rizatriptan ODT or tablets, and zolmitriptan tablets; **and**
    - medical necessity for the combination product instead of the commercially available separate agents.

sumatriptan/naproxen (> 16 units/30 days)
- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

sumatriptan 5 mg, 20 mg nasal spray for members < six years of age (≤ 18 units/30 days)
- Documentation of all of the following is required:
    - appropriate diagnosis; **and**
    - headache frequency; **and**
    - member is under the care of a neurologist; **and**
    - inadequate response, adverse reaction, or contraindication to both of the following: acetaminophen, nonsteroidal anti-inflammatory drug (e.g., ibuprofen or naproxen).

Tosymra (≤ 18 units/30 days)
- Documentation of all the following is required:
    - appropriate diagnosis; **and**
    - medical necessity for the requested formulation as noted by nausea or vomiting with migraine; **and**
    - inadequate response or adverse reaction to one or contraindication to both of the following:
        - sumatriptan 5 mg or 20 mg nasal spray; **or**
        - zolmitriptan nasal spray.

Tosymra (> 18 units/30 days)
- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

Vyepti
- Documentation of all of the following is required:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - appropriate dosing; **and**
    - migraine frequency ≥ four days per month; **and**

- inadequate response or adverse reaction to one or contraindication to all of the following: atenolol, metoprolol, nadolol, propranolol, timolol; **and**
- inadequate response or adverse reaction to one or contraindication to all of the following: Botox, topiramate, tricyclic antidepressant, valproic acid, venlafaxine; **and**
- inadequate response or adverse reaction to one or contraindication to all of the following: Aimovig, Ajovy, Emgality.

Zavzpret (≤ 12 units/30 days)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all triptan nasal sprays; **and**
  - medical necessity for the requested formulation as noted by nausea or vomiting with migraine.

Zavzpret (> 12 units/30 days)
- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

Zembrace (≤ 36 units/30 days)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation as noted by nausea or vomiting with migraine; **and**
  - inadequate response or adverse reaction to sumatriptan injection (generic Imitrex).

Zembrace (> 36 units/30 days)
- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

zolmitriptan ODT (≤ 18 units/30 days)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two of the following: naratriptan, rizatriptan ODT or tablets, sumatriptan tablets, and zolmitriptan tablets; **or**
  - both of the following:
    - medical necessity for the requested formulation as noted by nausea or vomiting with migraine; **and**
    - inadequate response or adverse reaction to rizatriptan ODT.

zolmitriptan ODT (> 18 units/30 days)
- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

zolmitriptan nasal spray (< 18 units/30 days)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation as noted by nausea or vomiting with migraine.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 15 - Hypnotics

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Hypnotics

I. Prior-Authorization Requirements

Hypnotics				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
daridorexant	Quviviq	PA		**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** **Please note: Concurrent therapy with two or more hypnotics (including hypnotic benzodiazepines) will also require PA. For additional information regarding hypnotic benzodiazepines (estazolam, flurazepam, temazepam, triazolam), please see: Table 69 - Barbiturates, Benzodiazepines and Miscellaneous Antianxiety Agents.** • Nonpharmacologic treatments, such as practicing good sleep hygiene, relaxation training, and cognitive therapy may be more effective than medications in some individuals. See “10 Tips for a Good Night's Sleep.” • There is limited medical evidence on the safety and efficacy of prolonged use of hypnotics. • To avoid tolerance and dependence, use the lowest dose, intermittently, and for the shortest possible duration. • Recommended hypnotic dosages are generally lower in the elderly.
doxepin tablet		PA	A90	
eszopiclone		PA - < 6 years and PA > 1 unit/day		
lemborexant	Dayvigo	PA		
ramelteon	Rozerem	PA - > 1 unit/day	BP, A90	
suvorexant	Belsomra	PA		
zaleplon		PA - < 6 years and PA > 1 unit/day		
zolpidem 1.75 mg, 3.5 mg sublingual tablet		PA		
zolpidem 10 mg tablet	Ambien	PA - < 6 years and PA > 1 unit/day	#	
zolpidem 5 mg tablet	Ambien	PA - < 6 years and PA > 1.5 units/day	#	
zolpidem 5 mg, 10 mg sublingual tablet	Edluar	PA		
zolpidem 7.5 mg capsule		PA		
zolpidem extended -release tablet	Ambien CR	PA - < 6 years and PA > 1 unit/day	#	

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Acute insomnia
- Chronic insomnia
- Insomnia characterized by middle-of-the-night awakenings with difficulty falling back asleep

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Documentation of the following is required:
  - All PA requests must include clinical diagnosis, drug name, dose, and frequency; **and**
  - Member's current medications.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Belsomra, Dayvigo, and Quviviq

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or a contraindication to all of the following: eszopiclone, ramelteon, zaleplon, zolpidem immediate-release or extended-release; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - medical necessity for > one unit/day; **and**
  - for Dayvigo, an inadequate response, adverse reaction or contraindication to Belsomra; **and**
  - for Quviviq, an inadequate response, adverse reaction, or contraindication to both of the following: Belsomra and Dayvigo.

doxepin tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: doxepin oral concentrate at an equivalent dose to the requested tablet, doxepin capsule; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following:
    - Belsomra, Dayvigo or Quviviq; **or**
    - eszopiclone; **or**
    - ramelteon; **or**
    - zaleplon; **or**
    - zolpidem immediate-release or zolpidem extended-release; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - medical necessity for > one unit/day.

Edluar

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for a sublingual formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - medical necessity for > one unit/day.

eszopiclone, ramelteon, zaleplon, zolpidem 10 mg tablet, and zolpidem extended-release tablet (quantities > one unit/day)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - requested dose is consolidated; **and**
  - one of the following:
    - requested dose is once daily at bedtime; **or**
    - clinical rationale for requiring more than once daily bedtime dosing; **and**
  - all of the following:
    - inadequate response to established quantity limit; **and**
    - trial of a higher dose was effective in alleviating symptoms; **and**
    - inadequate response or adverse reaction to two of the following other alternatives for sleep (one must be a non-benzodiazepine hypnotic): doxepin, eszopiclone, an orexin receptor antagonist (Belsomra, Dayvigo, Quviviq), ramelteon, zaleplon, zolpidem or zolpidem ER.

zolpidem 1.75 mg, 3.5 mg sublingual tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - medical necessity for a sublingual formulation as noted by one of the following:
      - member utilizes tube feeding (G-tube/J-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - inadequate response or adverse reaction to three of the following: eszopiclone, zaleplon, zolpidem immediate-release,

zolpidem extended-release; **and**

- one of the following:
  - requested quantity is ≤ one unit/day; **or**
  - medical necessity for > one unit/day.

zolpidem 5 mg tablet (quantities > 1.5 units/day)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - requested dose is consolidated; **and**
  - one of the following:
    - requested dose is once daily at bedtime; **or**
    - clinical rationale for requiring more than once daily bedtime dosing; **and**
  - all of the following:
    - inadequate response to established quantity limit; **and**
    - trial of a higher dose was effective in alleviating symptoms; **and**
    - inadequate response or adverse reaction to two of the following other alternatives for sleep (one must be a non-benzodiazepine hypnotic): doxepin, eszopiclone, an orexin receptor antagonist (Belsomra, Dayvigo, Quviviq), ramelteon, zaleplon, zolpidem or zolpidem ER.

zolpidem 7.5 mg capsule

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to both of the following: zolpidem 5 mg tablet, zolpidem 10 mg tablet; **and**
  - medical necessity for 7.5 mg capsule instead of formulations available without PA; **and**
  - requested quantity is ≤ one unit/day.

Brand-name Ambien CR

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to eszopiclone; **and**
  - medical records documenting an inadequate response or adverse reaction to generic zolpidem extended-release tablet; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - medical necessity for > one unit/day.

Hypnotic Polypharmacy (overlapping pharmacy claims for two or more hypnotics [including benzodiazepine hypnotics (estazolam, flurazepam, quazepam, temazepam, and triazolam) and non-benzodiazepine hypnotics] for at least 60 days within a 90-day period)

- For all requests, individual drug PA criteria must be met first where applicable within established quantity limits for the individual drug.
- Documentation of all of the following is required:
  - diagnosis of insomnia (acute or chronic); **and**
  - clear treatment plan; **and**
  - severity of sleep diagnosis; **and**
  - prescriber is a neurologist, sleep medicine specialist, or psychiatrist, or consultation notes from a specialist are provided; **and**
  - one of the following:
    - inadequate response or adverse reaction to all of the following alternative hypnotics indicated for diagnosis: an orexin receptor antagonist (Belsomra, Dayvigo, Quviviq), doxepin capsules or doxepin tablets, eszopiclone, ramelteon, zaleplon, zolpidem or zolpidem ER; **or**

- contraindication to all alternative hypnotics indicated for the diagnosis; **and**
- one of the following:
  - the hypnotic regimen includes two agents with different mechanisms of action; **or**
  - for concomitant zolpidem IR and ER, total dose requested does not exceed FDA-approved dosing of individual agents (not to exceed 12.5 mg/day).

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy (*pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, viloxazine, and xanomeline/trospium] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period) for members < 18 years of age*

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.
- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
    - one of the following:
      - member has a seizure diagnosis only; **or**

- member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
  - cross-titration/taper of mood stabilizer therapy; **or**
  - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
- member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
- member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and**
- one of the following:
  - cross-titration/taper of mood stabilizer therapy; **or**
  - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Hypnotic agents in members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required for members with a diagnosis of insomnia with other behavioral health comorbidities, excluding ADHD/ASD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnosis of insomnia without behavioral health comorbidities or insomnia with comorbid ASD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - inadequate response (defined by ≥ 10 days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnosis of insomnia with comorbid ADHD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**

- at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
- inadequate response (defined by ≥ 10 days of therapy), adverse reaction, or contraindication to melatonin; **and**
- inadequate response (defined by ≥ 10 days of therapy), adverse reaction, or contraindication to clonidine; **and**
- if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation.

†Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 16 - Corticosteroids - Topical

Drug Category: Dermatological

Medication Class/Individual Agents: Corticosteroids

I. Prior-Authorization Requirements

Topical Corticosteroids – Class II. Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betamethasone dipropionate cream			A90
betamethasone dipropionate spray	Sernivo	PA	
betamethasone dipropionate, augmented cream, lotion			A90
desoximetasone 0.25% cream			A90
desoximetasone 0.25% ointment, 0.05% gel		PA	A90
desoximetasone spray	Topicort	PA	A90
diflorasone cream / emollient	Apexicon-E	PA	
fluocinonide cream, gel, ointment, solution			A90
halcinonide cream, solution	Halog	PA	A90
halcinonide ointment	Halog		
mometasone ointment			A90
triamcinolone 0.5% ointment			A90

Topical Corticosteroids – Class I. Superpotent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betamethasone augmented gel			A90
betamethasone dipropionate lotion, ointment			A90
betamethasone dipropionate,	Diprolene		# , A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Product Potency:

- Relative potency of a product depends on the characteristics and concentration of the drug and the vehicle.
- Generally, ointments and gels are more potent than creams or lotions; however, some products have been formulated to yield comparable potency.

Product Selection:

- Selection of a specific corticosteroid, strength, and vehicle depends on the nature, location, and extent of the skin condition, member's age, and anticipated duration of treatment.
- Use the least-potent corticosteroid that would be effective.
- Low-potency agents are preferred for the face, intertriginous areas (e.g., groin, axilla), and large areas to reduce the potential for side effects.
- Low-potency agents are preferred in children.
- Reserve higher-potency agents for areas and conditions resistant to treatment with milder agents.

Adverse Reactions:

- Systemic absorption of topical corticosteroids has

Topical Corticosteroids – Class I. Superpotent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
augmented ointment			
clobetasol propionate 0.025% cream		PA	A90
clobetasol propionate 0.05% cream			A90
clobetasol propionate cream / emollient			A90
clobetasol propionate foam	Olux		# , A90
clobetasol propionate foam / emollient	Olux-E		BP, A90
clobetasol propionate gel, solution			A90
clobetasol propionate lotion, shampoo, spray	Clobex		A90
clobetasol propionate ointment	Temovate		# , A90
diflorasone ointment		PA	A90
fluocinonide 0.1% cream	Vanos		# , A90
halobetasol cream, ointment			A90
halobetasol foam	Lexette	PA	A90
halobetasol lotion	Bryhali	PA	
halobetasol lotion	Ultravate	PA	

Topical Corticosteroids – Class V. Lower Mid-Strength Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betamethasone valerate cream			A90
desonide cream	Desowen		A90
desonide lotion, ointment			A90
fluocinolone 0.01% cream			A90
fluocinolone 0.025% cream	Synalar		# , A90
fluocinolone shampoo	Capex	PA	
flurandrenolide cream, lotion		PA	A90
fluticasone cream			A90

Clinical Notes

produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, hyperglycemia, and glycosuria.

- Conditions that augment systemic absorption include application of more-potent steroids, use over large surface areas, prolonged use, addition of occlusive dressings, and member's age.
- Perform appropriate clinical and laboratory tests if a topical corticosteroid is used for long periods or over large areas of the body.

With chronic conditions, gradual discontinuation of therapy may reduce the chance of rebound.

Topical Corticosteroids – Class V. Lower Mid-Strength Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fluticasone lotion		PA	A90
hydrocortisone butyrate / emollient	Locoid Lipocream	PA	A90
hydrocortisone butyrate cream, ointment, solution			A90
hydrocortisone butyrate lotion	Locoid	PA	A90
hydrocortisone probutate cream	Pandel		
prednicarbate cream, ointment			A90
triamcinolone 0.1% lotion, 0.025% ointment			A90

Topical Corticosteroids – Class VI. Mild Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alclometasone cream, ointment			A90
betamethasone valerate lotion			A90
fluocinolone body oil, scalp oil	Derma-Smoothe-FS		# , A90
fluocinolone solution	Synalar		# , A90
triamcinolone 0.025% cream, lotion			A90

Topical Corticosteroids – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betamethasone / calcipotriene foam	Enstilar		
betamethasone / calcipotriene ointment		PA	A90
betamethasone / calcipotriene topical suspension	Taclonex	PA	BP, A90
clindamycin/benzoyl peroxide gel pump	Onexton	PA	BP, A90
halobetasol / tazarotene lotion	Duobrii	PA	
hydrocortisone /			A90

Topical Corticosteroids – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
pramoxine foam			
neomycin / fluocinolone cream		PA	A90

Topical Corticosteroids – Class IV. Mid-Strength Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
clocortolone cream		PA	A90
fluocinolone ointment	Synalar		# , A90
flurandrenolide ointment		PA	A90
hydrocortisone valerate			A90
mometasone cream, solution			A90
triamcinolone 0.05% ointment		PA	A90
triamcinolone 0.1% cream			A90
triamcinolone spray	Kenalog	PA	A90

Topical Corticosteroids – Class III. Upper Mid-Strength Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amcinonide cream		PA	A90
betamethasone valerate foam	Luxiq		# , A90
betamethasone valerate ointment			A90
desoximetasone 0.05% cream		PA	A90
desoximetasone 0.05% ointment	Topicort	PA	A90
diflorasone cream		PA	A90
fluocinonide / emollient			A90
fluticasone ointment			A90
triamcinolone 0.1% ointment, 0.5% cream			A90

Topical Corticosteroids – Class VII. Least Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
hydrocortisone cream, lotion, ointment			*, A90
hydrocortisone solution		PA	A90

Topical Corticosteroids – Dental Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
triamcinolone paste			A90

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Corticosteroid-responsive dermatoses with secondary infection
- Plaque psoriasis
- Psoriasis vulgaris
- Scalp-related conditions (i.e., dermatoses, psoriasis, seborrheic dermatitis)
- Topical inflammatory and pruritic dermatoses

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or

clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.

- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

amcinonide cream, clobetasol propionate 0.025% cream, clocortolone cream, desoximetasone 0.05% cream, gel, and ointment, desoximetasone 0.25% ointment and spray, diflorasone cream and ointment, flurandrenolide cream, lotion, and ointment, fluticasone lotion, halcinonide cream, halobetasol foam, hydrocortisone butyrate lotion, hydrocortisone solution, Locoid Lipocream, triamcinolone 0.05% ointment and spray, and brand-name topical corticosteroids (Apexicon-E, Bryhali, Halog solution, Ultravate lotion).

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - for Bryhali and desoximetasone spray, member is ≥ 18 years of age; **and**
  - for halobetasol foam and Ultravate lotion, member is ≥ 12 years of age; **and**
  - one of the following:
    - inadequate response or adverse reaction to all topical corticosteroids of the same potency range and formulation available without PA; **or**
    - medical necessity for the requested formulation.

betamethasone/calcipotriene ointment and topical suspension, and neomycin/fluocinolone cream

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - for betamethasone/calcipotriene topical suspension, member is ≥ 18 years of age; **and**
  - for betamethasone/calcipotriene ointment, member is ≥ 12 years of age; **and**
  - medical necessity for the combination product instead of the commercially available separate agents.

Capex

- Documentation of all of the following is required:
  - diagnosis of scalp-related condition; **and**
  - inadequate response or adverse reaction to a topical corticosteroid of a similar or greater potency available without PA and used on the scalp.

Duobrii (halobetasol/tazarotene lotion)

- Documentation of all of the following is required:
  - diagnosis of plaque psoriasis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one superpotent or potent topical corticosteroid available without PA; **and**
  - medical necessity for the combination product instead of the commercially available separate agents.

MassHealth Evaluation Criteria
Table 17 - Antidepressants

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Antidepressant

I. Prior-Authorization Requirements

Antidepressants – Tricyclic Antidepressants (TCA)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amitriptyline tablet		PA - < 6 years	A90
amoxapine		PA	A90
clomipramine	Anafranil	PA	A90
desipramine	Norpramin	PA	A90
doxepin capsule, oral concentrate		PA - < 6 years	A90
imipramine hydrochloride		PA - < 6 years	A90
imipramine pamoate		PA	A90
nortriptyline	Pamelor	PA - < 6 years	# , A90
protriptyline		PA	A90
trimipramine		PA	A90

Antidepressants – Norepinephrine/Dopamine Reuptake Inhibitors (NDRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bupropion hydrobromide extended-release	Aplenzin	PA	
bupropion hydrochloride extended-release 150 mg, 300 mg tablet	Wellbutrin XL	PA - < 6 years and PA > 1 unit/day	# , A90
bupropion hydrochloride extended-release 450 mg tablet	Forfivo XL	PA	A90
bupropion hydrochloride immediate-release		PA - < 6 years	A90
bupropion hydrochloride sustained-release-Wellbutrin SR	Wellbutrin SR	PA - < 6 years	# , A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- In general, the elderly are more sensitive to side effects of medications, especially to sedation, orthostatic hypotension, and anticholinergic symptoms. Because of changes in drug metabolism, older members need lower doses of antidepressants to reach therapeutic effect. Thus the maxim, “Start low and go slow.”
- MassHealth does not encourage the use of combination products and recommends that the active medications be prescribed individually.
- There is no evidence to support the use of two selective serotonin reuptake inhibitors (SSRIs) or a SSRI in combination with a serotonin/norepinephrine reuptake inhibitor (SNRI) or a serotonin modulator concurrently. These combinations may duplicate drug action, with increased side effects and minimal clinical benefit. PA is required when a member has an overlap of 60 days or more in prescriptions of two SSRIs or a SSRI in combination with a SNRI or serotonin modulator.
- Due to bupropion’s dose-dependent risk of seizure (0.33-0.4% within recommended dosing limits), please dose accordingly. Bupropion immediate-release (IR) should be dosed no greater than 150 mg per dose and 450 mg per day. Bupropion sustained release (SR) should be dosed no greater than 200 mg per dose and 400 mg per day.

Antidepressants – NMDA Receptor Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dextromethorphan / bupropion	Auvelity	PA	
esketamine	Spravato	PA	
ketamine injection	Ketalar	PA	MB

Antidepressants – Selective Serotonin Reuptake Inhibitors (SSRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
citalopram capsule		PA	A90
citalopram solution, tablet	Celexa	PA - < 6 years	# , A90
escitalopram	Lexapro	PA - < 6 years	# , A90
fluoxetine 10 mg, 20 mg tablet		PA - < 6 years	A90
fluoxetine 10 mg, 20 mg, 40 mg capsule, solution	Prozac	PA - < 6 years	# , A90
fluoxetine 60 mg tablet		PA	A90
fluoxetine 90 mg delayed-release capsule		PA	A90
fluvoxamine extended-release		PA	A90
fluvoxamine immediate-release		PA - < 6 years	A90
paroxetine controlled-release	Paxil CR	PA	A90
paroxetine hydrochloride	Paxil	PA - < 6 years	# , A90
sertraline capsule		PA	A90
sertraline oral concentrate, tablet	Zoloft	PA - < 6 years	# , A90

Antidepressants – Serotonin/Norepinephrine Reuptake Inhibitors (SNRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
desvenlafaxine extended-release		PA	A90
desvenlafaxine succinate extended-release 100 mg	Pristiq	PA - < 6 years and PA > 4 units/day	# , A90
desvenlafaxine	Pristiq	PA - < 6 years and	# , A90

Clinical Notes

Bupropion extended-release (XL) requires PA for quantities > one unit per day. It should be dosed no greater than 450 mg a day (300 mg tablet plus 150 mg tablet) as a single dose. Members with seizure disorders, brain injuries, and eating disorders are at highest risk of seizures.

- Brand-name Serzone is no longer available due to reports of life-threatening hepatic failure resulting in death or transplant. Nefazodone is still available from various manufacturers.
- Blood pressure should be monitored during venlafaxine therapy because it may cause a dose-related increase in diastolic blood pressure (reported in 3-13% of members). Sustained increases in diastolic blood pressure are reported with desvenlafaxine succinate as well (1.3-2.3% of members).
- Antidepressant discontinuation syndrome has been commonly reported with SSRIs and SNRIs. Among the SSRIs, this is most commonly reported with paroxetine (whose half-life is short and there is no active metabolite) and reported least with fluoxetine (with a long half-life and an active, long-acting metabolite). Symptoms include dizziness, nausea, fatigue, lethargy, flu-like symptoms, anxiety, irritability, and insomnia. This often occurs one-three days after abruptly stopping the medication. The agents in question should be slowly tapered to avoid this syndrome.
- In general, inadequate response to an antidepressant is defined as ≥ four weeks of therapy.

Monoamine Oxidase Inhibitors (MAOIs):

- Hypertensive crisis may occur when MAOIs are coadministered with some prescription and over-the-counter products and foods, especially those high in tyramine.
- Serotonin syndrome can occur when MAOIs are coadministered with other pro-serotonergic medications.
- Members should be counseled about dietary and medication restrictions and be given a list of food and drugs to be avoided.

Antidepressants – Serotonin/Norepinephrine Reuptake Inhibitors (SNRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
succinate extended-release 25 mg, 50 mg		PA > 1 unit/day	
duloxetine 20 mg, 30 mg, 60 mg capsule	Cymbalta	PA - < 6 years	# , A90
duloxetine 40 mg capsule		PA	A90
duloxetine sprinkle capsule	Drizalma	PA	
levomilnacipran	Fetzima	PA	
venlafaxine besylate extended -release tablet		PA	A90
venlafaxine extended-release capsule	Effexor XR	PA - < 6 years	# , A90
venlafaxine hydrochloride extended-release tablet		PA	A90
venlafaxine immediate-release		PA - < 6 years	A90

Antidepressants – Monoamine Oxidase Inhibitors (MAOI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
isocarboxazid	Marplan	PA	
phenelzine	Nardil	PA - < 6 years	# , A90
selegiline transdermal patch	Emsam	PA	
tranylcypromine		PA - < 6 years	A90

Antidepressants – Noradrenergic and Specific Serotonergic Antidepressants (NaSSA)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
mirtazapine	Remeron	PA - < 6 years	# , A90
mirtazapine orally disintegrating tablet	Remeron Sol Tab	PA	A90

Antidepressants – Second-Generation (Atypical) Antipsychotic and Selective Serotonin Reuptake Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
olanzapine / fluoxetine	Symbyax	PA	A90

Antidepressants – Serotonin Modulators			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
nefazodone		PA - < 6 years	A90
trazodone 300 mg tablet		PA	A90
trazodone 50 mg, 100 mg, 150 mg		PA - < 6 years	A90
vilazodone	Viibryd	PA	A90
vortioxetine	Trintellix	PA	

Antidepressants – Gamma-Aminobutyric (GABA)-A Receptor Positive Modulator			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
zuranolone	Zurzuvae PD	PA	

Antidepressants – Tricyclic Antidepressant (TCA) and Benzodiazepine			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amitriptyline / chlordiazepoxide		PA	

Antidepressants – Tricyclic Antidepressant (TCA) and First-Generation (Typical) Antipsychotic			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amitriptyline / perphenazine		PA	A90

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Anxiety disorders
- Bipolar disorder
- Chronic musculoskeletal pain
- Depressive disorders
- Diabetic peripheral neuropathy
- Obsessive-compulsive disorder
- Panic disorders
- Postpartum depression

non-FDA-approved, for example:

- Diabetic neuropathy
- Fibromyalgia
- Neuropathic pain
- Other psychiatric or neurologic condition requiring treatment with an antidepressant (i.e., psychotic disorder, neuropathic pain)
- Parkinson's Disease
- Postherpetic neuralgia
- Post-traumatic stress disorder

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status

of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

amitriptyline/chlordiazepoxide, amitriptyline/perphenazine, and fluoxetine/olanzapine
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents.

SmartPA: Claims for amitriptyline/chlordiazepoxide and amitriptyline/perphenazine will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

amoxapine and clomipramine
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to two or contraindication to all SSRIs.

SmartPA: Claims for amoxapine or clomipramine will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested medication for at least 90 days out of the last 120 days, or if the member has a history of MassHealth medical claims for an appropriate diagnosis and a history of paid MassHealth pharmacy claims for at least four weeks of therapy with two SSRIs.†

Aplenzin and bupropion hydrochloride extended-release 450 mg tablet
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to bupropion XL at an equivalent dose to the requested product; **and**
  - requested quantity is ≤ one unit/day.

Note: Bupropion hydrochloride extended-release quantities of one unit per day of both the 300 mg and the 150 mg tablets are available without PA and can be used in combination for 450 mg total daily dose.

SmartPA: Claims for Aplenzin with a quantity limit of one unit/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

Auvelity
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one SSRI and one other non-SSRI antidepressant or contraindication to all SSRI and non-SSRI antidepressants; **and**
  - requested quantity is ≤ two units/day.

SmartPA: Claims for Auvelity within polypharmacy requirements at a quantity ≤ two units per day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days, or if the member is ≥ 18 years of age, has a history of MassHealth medical claims for an appropriate diagnosis, and has a history of paid MassHealth pharmacy claims of at least four weeks of therapy with one SSRI and one non-SSRI.†

bupropion hydrochloride extended-release 150 mg, 300 mg and desvenlafaxine succinate ER 25 mg, 50 mg > 1 unit/day and desvenlafaxine succinate ER 100 mg > four units/day
- Documentation of the following is required:

- appropriate diagnosis; **and**
- one of the following:
  - clinical rationale why the dose cannot be consolidated; **or**
  - clinical rationale why the member requires dosing intervals exceeding what is recommended by the FDA.

citalopram capsule

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to citalopram tablets at an equivalent dose (three 10 mg tablets or one 10mg and one 20 mg tablet).

desipramine

- Documentation of all of the following is required for anxiety disorder, bipolar disorder, depressive disorder, obsessive-compulsive disorder, panic disorder, post-traumatic stress disorder, or other psychiatric or neurologic condition requiring treatment with an antidepressant (i.e., psychotic disorder):
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one or contraindication to both of the following: SSRI, SNRI; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one tricyclic antidepressant available without PA.
- Documentation of all of the following is required for diabetic neuropathy, fibromyalgia, or postherpetic neuralgia:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one other tricyclic antidepressant or contraindication to all other tricyclic antidepressants; **and**
  - appropriate dosing.

SmartPA: Claims for desipramine will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

desvenlafaxine ER

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to desvenlafaxine succinate ER.

Drizalma

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation instead of a solid oral formulation (e.g., swallowing disorder, dysphagia).

duloxetine 40 mg capsule

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to duloxetine at an equivalent dose (two 20 mg capsules).

Emsam

- Documentation of all of the following is required for major depressive disorder:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**

- one of the following:
  - medical necessity for the use of a transdermal formulation; **or**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to both of the following: SSRI, one other antidepressant that is not a SSRI; **or**
  - contraindication to all SSRI and non-SSRI antidepressants; **and**
- one of the following:
  - both of the following:
    - requested quantity is ≤ one patch/day; **and**
    - requested dose is ≤ 12 mg/day; **or**
  - clinical rationale for dosing higher than the FDA approved limits.
- Documentation of all of the following is required for Parkinson's disease:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical necessity for use of a transdermal formulation; **and**
  - requested quantity is ≤ 9 mg/day.

SmartPA: Claims for Emsam will usually process at the pharmacy without a PA request for members ≥ 18 years of age if the member has a history of MassHealth medical claims for a psychiatric diagnosis, a history of paid MassHealth pharmacy claims of the requested medication for at least 90 days out of the last 120 days, and the request is for ≤ one patch per day or ≤ 12 mg/day.†

Fetzima, Trintellix, and vilazodone

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one SSRI and one other non-SSRI antidepressant or contraindication to all SSRI and non-SSRI antidepressants; **and**
  - requested quantity is ≤ one unit/day.

SmartPA: Claims for Fetzima, Trintellix, and vilazodone within polypharmacy requirements at a quantity ≤ one unit per day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days, or if the member is ≥ 18 years of age, has a history of MassHealth medical claims for an appropriate diagnosis, and has a history of paid MassHealth pharmacy claims of at least four weeks of therapy with one SSRI and one non-SSRI.†

fluoxetine 60 mg tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to fluoxetine at an equivalent dose (three 20 mg capsules or tablets).

fluoxetine 90 mg delayed-release capsule

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to fluoxetine daily at an equivalent dose.

fluvoxamine extended-release

- Documentation of all of the following is required:

- appropriate diagnosis; **and**
- appropriate dosing; **and**
- medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to fluvoxamine immediate-release at an equivalent dose.

imipramine pamoate

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to imipramine hydrochloride at an equivalent dose.

Ketalar

- Documentation of all of the following is required for a diagnosis of treatment-resistant depression:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., psychiatrist) or consult notes from a specialist are provided; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy), adverse reaction, or contraindication to both of the following: one SSRI and one other non-SSRI antidepressant; **and**
  - requested agent will be used in combination with an oral antidepressant; **and**
  - inadequate response (defined as concomitant use of an augmenting agent plus antidepressant therapy combined ≥ four weeks of therapy) or adverse reaction to one or contraindication to all of the following augmentation strategies: second-generation antipsychotic, a mood stabilizer such as lithium or lamotrigine, a second antidepressant from a different class, or thyroid hormone; **and**
  - appropriate dosing.

Marplan, protriptyline, and trimipramine

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one or contraindication to both of the following: SSRI, SNRI; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one tricyclic antidepressant available without PA.

SmartPA: Claims for Marplan, protriptyline, and trimipramine will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

mirtazapine orally disintegrating tablets

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - medical necessity for the orally disintegrating tablet formulation; **or**
    - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to mirtazapine tablets.

paroxetine controlled-release

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**

- inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to paroxetine immediate-release.

sertraline capsule

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to sertraline tablets at an equivalent dose (one 50 mg and one 100 mg tablet [150 mg capsule] or two 100 mg tablets [200 mg capsule]).

Spravato

- Documentation of all of the following is required for a diagnosis of treatment-resistant depression:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., psychiatrist) or consult notes from a specialist are provided; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy), adverse reaction, or contraindication to both of the following: one SSRI and one other non-SSRI antidepressant; **and**
  - medical records documenting an inadequate response (defined as concomitant use of an augmenting agent plus antidepressant therapy combined ≥ four weeks of therapy) or adverse reaction to one or contraindication to all of the following augmentation strategies: second-generation antipsychotic, a mood stabilizer such as lithium or lamotrigine, a second antidepressant from a different class, thyroid hormone; **and**
  - appropriate dosing based on one of the following:
    - for induction phase (weeks one to four): 56 mg or 84 mg twice weekly; **or**
    - for maintenance phase (weeks five to eight): 56 mg or 84 mg once weekly or twice weekly dosing, noting attempts to decrease to once weekly resulted in destabilization; **or**
    - for maintenance phase (weeks nine+): 56 mg or 84 mg once weekly or every other week for up to 12 months or twice weekly dosing, noting attempts to decrease to once weekly resulted in destabilization; **or**
    - for maintenance phase (>12 months): 56 mg or 84 mg ≤ once weekly or twice weekly dosing, noting attempts to decrease to once weekly resulted in destabilization.
- Documentation of all of the following is required for treatment of depressive symptoms in adults with major depressive disorder with acute suicidal ideation or behavior:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., psychiatrist) or consult notes from a specialist are provided; **and**
  - one of the following:
    - medical records documenting current acute suicidal ideation or behavior related to depressive symptoms of major depressive disorder; **or**
    - member was stabilized on esketamine during a psychiatric hospitalization; **and**
  - requested agent will be used in combination with an oral antidepressant; **and**
  - appropriate dosing based on one of the following:
    - requested dose is 84 mg twice weekly for four weeks; **or**
    - requested dose is 84 mg once weekly, 56 mg twice weekly, or 56 mg once weekly for completion for four weeks noting, member is unable to tolerate 84 mg twice weekly dosing.
- For recertification, documentation that the member meets criteria above for treatment-resistant depression is required.

trazodone 300 mg tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**

- medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to trazodone immediate-release at an equivalent dose (two 150 mg tablets).

venlafaxine besylate extended-release tablet and venlafaxine hydrochloride extended-release tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to venlafaxine extended-release capsules at an equivalent dose.

Zurzuvae

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., obstetrician-gynecologist/family medicine or psychiatrist) or consult notes from a specialist are provided; **and**
  - member is ≤ 12 months postpartum; **and**
  - member is not currently pregnant; **and**
  - one of the following:
    - requirement for rapid symptom reduction; **or**
    - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one or contraindication to all of the following: bupropion, citalopram, duloxetine, escitalopram, fluoxetine, mirtazapine, sertraline, venlafaxine; **and**
  - one of the following:
    - for 30 mg capsule, requested quantity is ≤ one unit/day for 14 days total (start date required); **or**
    - for 20 mg and 25 mg capsule, requested quantity is ≤ two units/day for 14 days total (start date required); **and**
  - for 30 mg capsule, one of the following:
    - severe hepatic impairment (Child-Pugh Class C); **or**
    - moderate to severe renal impairment.

SSRI, SNRI, or Serotonin Modulator Polypharmacy *(overlapping pharmacy claims for two or more agents for at least 60 days within a 90-day period)* for members ≥ 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of all of the following is required:
  - psychiatric diagnosis included severe or treatment-resistant conditions; **and**
  - clear treatment plan including names and doses of current antidepressants and corresponding diagnoses; **and**
  - prescriber is a psychiatrist or consult notes from a psychiatrist are provided; **and**
  - one of the following:
    - cross-titration/taper of antidepressant therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials as clinically appropriate; **or**
    - member had a recent psychiatric hospitalization and was discharged on the current regimen.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy (*pharmacy claims for any combination of four or more behavioral health medications*

[i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, viloxazine, and xanomeline/trospium] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period) for members < 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
    - one of the following:
      - member has a seizure diagnosis only; **or**
      - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
      - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
      - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed;

therefore, multiple mood stabilizers are needed, **and** one of the following:
- cross-titration/taper of mood stabilizer therapy; **or**
- inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Antidepressant Polypharmacy (*overlapping pharmacy claims for two or more antidepressants for at least 60 days within a 90-day period, except esketamine*) for members < 18 years of age
- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate psychiatric diagnosis; **and**
    - treatment plan including names of current antidepressants and corresponding diagnoses; **and**
    - prescriber is a is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation**; and**
    - one of the following:
      - cross-titration/taper of antidepressant therapy; **or**
      - inadequate response (defined as four weeks of therapy) or adverse reaction to two monotherapy trials as clinically appropriate; **or**
      - antidepressant polypharmacy regimen of ≤ two antidepressants includes one of the following: bupropion, mirtazapine, trazodone, zuranolone; **or**
      - one antidepressant in the regimen is indicated for a comorbid condition in which antidepressants may be clinically appropriate.

SmartPA: Claims will usually process at the pharmacy without a PA request if the member is < 18 years of age and has a history of paid MassHealth pharmacy claims for two antidepressants (except esketamine) for at least 60 days of therapy out of the last 90 days and one or both agents are bupropion, trazodone, mirtazapine, or zuranolone.†

Antidepressant for members < six years of age
- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**

- family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
- other significant barrier for therapy discontinuation.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 18 - Cardiovascular Agents

Drug Category: Cardiovascular Agents

Medication Class/Individual Agents: Cardiovascular Agents

I. Prior-Authorization Requirements

Cardiovascular Agents – Renin Angiotensin System Antagonists - Angiotensin-Converting Enzyme (ACE) Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

benazepril	Lotensin		# , M90	**captopril**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response or adverse reaction to two ACE inhibitors available without PA.
				SmartPA: Claims for captopril will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days, or if the member has MassHealth medical claims for hypertension, heart failure, left ventricular dysfunction, myocardial infarction, or diabetic nephropathy and a history of paid MassHealth pharmacy claims for two ACE inhibitors that are available without PA.†
				
				Epaned and Qbrelis
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • medical necessity for the use of a solution formulation as noted by one of the following:
				  • member utilizes tube feeding (G-tube/J-tube); **or**
				  • member has a swallowing disorder or condition affecting ability to swallow; **or**
				  • member is < 13 years of age
				SmartPA: Claims for Epaned will usually process at the pharmacy without a PA request if the member is < 13 years of age and has a history of MassHealth medical claims for hypertension, heart failure, or asymptomatic left ventricular dysfunction.†
				SmartPA: Claims for Qbrelis will usually process at the pharmacy without a PA request if the member is < 13 years of age and has a history of MassHealth medical claims for

captopril		PA	M90	
enalapril	Vasotec		# , M90	
enalapril solution	Epaned	PA	M90	
fosinopril			M90	
lisinopril	Zestril		# , M90	
lisinopril			M90	
lisinopril solution	Qbrelis	PA		
moexipril			M90	
perindopril			M90	
quinapril	Accupril	PA	M90	
ramipril	Altace		# , M90	
trandolapril			M90	

	Clinical Notes

	hypertension, heart failure, or acute myocardial infarction.†
	
	quinapril
	• Documentation of all of the following is required:
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to two ACE inhibitors available without PA.
	SmartPA: Claims for quinapril will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days, or if the member has MassHealth medical claims for hypertension or heart failure and a history of paid MassHealth pharmacy claims for two ACE inhibitors that are available without PA.†
	
	Concurrent therapy – ACE inhibitor, ARB, and/or direct renin inhibitor
	Requests for concurrent therapy with two or more renin angiotensin system agents are evaluated on a case-by-case basis.

Cardiovascular Agents – Combination Antihypertensives

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

amiloride / hydrochlorothiazide			M90	**amlodipine/atorvastatin**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • medical necessity for use of the combination product instead of the commercially available separate agents; **and**
				  • one of the following:
				  • requested quantity is ≤ one unit/day; **or**
				  • medical necessity for exceeding the quantity limits; **or**
				  • for requests above the maximum FDA-approved dose, inadequate response (defined as ≥ the last 3 months) to atorvastatin 80mg daily.
				SmartPA: Claims for amlodipine/atorvastatin at a quantity of ≤ one unit/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for 90 days out of the last 120

amlodipine / atorvastatin	Caduet	PA	M90	
amlodipine / benazepril	Lotrel		# , M90	
amlodipine / olmesartan	Azor		# , M90	
amlodipine / olmesartan / hydrochlorothiazide	Tribenzor	PA	M90	
amlodipine / telmisartan	Twynsta	PA	M90	
amlodipine / valsartan	Exforge		# , M90	
amlodipine / valsartan / hydrochlorothiazide	Exforge HCT		# , M90	
atenolol / chlorthalidone	Tenoretic		# , M90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
azilsartan / chlorthalidone	Edarbyclor			days of the requested agent or has a history of paid MassHealth pharmacy claims for rosuvastatin at a dose of at least 20 mg or atorvastatin at a dose of at least 40 mg for at least 90 days in all claims history.†
benazepril / hydrochlorothiazide	Lotensin HCT		# , M90	
bisoprolol / hydrochlorothiazide			M90	
candesartan / hydrochlorothiazide	Atacand HCT	PA	M90	**amlodipine/olmesartan/hydrochlorothiazide, amlodipine/telmisartan, candesartan/hydrochlorothiazide, captopril/hydrochlorothiazide, trandolapril/verapamil, quinapril/hydrochlorothiazide** • Documentation of one of the following is required: • medical necessity for use of the combination product instead of the commercially available separate agents.
captopril / hydrochlorothiazide		PA	M90	
enalapril / hydrochlorothiazide	Vaseretic		# , M90	
fosinopril / hydrochlorothiazide			M90	
hydrochlorothiazide / triamterene			M90	**Concurrent therapy – ACE inhibitor, ARB, and/or direct renin inhibitor** • Requests for concurrent therapy with two or more renin angiotensin system agents are evaluated on a case-by-case basis.
irbesartan / hydrochlorothiazide	Avalide		# , M90	
isosorbide dinitrate / hydralazine	Bidil		# , M90	
lisinopril / hydrochlorothiazide	Zestoretic		# , M90	
losartan / hydrochlorothiazide	Hyzaar		# , M90	
methyldopa / hydrochlorothiazide			M90	
olmesartan / hydrochlorothiazide	Benicar HCT		# , M90	
propranolol / hydrochlorothiazide			M90	
quinapril / hydrochlorothiazide	Accuretic	PA	M90	
spironolactone / hydrochlorothiazide			M90	
telmisartan / hydrochlorothiazide	Micardis HCT		# , M90	
trandolapril / verapamil		PA	M90	
triamterene / hydrochlorothiazide			M90	
valsartan / hydrochlorothiazide	Diovan HCT		# , M90	

Cardiovascular Agents – Aldosterone Receptor Antagonists

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

eplerenone	Inspra		BP, M90	**Kerendia**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • concurrent therapy with an ACE-I or ARB; **and**
				  • inadequate response or adverse reaction to one or contraindication to all of the following: Farxiga, Inpefa, Invokana, Jardiance, Steglatro; **and**
				  • requested quantity ≤ one unit/day.
				spironolactone suspension
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • medical necessity for the use of a suspension formulation as noted by one of the following:
				  • member utilizes tube feeding (G-tube, J tube); **or**
				  • member has a swallowing disorder or condition affecting ability to swallow; **or**
				  • member is < 13 years of age.
				SmartPA: Claims for spironolactone suspension will usually process at the pharmacy without a PA request if the member is < 13 years of age and has a history of MassHealth medical claims for edema, heart failure, or hypertension.†

finerenone	Kerendia	PA		
spironolactone suspension	Carospir	PA	M90	
spironolactone tablet	Aldactone		# , M90	

Cardiovascular Agents – Anti-Anginal Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

isosorbide dinitrate 40 mg tablet	Isordil	PA	BP, M90	**Aspruzyo**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response or adverse reaction to one or contraindication to all of the following: beta-blockers, calcium channel blockers, nitrates**,** ranolazine tablets; **and**
				  • one of the following:
				  • member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets); **or**
				  • member utilizes tube feeding; **or**
				  • medical necessity for the requested formulation instead of ranolazine tablets; **and**
				• appropriate dosing; **and**
				• requested quantity is ≤ two units/day.

isosorbide dinitrate 5 mg, 10 mg, 20 mg, 30 mg tablet	Isordil		# , M90	
isosorbide mononitrate			M90	
nitroglycerin 2% ointment	Nitro-Bid		# , A90	
nitroglycerin injection			MB	
nitroglycerin lingual spray	Nitrolingual	PA	BP, A90	
nitroglycerin patch	Nitro-Dur		# , M90	
nitroglycerin sublingual powder	Gonitro	PA		
nitroglycerin sublingual tablet	Nitrostat		# , A90	
ranolazine extended-release granules	Aspruzyo	PA		

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

ranolazine extended-release tablet			A90	**Gonitro, nitroglycerin lingual spray**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to nitroglycerin sublingual tablets.
				isosorbide dinitrate 40mg
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • requested dose is > 40 mg/dose; **and**
				  • medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to two units of isosorbide dinitrate 20 mg tablet.

Cardiovascular Agents – Renin Angiotensin System Antagonists - Angiotensin II Receptor Antagonists (ARBS)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

azilsartan	Edarbi			**candesartan**
				• Documentation of all of the following is required for the diagnosis of hypertension or heart failure:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to both of the following: losartan, irbesartan or valsartan.
				• Documentation of all of the following is required for the diagnosis of migraine prevention:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • appropriate dosing; **and**
				  • requested quantity is ≤ one unit/day.
				SmartPA: Claims for candesartan will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days, or if the member has a history of MassHealth medical claims for hypertension or heart failure and a history of paid MassHealth pharmacy claims for losartan and irbesartan or valsartan.†
				eprosartan
				• Documentation of all of the following is required:
				  • diagnosis of hypertension; **and**

candesartan	Atacand	PA	M90	
eprosartan		PA	M90	
irbesartan	Avapro		# , M90	
losartan	Cozaar		# , M90	
olmesartan	Benicar		# , M90	
telmisartan	Micardis		# , M90	
valsartan solution		PA	M90	
valsartan tablet	Diovan		# , M90	

	Clinical Notes

	• inadequate response, adverse reaction, or contraindication to both of the following: losartan, irbesartan or valsartan.
	SmartPA: Claims for eprosartan will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days, or if the member has a history of MassHealth medical claims for hypertension and a history of paid MassHealth pharmacy claims for losartan and irbesartan or valsartan.†
	
	valsartan solution
	Documentation of all of the following is required:
	• appropriate diagnosis; **and**
	• medical necessity for the use of the solution formulation as noted by one of the following:
	  • member utilizes tube feeding (G-tube/J-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • member is < 13 years of age.
	SmartPA: Claims for valsartan solution will usually process at the pharmacy without a PA request if the member is < 13 years of age and has a history of MassHealth medical claims for hypertension, heart failure, or left ventricular failure or left ventricular dysfunction following myocardial infarction.†
	
	Concurrent therapy – ACE inhibitor, ARB, and/or direct renin inhibitor
	Requests for concurrent therapy with two or more renin angiotensin system agents are evaluated on a case-by-case basis.

Cardiovascular Agents – Beta-Adrenergic Blocking Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

acebutolol			M90	**carvedilol extended-release**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction or contraindication to carvedilol immediate-release.

atenolol	Tenormin		# , M90	
betaxolol tablet			M90	
bisoprolol			M90	
carvedilol	Coreg		# , M90	
carvedilol extended-release	Coreg CR	PA	M90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
esmolol	Brevibloc		MB	
labetalol			M90	
metoprolol	Lopressor		# , M90	
metoprolol extended-release capsule	Kapspargo	PA		
metoprolol extended-release tablet	Toprol XL		# , M90	
nadolol	Corgard		# , M90	
nebivolol	Bystolic		# , M90	
pindolol			M90	
propranolol extended-release	Inderal LA		# , M90	
propranolol immediate-release			A90	
propranolol long-acting capsule	Inderal XL	PA		
propranolol long-acting capsule	Innopran XL	PA		
propranolol solution	Hemangeol	PA	M90	
sotalol solution	Sotylize	PA		
sotalol tablet	Betapace		# , M90	
timolol tablet			M90	

Hemangeol

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the use of a solution formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age.

SmartPA: Claims for Hemangeol will usually process at the pharmacy without a PA request if the member is < 13 years of age and has a history of MassHealth medical claims for proliferating infantile hemangioma.†

Inderal XL, Innopran XL

- Documentation of all of the following is required for a diagnosis of hypertension:
  - diagnosis of hypertension; **and**
  - inadequate response or adverse reaction to all of the following: a long-acting formulation of propranolol that is available without PA, a beta-blocker, and one other antihypertensive agent.
- Documentation of all of the following is required for a diagnosis of migraine, angina, pulmonary hypertension, Raynaud's syndrome:
  - diagnosis of migraine, angina, pulmonary hypertension, Raynaud's syndrome; **and**
  - inadequate response or adverse reaction to a long-acting formulation of propranolol that is available without PA.

Kapspargo

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the use of the requested formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age.

SmartPA: Claims for Kapspargo will usually process at the pharmacy without a PA request if the member is < 13 years

	Clinical Notes

	of age and has a history of MassHealth medical claims for hypertension, angina pectoris, or heart failure.†
	
	Sotylize
	• Documentation of all of the following is required:
	  • diagnosis of life-threatening ventricular arrhythmias or highly symptomatic atrial fibrillation or atrial flutter; **and**
	  • medical necessity for the use of a solution formulation as noted by one of the following:
	  • member utilizes tube feeding (G-tube/J-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • member is < 13 years of age.
	SmartPA: Claims for Sotylize will usually process at the pharmacy without a PA request if the member is < 13 years of age and has a history of MassHealth medical claims for ventricular arrythmias, atrial fibrillation, or atrial flutter.†

Cardiovascular Agents – Not Otherwise Classified

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

droxidopa	Northera	PA	A90	**Camzyos**
				• Documentation of all of the following is required:
				  • diagnosis of NYHA class II-III obstructive hypertrophic cardiomyopathy; **and**
				  • prescriber is a cardiologist or consultation notes from a cardiologist are provided; **and**
				  • inadequate response or adverse reaction to one or contraindication to all beta blockers; **and**
				  • inadequate response or adverse reaction to one or contraindication to both of the following: diltiazem, verapamil; **and**
				  • inadequate response, adverse reaction, or contraindication to disopyramide; **and**
				  • appropriate dosing; **and**
				  • requested quantity is ≤ one unit/day.
				• For recertification, documentation of positive response to therapy is required.
				droxidopa
				• Documentation of all of the following is required:
				  • diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) caused by one of the following:

mavacamten	Camzyos	PA		
metyrosine	Demser		BP	

	Clinical Notes
	• primary autonomic failure; **or** • dopamine beta-hydroxylase deficiency; **or** • non-diabetic autonomic neuropathy (NDAN); **and** • inadequate response or adverse reaction to one or contraindication to both of the following: atomoxetine, midodrine; **and** • inadequate response, adverse reaction, or contraindication to fludrocortisone. • For recertification, medical records documenting positive response to therapy (e.g., increased standing blood pressure following treatment with droxidopa without increasing supine blood pressure, improvement on the Orthostatic Hypotension Questionnaire or Orthostatic Hypotension Symptom Assessment score for dizziness/lightheadedness, decreased symptoms of dizziness, lightheadedness, fainting episodes) is required.

Cardiovascular Agents – Calcium Channel Blocking Agents - Non-Dihydropyridine

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
diltiazem extended -release capsule	Cardizem CD		# , M90	
diltiazem extended -release tablet	Cardizem LA		# , M90	
diltiazem-Cardizem	Cardizem		# , M90	
diltiazem-Tiazac ER	Tiazac ER		# , M90	
verapamil			M90	
verapamil extended-release			M90	
verapamil sustained-release			M90	

Cardiovascular Agents – Alpha Blocking Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
doxazosin immediate-release	Cardura		# , M90	**phenoxybenzamine** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all selective α-1 blockers (prazosin, terazosin or doxazosin).
phenoxybenzamine		PA	M90	
prazosin		PA - < 6 years	A90	
terazosin			M90	

Cardiovascular Agents – HCN Channel Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
ivabradine	Corlanor	PA	A90	ivabradine • Documentation of all of the following is required for a diagnosis of chronic heart failure with LVEF ≤ 35%: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is a cardiologist or consultation notes from a cardiologist are provided; **and** • member has a resting heart rate of ≥ 70 beats per minute (bpm); **and** • one of the following: • member is currently receiving a beta-blocker (carvedilol, metoprolol succinate or bisoprolol) at maximally tolerated doses; **or** • adverse reaction to one or contraindication to all beta-blockers; **and** • one of the following: • member is currently receiving standard of care therapy with an ACE inhibitor, ARB, or angiotensin -receptor neprilysin inhibitor (ARNI); **or** • contraindication to all ACE inhibitors, ARBs and ARNIs; **and** • for tablet formulation, requested quantity is ≤ two units/day; **and** • for solution formulation, medical necessity for the use of the solution formulation as noted by one of the following: • member utilizes tube feeding (G-tube, J-tube); **or** • member has a swallowing disorder or condition affecting ability to swallow. • Documentation of all of the following is required for a diagnosis of heart failure due to dilated cardiomyopathy: • appropriate diagnosis; **and** • member is ≥ six months of age and < 18 years of age; **and** • member has normal sinus rhythm with an elevated heart rate; **and** • prescriber is a cardiologist or consultation notes from a cardiologist are provided; **and** • one of the following: • member is currently receiving a beta-blocker (carvedilol, metoprolol succinate or bisoprolol) at maximally tolerated doses; **or**

	Clinical Notes
	• adverse reaction to one or contraindication to all beta-blockers; **and** • one of the following: • member is currently receiving standard of care therapy with an ACE inhibitor, ARB, or angiotensin -receptor neprilysin inhibitor (ARNI); **or** • adverse reaction to one or contraindication to all ACE inhibitors, ARBs and ARNIs; **and** • for tablet formulation, requested quantity is ≤ two units/day; **and** • for solution formulation, medical necessity for use of the solution formulation as noted by one of the following: • member is < 13 years of age; **or** • requested dose is < 2.5 mg; **or** • member utilizes tube feeing (G-tube/J-tube); **or** • member has a swallowing disorder or condition affecting ability to swallow. • Documentation of all of the following is required for a diagnosis of postural tachycardia syndrome (POTS): • appropriate diagnosis; **and** • inadequate response or adverse reaction to two or contraindication to all of the following: a beta blocker, droxidopa, fludrocortisone, midodrine, pyridostigmine; **and** • for tablet formulation, requested quantity is ≤ two units/day; **and** • for solution formulation, medical necessity for use of the solution formulation as noted by one of the following: • member is < 13 years of age; **or** • member utilizes tube feeing (G-tube/J-tube); **or** • member has a swallowing disorder or condition affecting ability to swallow. • Documentation of all of the following is required for a diagnosis of inappropriate sinus tachycardia: • appropriate diagnosis; and • for tablet formulation, requested quantity is ≤ two units/day; **and** • for solution formulation, medical necessity for use of the solution formulation as noted by one of the following:

	Clinical Notes
	• member is < 13 years of age; **or** • member utilizes tube feeing (G-tube/J-tube); **or** • member has a swallowing disorder or condition affecting ability to swallow.

Cardiovascular Agents – Diuretics

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

amiloride			M90	**ethacrynic acid tablet**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response or adverse reaction to one or contraindication to all of the following: bumetanide, furosemide, torsemide.
				SmartPA: Claims for ethacrynic acid tablet will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for furosemide, bumetanide or torsemide.†
				
				Furoscix
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is a specialist (e.g., cardiologist, heart failure specialist) or consultation notes from a specialist are provided; **and**
				  • member continues to have fluid overload despite loop diuretic therapy with 40 to 160 mg of oral furosemide equivalents; **and**
				  • treatment with oral diuretics will be discontinued until transitioned back to oral diuretic maintenance therapy; **and**
				  • requested quantity is ≤ eight units.
				
				furosemide solution for members ≥ 13 years of age
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • medical necessity for the requested formulation as noted by one of the following:
				  • member utilizes tube feeding (G-tube/J-tube); **or**
				  • member has a swallowing disorder or condition affecting ability to swallow.
				SmartPA: Claims for furosemide solution for members < 13

bumetanide			M90	
chlorothiazide injection			MB	
chlorothiazide suspension	Diuril			
chlorthalidone	Thalitone			
chlorthalidone			M90	
ethacrynic acid tablet	Edecrin	PA	M90	
furosemide on-body infusor	Furoscix	PA		
furosemide solution		PA - ≥ 13 years	M90	
furosemide tablet, injection	Lasix		# , M90	
hydrochlorothiazide			M90	
indapamide			M90	
metolazone			M90	
torsemide			M90	
triamterene		PA	M90	

	Clinical Notes

	years of age will usually process at the pharmacy without a PA request.
	
	triamterene
	• Documentation of all of the following is required:
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to one or contraindication to both of the following: amiloride, spironolactone.
	SmartPA: Claims for triamterene will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for amiloride or spironolactone.†

Cardiovascular Agents – Renin Angiotensin System Antagonists – Angiotensin Receptor Neprilysin Inhibitor (ARNI)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

sacubitril / valsartan oral pellet	Entresto	PA		**sacubitril/valsartan tablet**
				• Documentation of all the following is required:
				  • appropriate diagnosis; **and**
				  • member is ≥ one year of age; **and**
				  • requested quantity is ≤ two units/day.
				SmartPA: Claims for sacubitril/valsartan tablet at a quantity of ≤ two tablets/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days or if the member is ≥ one year of age and has a history of MassHealth medical claims for a diagnosis of chronic heart failure.†
				
				Entresto pellet
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • member's weight is ≥ 13 kg and < 50 kg; **and**
				  • appropriate dosing; **and**
				  • one of the following:
				  • inadequate response, adverse reaction, or contraindication to Entresto tablets; **or**
				  • medical necessity for the requested formulation instead of the tablet formulation as noted by one of the following:
				  • member has swallowing disorder or condition affecting ability to swallow; **or**

sacubitril / valsartan tablet	Entresto	PA	BP	

	Clinical Notes
	• member is unable to swallow tablets.

Cardiovascular agents – Renin Angiotensin System Antagonists – Endothelin Type A Receptor and Angiotensin II Type 1 Receptor Antagonist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
sparsentan	Filspari	PA		Filspari • Documentation of all of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is a nephrologist or consult notes from a nephrologist are provided; **and** • medical records documenting one of the following despite treatment with a maximally tolerated dose of an ACE inhibitor or ARB for ≥ 90 days: • urine protein-to-creatinine ratio (UPCR) ≥0.5 g/g; **or** • proteinuria >0.5 g/day; **and** • both of the following: • requested initial dose of 200 mg daily for two weeks followed by 400 mg daily for maintenance treatment; **and** • requested quantity is ≤ one unit/day; **and** • one of the following: • inadequate response (defined as ≥ 90 days of therapy) to the maximum FDA-approved dose of an ACE inhibitor or ARB; **or** • both of the following: • inadequate response (defined as ≥ 90 days of therapy) to the maximally tolerated dose of an ACE inhibitor or ARB; **and** • medical records documenting intolerance to an ACE inhibitor or ARB at a dose above the maximally tolerated dose.

Cardiovascular Agents – Calcium Channel Blocking Agents - Dihydropyridine

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amlodipine	Norvasc		# , M90	Katerzia and Norliqva • Documentation of all of the following is required: • appropriate diagnosis; **and** • medical necessity for the use of a suspension formulation as noted by one of the following: • member utilizes tube feeding (G-tube/J-tube); **or** • member has a swallowing disorder or condition
amlodipine solution	Norliqva	PA		
amlodipine suspension	Katerzia	PA		
felodipine extended-release			M90	
isradipine immediate-		PA	M90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
release				affecting ability to swallow; **or** • member is < 13 years of age. **SmartPA:** Claims for Katerzia and Norliqva will usually process at the pharmacy without a PA request if the member is < 13 years of age and has a history of MassHealth medical claims for hypertension or coronary artery disease.† **levamlodipine** • Documentation of all the following is required: • appropriate diagnosis; **and** • inadequate response, adverse drug reaction or contraindication to amlodipine; **and** • inadequate response or adverse drug reaction to one or contraindication to all other calcium channel blockers available without PA. **nimodipine capsule and nimodipine oral solution > 21 days treatment/365 days** • Documentation of all of the following is required: • appropriate diagnosis (subsequent episode of subarachnoid hemorrhage); **and** • appropriate dosing; **and** • for solution formulation, medical necessity for the use of a solution formulation as noted by one of the following: • member utilizes tube feeding (G-tube/J-tube); **or** • member has a swallowing disorder or condition affecting ability to swallow. **isradipine, nicardipine capsules, nisoldipine** • Documentation of all of the following is required: • appropriate diagnosis; **and** • inadequate response or adverse reaction to two or contraindication to all calcium channel blockers available without PA. **SmartPA:** Claims for isradipine, nicardipine capsules, and nisoldipine will usually process at the pharmacy without a PA request if the member has MassHealth medical claims for an appropriate clinical indication (for example: hypertension, migraine, angina, pulmonary hypertension, or Raynaud's phenomenon), and a history of paid MassHealth pharmacy claims for two calcium channel blockers
levamlodipine		PA	M90	
nicardipine capsule		PA	M90	
nicardipine injection			MB	
nifedipine capsule			M90	
nifedipine extended-release	Procardia XL		# , M90	
nifedipine tablet			M90	
nimodipine capsule		PA - > 21 days treatment/365 days		
nimodipine oral solution	Nymalize	PA - > 21 days treatment/365 days	#	
nisoldipine	Sular	PA	M90	

	Clinical Notes
	available without PA.†

Cardiovascular Agents – Cardiac glycosides

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

digoxin 125 mcg, 250 mcg tablet			A90	**digoxin 62.5 mcg tablet**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • medical necessity for use of the requested agent instead of digoxin formulations available without PA; **and**
				  • requested quantity is one unit/day.
				
				digoxin oral solution for members ≥ 13 years of age
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • medical necessity for the requested formulation as noted by one of the following:
				  • member utilizes tube feeding (G-tube/J-tube); **or**
				  • member has swallowing disorder or condition affecting ability to swallow.
				SmartPA: Claims for digoxin solution for members < 13 years of age will usually process at the pharmacy without a PA request.

digoxin 62.5 mcg tablet		PA	A90	
digoxin injection	Lanoxin		MB	
digoxin solution		PA - ≥ 13 years	A90	

Cardiovascular Agents – Alkaloids

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

colchicine 0.5 mg tablet	Lodoco	PA		**Lodoco**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is a cardiologist or consult notes from a cardiologist are provided; **and**
				  • clinical rationale for use of the requested agent instead of colchicine 0.6 mg tablet; **and**
				  • requested quantity is ≤ one unit/day.

Cardiovascular Agents – Antiarrhythmics

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	
amiodarone			MB	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

injection				**quinidine gluconate extended-release**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to quinidine sulfate.
				SmartPA: Claims for quinidine gluconate extended-release will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for quinidine sulfate.†

amiodarone tablet			M90	
disopyramide controlled-release	Norpace CR			
disopyramide immediate-release	Norpace		# , A90	
dofetilide	Tikosyn		# , M90	
dronedarone	Multaq		A90	
flecainide			M90	
mexiletine			M90	
propafenone extended-release			M90	
propafenone immediate-release			M90	
quinidine gluconate extended-release		PA	A90	
quinidine sulfate			M90	

Cardiovascular Agents – Alpha Agonists / Centrally Acting Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

clonidine extended-release 0.17 mg tablet	Nexiclon	PA	A90	**clonidine extended-release 0.17 mg tablet**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to clonidine immediate-release tablets; **and**
				  • inadequate response or adverse reaction to two or contraindication to all other antihypertensive agents; **and**
				  • appropriate dosing.
				
				clonidine patch
				• Documentation of all of the following is required for a diagnosis of hypertension:
				  • appropriate diagnosis; **and**
				  • one of the following:
				  • medical records documenting an inadequate response or adverse reaction to oral clonidine; **or**
				  • member has a swallowing disorder or condition affecting ability to swallow; **and**
				  • inadequate response or adverse reaction to two or contraindication to all other antihypertensive agents.
				• Documentation of all of the following is required for a diagnosis of ADHD:

clonidine patch		PA	A90	
clonidine tablet		PA - < 3 years	A90	
guanfacine		PA - < 3 years	A90	
methyldopa			M90	

	Clinical Notes

	• appropriate diagnosis; **and**
	• one of the following:
	  • medical records documenting an inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to oral clonidine; **or**
	  • medical necessity for the transdermal formulation; **and**
	• inadequate response (defined as ≥ seven days of therapy) or adverse reaction to one or contraindication both of the following: an amphetamine product, a methylphenidate product.
	• Documentation of all of the following is required for a diagnosis of ASD:
	• appropriate diagnosis; **and**
	• one of the following:
	  • medical records documenting an inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to oral clonidine; **or**
	  • medical necessity for the transdermal formulation.
	In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions (see below).

Cardiovascular Agents – Vasopressin Antagonist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

tolvaptan-Samsca	Samsca	PA	A90	**tolvaptan (generic Samsca)**
				• Documentation of all of the following is required:
				• appropriate diagnosis; **and**
				• member is ≥ 18 years of age; **and**
				• member is currently taking and stabilized on the requested agent; **and**
				• one of the following:
				  • for 15 mg tablet, requested quantity is ≤ one unit/day; **or**
				  • for 30 mg tablet, requested quantity is ≤ two units/day; **or**
				  • clinical rationale for high dose.

Cardiovascular Agents – Renin Angiotensin System Antagonists - Direct Renin Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

aliskiren	Tekturna	PA	BP, M90	**aliskiren**
				• Documentation of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to both of the following: ARB and ACE inhibitor.
				
				Concurrent therapy – ACE inhibitor, ARB, and/or direct renin inhibitor
				Requests for concurrent therapy with two or more renin angiotensin system agents are evaluated on a case-by-case basis.

Cardiovascular Agents – Endothelin Receptor Antagnoist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

aprocitentan	Tryvio	PA		**Tryvio**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • inadequate response (defined as ≥ four weeks of therapy), adverse reaction, or contraindication to all of the following: RAAS inhibitor, calcium channel blocker, thiazide-type diuretic, mineralcorticoid receptor antagonist, one other antihypertensive agent; **and**
				  • member will continue background therapy with three or more antihypertensive agents; **and**
				  • requested quantity is ≤ one unit/day.

Cardiovascular Agents – Soluble Guanylate Cyclase (sGC) Stimulator

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

vericiguat	Verquvo	PA		**Verquvo**
				• Documentation of all of the following is required:
				  • diagnosis of chronic heart failure NYHA Class II to IV; **and**
				  • left ventricular ejection fraction (LVEF) < 45%; **and**
				  • member is ≥ 18 years of age; **and**
				  • one of the following:
				  • member has had a hospitalization related to heart

	Clinical Notes
	failure within the last six months; **or** • member has received outpatient IV diuretic therapy for heart failure within the last three months; **and** • prescriber is a cardiologist or consultation notes from a cardiologist are provided; **and** • one of the following: • member has remained symptomatic despite receiving standard of care therapy with an ACEI/ARB/ARNI in combination with a β-blocker (carvedilol, metoprolol succinate or bisoprolol); **or** • adverse reaction to one ACE inhibitor, ARB, ARNI and/or beta blocker, or contraindication to all ACE inhibitors, ARBs, ARNIs and beta blockers; **and** • requested quantity is ≤ one unit/day.

Cardiovascular Agents – Direct Vasodilators

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
hydralazine			M90	
minoxidil			M90	

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

M90 Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Angina pectoris
- Arrhythmias, paroxysmal supraventricular tachycardia
- Cardiac arrhythmias
- Cardiovascular events risk reduction

- Chronic kidney disease associated with type 2 diabetes (Kerendia)
- Congestive heart failure
- Congestive heart failure post-MI
- Coronary artery disease (stable or variant angina)
- Diabetic nephropathy
- Euvolemic hyponatremia (SIADH)
- Heart failure
- Hypertension
- Hypertrophic subaortic stenosis
- Hypervolemic hyponatremia (CHF)
- Immunoglobulin A nephropathy (IgAN)
- Left ventricular dysfunction
- Left ventricular dysfunction following MI
- Migraine prophylaxis
- Myocardial infarction
- New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) (Camzyos)
- Pheochromocytoma
- Post-myocardial infarction
- Proliferating infantile hemangioma
- Raynaud phenomenon
- Reduction of stroke risk with left ventricular hypertrophy
- Subarachnoid hemorrhage (nimodipine)

non-FDA-approved, for example:

- Angina pectoris
- Arrhythmias, paroxysmal supraventricular tachycardia
- Attention deficit hyperactivity disorder (ADHD)
- Cardiac arrhythmias
- Postural tachycardia syndrome (POTS)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member’s condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested

medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Please see clinical criteria for agents requiring PA in the table above under the Clinical Notes section.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy ***(pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, viloxazine, and xanomeline/trospium] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
    - one of the following:

- member has a seizure diagnosis only; **or**
- member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
  - cross-titration/taper of mood stabilizer therapy; **or**
  - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
- member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
- member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and** one of the following:
  - cross-titration/taper of mood stabilizer therapy; **or**
  - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Alpha Agonist for members < three years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - member has a cardiovascular diagnosis only; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - treatment plan including names of current alpha agonist(s) and corresponding diagnoses; **and**
    - clinical rationale for use of alpha agonist in member < three years of age.

prazosin for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **and**
  - all of the following:
    - appropriate diagnosis; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 19 - Benign Prostatic Hyperplasia (BPH) Agents

Drug Category: Men's Health

Medication Class/Individual Agents: Alpha-1 Blockers, 5-Alpha-Reductase Inhibitors, & Phosphodiesterase Inhibitors

I. Prior-Authorization Requirements

Benign Prostatic Hyperplasia (BPH) Agents – Alpha-1 Blockers			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alfuzosin extended -release			M90
doxazosin extended-release	Cardura XL		
doxazosin immediate-release	Cardura		# , M90
prazosin		PA - < 6 years	A90
silodosin	Rapaflo	PA	M90
tamsulosin	Flomax		# , M90
terazosin			M90

Benign Prostatic Hyperplasia (BPH) Agents – Phosphodiesterase Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
tadalafil tablet-Cialis	Cialis	PA	

Benign Prostatic Hyperplasia (BPH) Agents – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dutasteride / tamsulosin	Jalyn	PA	M90

Benign Prostatic Hyperplasia (BPH) Agents – 5-Alpha-Reductase Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dutasteride			M90
finasteride	Proscar		# , M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

FDA-approved indications:

- Hypertension: doxazosin, prazosin, terazosin
- BPH: alfuzosin, doxazosin, silodosin, tadalafil, tamsulosin, terazosin

Dose and administration:

- Doxazosin, prazosin, and terazosin: take first dose and subsequent first increased dose at bedtime to minimize lightheadedness and syncope.
- Titrate to therapeutic maintenance doses to minimize dizziness and orthostatic hypotension.
- If therapy is discontinued or interrupted for two or more days, reinstitute therapy cautiously.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Benign prostatic hyperplasia (BPH)/Lower urinary tract symptoms (LUTS)
- status post-transurethral resection of the prostate (TURP) with persistent urinary symptoms

Non-FDA-approved, for example:

- kidney stones

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

dutasteride/tamsulosin

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one unit/day; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents.

silodosin

- Documentation of the following is required for a diagnosis of BPH/LUTS or TURP:

- appropriate diagnosis; **and**
- member is ≥ 18 years of age; **and**
- one of the following:
  - inadequate response or adverse reaction to two or contraindication to all of the following: alfuzosin, doxazosin, tamsulosin, terazosin; **or**
  - member has swallowing disorder or condition affecting ability to swallow; **and**
- requested quantity is ≤ one unit/day.

- Documentation of the following is required for a diagnosis of kidney stones:
  - appropriate diagnosis; **and**
  - prescriber is a urologist; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: a calcium channel blocker, tamsulosin; **and**
  - requested duration of therapy is ≤ 60 days.

SmartPA: Claims for silodosin at a quantity of ≤ one unit/day will usually process at the pharmacy without a PA request if the member is ≥ 18 years of age, has a history of MassHealth medical claims for BPH/LUTS or status post-TURP, and has a history of paid MassHealth pharmacy claims for two of the following: alfuzosin, doxazosin, tamsulosin, terazosin, or a history of MassHealth medical claims for swallowing disorder.†

tadalafil

- Documentation of the following is required:
  - diagnosis of one of the following:
    - BPH/LUTS; **or**
    - TURP; **and**
  - member is ≥ 18 years of age; **and**
  - requested strength is 5 mg daily; **and**
  - requested quantity is ≤ one unit/day.

Please Note: The MassHealth agency does not pay for any drug when used for the treatment of sexual dysfunction as described in 130 CMR 406.413(B) “Limitations on Coverage of Drugs – Drug Exclusions” (see link below).

https://www.mass.gov/regulations/130-CMR-406000-pharmacy-services

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 20 - Anticonvulsants

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Anticonvulsants

I. Prior-Authorization Requirements

Anticonvulsants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
brivaracetam injection	Briviact		MB
brivaracetam solution, tablet	Briviact	PA	
cannabidiol	Epidiolex	PA	
carbamazepine extended-release	Carbatrol	PA - < 6 years	# , A90
carbamazepine extended-release	Equetro	PA - < 6 years	
carbamazepine extended-release	Tegretol XR	PA - < 6 years	BP, A90
carbamazepine-Tegretol	Tegretol	PA - < 6 years	# , A90
cenobamate	Xcopri	PA	
clobazam film	Sympazan	PA	
clobazam suspension, tablet	Onfi		#
diazepam buccal film	Libervant	PA - ≥ 6 years and PA > 10 units/30 days	
diazepam nasal spray	Valtoco	PA - > 10 units/30 days	
diazepam rectal gel	Diastat	PA - > 5 kits (10 syringes)/30 days	#
divalproex delayed -release capsule	Depakote Sprinkle	PA - < 6 years	BP, A90
divalproex delayed -release tablet	Depakote	PA - < 6 years	# , A90
divalproex extended-release	Depakote ER	PA - < 6 years	# , A90
eslicarbazepine	Aptiom	PA	A90
ethosuximide	Zarontin		# , A90
everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg	Afinitor	PA	A90
everolimus tablets for oral suspension	Afinitor Disperz	PA	BP, A90
felbamate	Felbatol		# , A90
fenfluramine	Fintepla	PA	
fosphenytoin	Cerebyx		MB

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Everolimus is indicated as adjunctive therapy in epilepsy associated with tuberous sclerosis complex (TSC).
- Diazepam buccal film, diazepam nasal spray, diazepam rectal gel, and midazolam nasal spray are indicated for use as needed (intermittent) for the treatment of acute seizure clusters that are distinct from a member's usual seizure pattern.

Precautions/warnings:

- About 25% to 35% of members who experience a hypersensitivity reaction to carbamazepine will experience a hypersensitivity reaction to oxcarbazepine.
- Carbamazepine has been associated with rare cases of aplastic anemia and agranulocytosis. Hematologic studies should be performed before therapy is initiated.
- Felbamate is not a first-line antiepileptic agent and is recommended only in members who have shown an inadequate response to alternative treatments and whose epilepsy is so severe that the benefits outweigh the potential risks of aplastic anemia or liver failure.
- Lamotrigine has been associated with serious, life-threatening rashes, which required hospitalization and discontinuation of treatment. Most cases of life-threatening rashes occurred within two to eight weeks of treatment initiation.

Anticonvulsants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ganaxolone	Ztalmy	PA	
lacosamide extended-release capsule	Motpoly XR	PA	
lacosamide injection	Vimpat		MB
lacosamide tablet, solution	Vimpat		# , A90
lamotrigine dispersible tablet	Lamictal	PA - < 6 years	# , A90
lamotrigine extended-release tablet	Lamictal XR	PA	A90
lamotrigine extended-release tablet starter kit	Lamictal XR	PA	
lamotrigine orally disintegrating tablet	Lamictal ODT	PA	A90
lamotrigine orally disintegrating tablet starter kit	Lamictal ODT	PA	
lamotrigine tablet	Lamictal	PA - < 6 years	# , A90
lamotrigine tablet starter kit	Lamictal	PA	
levetiracetam extended-release-Elepsia XR	Elepsia XR	PA	
levetiracetam extended-release-Keppra XR	Keppra XR		# , A90
levetiracetam injection	Keppra		MB
levetiracetam solution, tablet	Keppra		# , A90
levetiracetam tablet for oral suspension	Spritam	PA	BP
methsuximide	Celontin		# , A90
midazolam nasal spray	Nayzilam	PA - > 10 units/30 days	
oxcarbazepine extended-release	Oxtellar XR	PA	BP, A90
oxcarbazepine suspension	Trileptal	PA - < 6 years	BP, A90
oxcarbazepine tablet	Trileptal	PA - < 6 years	# , A90
perampanel	Fycompa	PA	BP
phenytoin chewable tablet	Dilantin Infatab		# , A90
phenytoin extended 200 mg and 300 mg capsule			A90
phenytoin	Dilantin		# , A90

Clinical Notes

- Phenytoin may cause gingival hyperplasia; the incidence may be reduced by good oral hygiene.
- Valproic acid and its derivatives have been associated with hepatic failure resulting in fatalities. Liver function tests should be performed before initiating therapy and subsequently at frequent intervals, especially during the first six months of therapy.

Anticonvulsants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
extended 30 mg and 100 mg capsule			
phenytoin injection			MB
phenytoin suspension	Dilantin-125		# , A90
primidone	Mysoline		# , A90
rufinamide	Banzel	PA	BP, A90
stiripentol	Diacomit	PA	
tiagabine	Gabitril	PA	A90
topiramate extended-release capsule-Qudexy XR	Qudexy XR	PA - < 6 years	BP, A90
topiramate extended-release capsule-Trokendi XR	Trokendi XR	PA	BP, A90
topiramate solution	Eprontia	PA	
topiramate sprinkle capsule	Topamax	PA - < 6 years	# , A90
topiramate tablet	Topamax	PA - < 6 years	# , A90
valproate injection			MB
valproate solution			
valproic acid	Depakene	PA - < 6 years	# , A90
vigabatrin powder packet, tablet	Sabril	PA	BP, A90
vigabatrin solution	Vigafyde	PA	
zonisamide capsule			A90
zonisamide suspension	Zonisade	PA	

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- bipolar disorder
- fibromyalgia
- migraine prophylaxis
- neuropathic pain associated with diabetic peripheral neuropathy
- postherpetic neuralgia
- seizure disorder(s) including Dravet syndrome, treatment-resistant epilepsy associated with tuberous sclerosis complex (TSC), infantile spasms, Lennox-Gastaut syndrome (LGS), partial seizures, and primary generalized tonic-clonic seizures

Non-FDA-approved, for example:

- non-FDA-approved refractory epilepsy syndrome, refractory epilepsy, or refractory seizures

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Briviact

- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response or adverse reaction to any two anticonvulsants; **and**
  - for the tablet formulation, requested quantity is ≤ two tablets/day.

SmartPA: Claims for Briviact (within the quantity limit of two tablets/day for the tablet formulation) will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for epilepsy/seizures, the prescriber is a neurologist, and if the member has a history of paid MassHealth pharmacy claims for any two anticonvulsants. Claims for Briviact (within the quantity limit of two tablets/day for the tablet formulation) will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days of the requested agent and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Diacomit

- Documentation of the following is required:
  - diagnosis of Dravet syndrome; **and**
  - member is ≥ two years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - requested medication will be used in combination with clobazam; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

Diacomit, Epidiolex, and Fintepla for non-FDA-approved refractory epilepsy syndrome, refractory epilepsy, or refractory seizures

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - for Diacomit and Fintepla, member is ≥ two years of age; **and**
  - inadequate response or adverse reaction to three anticonvulsants; **and**
  - member will be using the requested agent as adjunctive therapy.

diazepam rectal gel > 5 kits (10 syringes)/30 days, Nayzilam > 10 units/30 days, and Valtoco > 10 units/30 days

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - for diazepam rectal gel, medical necessity for greater than 5 kits (10 syringes)/30 days; **or**
    - for Nayzilam and Valtoco, medical necessity for greater than 10 units/30 days; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided.

Elepsia XR

- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for the requested agent instead of the levetiracetam extended-release formulation available without PA.

Epidiolex

- Documentation of the following is required for the diagnosis of Dravet syndrome or Lennox-Gastaut syndrome:
  - medical records supporting the diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member will be using the requested agent as adjunctive therapy; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.
- Documentation of the following is required for the diagnosis of seizures associated with tuberous scleroris complex (TSC):
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member will be using the requested agent as adjunctive therapy.

Eprontia

- Documentation of the following is required:
  - one of the following:
    - diagnosis of epilepsy or a seizure disorder; **or**
    - diagnosis of migraine prophylaxis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - one of the following:

- member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed; **or**
- member utilizes tube feeding (G-tube/J-tube) and is unable to utilize crushed tablets; **or**
- member is ≤ 16 years of age and requested dose cannot be obtained from topiramate formulations available without PA; **or**
- medical necessity for the requested formulation instead of other topiramate formulations available without PA.

eslicarbazepine

- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - member is ≥ four years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for eslicarbazepine will usually process at the pharmacy without a PA request if the member is ≥ four years of age, has a history of MassHealth medical claims for epilepsy/seizures, the prescriber is a neurologist, and the member has a history of paid MassHealth pharmacy claims for any two anticonvulsants. Claims for eslicarbazepine will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days of the requested agent and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

everolimus tablets for oral suspension and everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg

- Documentation of the following is required:
  - diagnosis of treatment-resistant epilepsy associated with tuberous sclerosis complex (TSC); **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response to combination therapy with at least two anticonvulsants or contraindication to all other anticonvulsants; **and**
  - requested agent will be used as adjunctive therapy with at least one anticonvulsant agent; **and**
  - requested quantity is ≤ one unit/day.

Fintepla

- Documentation of the following is required:
  - diagnosis of Dravet syndrome or Lennox-Gastaut Syndrome; **and**
  - member is ≥ two years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member will be using the requested agent as adjunctive therapy; **and**
  - inadequate response or adverse reaction to any two anticonvulsants; **and**
  - one of the following:
    - if not used in combination with stiripentol, requested quantity is ≤ 11.9 mL/day (26 mg/day); **or**
    - if used in combination with stiripentol and clobazam, requested quantity is ≤ 7.8 mL/day (17 mg/day).

Fycompa

- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - member is ≥ four years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for Fycompa will usually process at the pharmacy without a PA request if the member is ≥ four years of age, has a history of MassHealth medical claims for epilepsy/seizures, the prescriber is a neurologist, and the member has a history of paid MassHealth pharmacy claims for any two anticonvulsants. Claims for Fycompa will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Lamictal XR starter kit and lamotrigine extended-release

- Documentation of the following is required for the diagnosis of bipolar disorder:
  - appropriate diagnosis; **and**
  - prescriber is a psychiatrist or consult notes from a psychiatry office are provided; **and**
  - medical necessity for the extended-release formulation instead of the immediate-release formulation.
- Documentation of the following is required for the diagnosis of epilepsy or a seizure disorder:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for the extended-release formulation instead of the immediate-release formulation.

SmartPA: Claims for lamotrigine extended-release will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures or bipolar disorder.†

lamotrigine tablet starter kit

- Documentation of the following is required for the diagnosis of bipolar disorder:
  - appropriate diagnosis; **and**
  - prescriber is a psychiatrist or consult notes from a psychiatry office are provided; **and**
  - medical necessity for use instead of lamotrigine tablets.
- Documentation of the following is required for the diagnosis of epilepsy or a seizure disorder:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for use instead of lamotrigine tablets.

lamotrigine ODT and lamotrigine ODT starter kit

- Documentation of the following is required for the diagnosis of bipolar disorder:
  - appropriate diagnosis; **and**
  - prescriber is a psychiatrist or consult notes from a psychiatry office are provided; **and**
  - medical necessity for the requested formulation instead of formulation available without PA; **and**
  - inadequate response or adverse reaction to lamotrigine dispersible tablets.
- Documentation of the following is required for the diagnosis of epilepsy or a seizure disorder:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for the requested formulation instead of formulation available without PA; **and**
  - inadequate response or adverse reaction to lamotrigine dispersible tablets.

SmartPA: Claims for lamotrigine ODT (excluding starter kit) will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures or bipolar disorder.†

levetiractetam tablet for oral suspension

- Documentation of the following is required:
  - diagnosis of myoclonic seizures, epilepsy, or a seizure disorder; **and**
  - medical necessity for this oral tablet for suspension formulation instead of levetiracetam solution; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - one of the following:
    - diagnosis of myoclonic seizures **and** member is ≥ 12 years of age; **or**
    - diagnosis of epilepsy or a seizure disorder and all of the following:
      - member is ≥ four years of age; **and**
      - one of the following:

- member has been stabilized on levetiracetam (any formulation); **or**
- inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for levetiracetam tablet for oral suspension will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Libervant > 10 units/30 days, ≥ six years of age

- Documentation of all of the following is required for > 10 units/30 days:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - single requested dose does not exceed 15 mg; **and**
  - medical necessity for exceeding the quantity limit.
- Documentation of all of the following is required for members ≥ six years of age:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response, adverse reaction, or contraindication to Valtoco nasal spray; **and**
  - single requested dose does not exceed 15 mg; **and**
  - appropriate dose.

Motpoly XR

- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member weight is ≥ 50 kg; **and**
  - medical necessity for the extended-release formulation instead of the immediate-release formulation; **and**
  - requested dose is once daily; **and**
  - one of the following:
    - for Motpoly XR 100 mg, requested quantity is ≤ one unit/day; **or**
    - for Motpoly XR 150 mg, 200 mg, requested quantity is ≤ two units/day.

SmartPA: Claims for Motpoly (within the quantity limit of two units/day for the 150 mg and 200 mg or within the quantity limit of one unit/day for the 100 mg) will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days of the requested agent and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

oxcarbazepine extended-release

- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - member is ≥ six years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for this branded extended-release formulation instead of both of the following: oxcarbazepine tablets, oxcarbazepine suspension; **and**
  - one of the following:
    - member has been stabilized on oxcarbazepine (any formulation); **or**
    - inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for oxcarbazepine extended-release will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

rufinamide

- Documentation of the following is required:
  - diagnosis of Lennox-Gastaut Syndrome, epilepsy, or a seizure disorder; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for rufinamide will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for epilepsy/seizures, the prescriber is a neurologist, and the member has a history of paid MassHealth pharmacy claims for any two anticonvulsants. Claims for rufinamide will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Sympazan

- Documentation of the following is required:
  - diagnosis of Lennox-Gastaut Syndrome, epilepsy, or a seizure disorder; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member will be using the requested agent as adjunctive therapy; **and**
  - member is ≥ two years of age; **and**
  - medical necessity for this branded film formulation instead of both of the following: clobazam tablets and clobazam suspension; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for clobazam suspension and tablet will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

tiagabine

- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - member is ≥ 12 years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member will be using the requested agent as adjunctive therapy; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for tiagabine will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

topiramate extended-release capsules (generic Trokendi XR)

- Documentation of the following is required for the diagnosis of Lennox-Gastaut Syndrome, epilepsy, or a seizure disorder:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for use instead of topiramate extended-release capsules (generic Qudexy XR); **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

- Documentation of the following is required for the diagnosis of migraine prophylaxis:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**

- medical necessity for use instead of topiramate extended-release capsules (generic Qudexy XR); **and**
- inadequate response or adverse reaction to topiramate tablets; **and**
- inadequate response or adverse reaction to one or contraindication to all of the following prophylactic treatments:
  - beta-blocker; **or**
  - calcium channel blocker; **or**
  - divalproex or valproic acid; **or**
  - tricyclic antidepressant.

SmartPA: Claims for topiramate extended-release capsules (generic Trokendi XR) will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

vigabatrin powder packet, tablet

- Documentation of the following is required for the diagnosis of epilepsy or a seizure disorder:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member is ≥ two years of age; **and**
  - member will be using the requested agent as adjunctive therapy; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.
- Documentation of the following is required for the diagnosis of infantile spasms:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member is < two years of age.

SmartPA: Claims for vigabatrin powder packet and tablet will usually process at the pharmacy without a PA request if the member is < two years of age, has a history of MassHealth medical claims for infantile spasms, and the prescriber is a neurologist. Claims for vigabatrin powder packet and tablet will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures. †

Vigafyde

- Documentation of the following is required:
  - diagnosis of infantile spasms; **and**
  - member is < two years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for the requested agent instead of vigabatrin powder packet; **and**
  - member's current weight; **and**
  - appropriate dosing.
- For recertification, documentation of the following is required:
  - member is < two years of age; **and**
  - continued medical necessity for the requested agent instead of vigabatrin powder packet; **and**
  - clinical rationale for long-term treatment with vigabatrin; **and**
  - member's current weight; **and**
  - appropriate dosing.

Xcopri

- Documentation of the following is required for members ≥ 18 years of age:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - member is ≥ 18 years of age; **and**

- prescriber is a neurologist or consult notes from a neurology office are provided; **and**
- inadequate response or adverse reaction to any two anticonvulsants; **and**
- one of the following:
  - for the 25 mg tablet, 50 mg tablet, 100 mg tablet, or titration pack formulation, requested quantity is ≤ one unit/day; **or**
  - for the 150 mg tablet, 200 mg tablet, or dose pack formulation, requested quantity is ≤ two units/day.

SmartPA: Claims for Xcopri (within the quantity limit) will usually process at the pharmacy without a PA request if the member is ≥ 18 years of age, has a history of MassHealth medical claims for epilepsy/seizures, the prescriber is a neurologist, and if the member has a history of paid MassHealth pharmacy claims for any two anticonvulsants. Claims for Xcopri (within the quantity limit) will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Zonisade
- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - one of the following:
    - member has severe dysphagia and is currently utilizing only formulations that can be easily swallowed; **or**
    - member utilizes tube feeding; **or**
    - member is < 13 years of age; **or**
    - medical necessity for the requested formulation instead of zonisamide formulations available without prior authorization; **and**
  - requested quantity is ≤ 30 mL/day.

SmartPA: Claims for Zonisade (within the quantity limit) will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Ztalmy
- Documentation of the following is required:
  - diagnosis of CDKL5 deficiency disorder (CDD); **and**
  - member is ≥ two years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - genetic testing to confirm pathogenic or likely-pathogenic CDKL5 mutation; **and**
  - inadequate response or adverse reaction to any two anticonvulsants; **and**
  - requested quantity is ≤ 36 mL/day (1,800 mg/day).

Non-preferred Brand Name
- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - diagnosis of epilepsy or a seizure disorder and member is stable on the requested formulation; **or**
    - medical records documenting one of the following:
      - allergic response or adverse reaction to the generic product or history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain product; **or**
      - inadequate response to the generic product.

Non-preferred generic
- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:

- medical records documenting one of the following:
  - allergic response or adverse reaction to the brand name product or history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain product; **or**
  - inadequate response to the Brand Name product.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy ***(pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, viloxazine, and xanomeline/trospium] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
  - one of the following:
    - member has a seizure diagnosis only; **or**

- member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
  - cross-titration/taper of mood stabilizer therapy; **or**
  - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
- member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
- member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with and without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and** one of the following:
  - cross-titration/taper of mood stabilizer therapy; **or**
  - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Mood Stabilizer Polypharmacy (*overlapping pharmacy claims for three or more mood stabilizers [agents considered to be used only for seizure diagnoses are not included] for at least 60 days within a 90-day period*) for members < 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required for members with seizure diagnosis only:
  - appropriate diagnosis (seizure) without comorbid condition.

- Documentation of the following is required for members with psychiatric diagnoses, with or without seizure diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate psychiatric diagnoses; **and**
    - treatment plan including names of current mood stabilizers and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - one of the following:
      - cross-titration/taper of mood stabilizer therapy; **or**
      - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnoses in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain); **and**
    - treatment plan including names of current mood stabilizers and corresponding diagnoses; **and**
    - other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed.

- Documentation of the following is required for members with a psychiatric diagnosis and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - psychiatric diagnosis and diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain); **and**
    - treatment plan including names of current mood stabilizers and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **and**
    - one of the following:
      - cross-titration/taper of mood stabilizer therapy; **or**
      - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

Mood Stabilizer for members < six years of age ***(agents considered to be used only for seizure diagnoses are not included)***

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - member has a seizure diagnosis only; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding indications; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

SmartPA: Claims for mood stabilizers or benzodiazepines will usually process at the pharmacy without a PA request if the member is < six years of age, has a history of MassHealth medical claims for seizure, and does not have a history of MassHealth medical claims for psychiatric diagnoses and/or other diagnoses in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain).†

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 21 - Cystic Fibrosis Agents

Drug Category: Respiratory Agents

Medication Class/Individual Agents: Cystic Fibrosis Transmembrane Conductance Regulator Modulators

I. Prior-Authorization Requirements

Cystic Fibrosis Agents – Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
elexacaftor / tezacaftor / ivacaftor	Trikafta PD	PA	
ivacaftor	Kalydeco PD	PA	
lumacaftor / ivacaftor	Orkambi PD	PA	
tezacaftor / ivacaftor	Symdeko PD	PA	
vanzacaftor / tezacaftor / deutivacaftor	Alyftrek PD	PA	

Cystic Fibrosis Agents – Mucolytics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dornase alfa	Pulmozyme		
mannitol inhalation powder	Bronchitol	PA	

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Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

ivacaftor

- A potentiator of the CFTR protein thought to work by facilitating increased chloride transport by potentiating the channel-open probability of the CFTR protein.
- Approved for individuals ≥ one month of age with cystic fibrosis (CF) and one of the FDA-approved mutations in the CFTR gene that is responsive to ivacaftor.
- Strongly recommended by the CFF for individuals with CF and specific gene mutation noted above to improve lung function and quality of life, and to reduce exacerbations.[1]
- Dosing for individuals one to < two months of age and weight 3 kg or greater: 5.8 mg packet every 12 hours - mix with 5 mL soft food or liquid and administer with fat -containing food.*
- Dosing for individuals two to < four months of age and weight 3 kg or greater: 13.4 mg packet every 12 hours - mix with 5 mL soft food or liquid and administer with fat -containing food.*
- Dosing for individuals four months to < six months of age and weight 5 kg or greater: 25 mg packet every 12 hours - mix with 5 mL soft food or liquid and administer with fat-containing food.*
- Dosing for individuals six months to < six years of age

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	and weight < 7 kg: 25 mg packet every 12 hours - mix with 5 mL soft food or liquid and administer with fat-containing food.* • Dosing for individuals six months to < six years of age and weight 7 kg to < 14 kg: 50 mg packet every 12 hours - mix with 5 mL soft food or liquid and administer with fat-containing food.* • Dosing for individuals six months to < six years of age and weight 14 kg or greater: 75 mg packet every 12 hours - mix with 5 mL soft food or liquid and administer with fat-containing food.* • Dosing for individuals ≥ six years of age: 150 mg every 12 hours with fat-containing food.* *Notes: Adjust dose for individuals with concomitant use of moderate and strong CYP3A inhibitors, moderate hepatic impairment, and use with caution in those with severe hepatic impairment. If possible, avoid concomitant use of CYP3A inducers (e.g., carbamazepine, rifampin, phenobarbital, phenytoin, St. John's wort, etc). lumacaftor/ivacaftor • A combination product that contains ivacaftor, a potentiator of the CFTR protein as well as lumacaftor, a CFTR corrector. • Approved for individuals ≥ one year of age with CF and two copies (homozygous) of the F508del mutation in the CFTR gene. • Dosing for individuals one to two years of age and weight seven kg to < nine kg: One packet (75 mg/94 mg) every 12 hours- mix with 5 mL of soft food or liquid and administer with fat-containing food.** • Dosing for individuals one to two years of age and weight nine kg to < 14 kg: One packet (100 mg/125 mg) every 12 hours- mix with 5 mL of soft food or liquid and administer with fat-containing food.** • Dosing for individuals one to two years of age and weight 14 kg or greater: One packet (150 mg/188 mg) every 12 hours- mix with 5 mL of soft food or liquid and administer with fat-containing food.** • Dosing for individuals two to five years of age and weight < 14 kg: One packet (100mg/125 mg) every 12 hours- mix with 5 mL soft food or liquid and administer with fat-containing food.** • Dosing for individuals two to five years of age and

	Clinical Notes
	weight 14 kg or greater: One packet (150mg/188 mg) every 12 hours- mix with 5 mL soft food or liquid and administer with fat-containing food.** • Dosing for individuals six to < 12 years of age: Two tablets (100mg/125 mg) every 12 hours with fat-containing food.** • Dosing for individuals ≥ 12 years of age: Two tablets (200mg/125 mg) every 12 hours with fat-containing food.** **Notes: Adjust dose for individuals with hepatic impairment and concomitant use of strong CYP3A inhibitors (e.g., azole antifungals, clarithromycin, etc). If possible, avoid concomitant use of CYP3A inducers (e.g., carbamazepine, rifampin, phenobarbital, phenytoin, St. John's wort, etc). tezacaftor/ivacaftor • A combination product that contains ivacaftor, a potentiator of the CFTR protein, as well as tezacaftor, a CFTR corrector. • Approved for individuals ≥ six years of age with CF and two copies (homozygous) of the F508del mutation in the CFTR gene or who have at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor. • Dosing for individuals six to < 12 years of age weighing < 30 kg: One tablet (50mg/75 mg) every morning and one ivacaftor 75 mg tablet every evening with fat-containing food.*** • Dosing for individuals six to < 12 years of age weighing ≥ 30 kg: One tablet (100mg/150 mg) every morning and one ivacaftor 150 mg tablet every evening with fat-containing food.*** • Dosing for individuals ≥ 12 years of age: One tablet (100mg/150 mg) every morning and one ivacaftor 150 mg tablet every evening with fat-containing food.*** ***Notes: Adjust dose for individuals with moderate or severe hepatic impairment or when coadministered with moderate or strong CYP3A inhibitors (e.g., azole antifungals, clarithromycin, etc). elexacaftor/tezacaftor/ivacaftor • This agent contains two CFTR correctors, elexacaftor and tezacaftor as well as the potentiator, ivacaftor.

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	• Approved for individuals aged two years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to elexacaftor/tezacaftor/ivacaftor. • Dosing for individuals 2 to < 6 years of age and weighing < 14 kg is one elexacaftor 80 mg/ tezacaftor 40 mg/ ivacaftor 60 mg packet every morning and one ivacaftor 59.5 mg packet every evening.*** • Dosing for individuals 2 to < 6 years of age and weighing ≥ 14 kg is one elexacaftor 100 mg /tezacaftor 50 mg/ ivacaftor 75 mg packet every morning and one ivacaftor 75 mg packet every evening.*** • Dosing for individuals six to < 12 years of age weighing < 30 kg is two elexacaftor 50 mg/ tezacaftor 25 mg/ ivacaftor 37.5 mg tablets in the morning and one ivacaftor 75 mg tablet in the evening.*** • Dosing for individuals six to < 12 years of age weighing ≥ 30 kg is two elexacaftor 100 mg/ tezacaftor 50 mg/ ivacaftor 75 mg tablets in the morning and one ivacaftor 150 mg tablet in the evening.*** • Dosing for individuals ≥ 12 years of age is two elexacaftor 100 mg/ tezacaftor 50 mg/ ivacaftor 75 mg tablets in the morning and one ivacaftor 150 mg tablet in the evening.*** ***Notes: Adjust dose for individuals with moderate hepatic impairment or when coadministered with moderate or strong CYP3A inhibitors (e.g., azole antifungals, clarithromycin, etc). Do not use in individuals with severe hepatic impairment or with concomitant strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, etc). vanzacaftor/tezacaftor/deutivacaftor • The newest agent contains two CFTR correctors, vanzacaftor and tezacaftor, as well as deutivacaftor, an altered form of the potentiator, ivacaftor. Deutivacaftor has been shown to be more stable in the body than regular ivacaftor, which allows it to be taken once a day. • It is approved for the treatment of CF in patients ≥ 6 years of age who have at least one F508del mutation or

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	another responsive mutation in the CFTR gene. • Dosing for individuals 6 to < 12 years old and < 40 kg is three tablets of vanzacaftor 4 mg/tezacaftor 20 mg/deutivacaftor 50 mg (total dose of vanzacaftor 12 mg/tezacaftor 60 mg/ deutivacaftor 150 mg).*** • Dosing for individuals 6 to < 12 years old and ≥ 40 kg is two tablets of vanzacaftor 10 mg/tezacaftor 50 mg/deutivacaftor 125 mg (total dose of vanzacaftor 20 mg/tezacaftor 100 mg/ deutivacaftor 250 mg).*** • Dosing for individuals ≥ 12 years old is two tablets of vanzacaftor 10 mg/tezacaftor 50 mg/deutivacaftor 125 mg (total dose of vanzacaftor 20 mg/tezacaftor 100 mg/ deutivacaftor 250 mg).*** ***Notes: Adjust dose for individuals with moderate hepatic impairment or when coadministered with moderate or strong or moderate CYP3A inhibitors (e.g., azole antifungals, clarithromycin, etc). Do not use in individuals with severe hepatic impairment or with concomitant strong or moderate CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, etc). References *1. Mogayzel PJ, Naureckas ET, Robinson KA, Mueller G, Hadjiliadis D, Hoag JB, et al. Cystic fibrosis pulmonary guidelines: chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013 Apr 1;187(7):680-9.*

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

II. Therapeutic Uses

FDA-approved, for example:

- treatment of cystic fibrosis (CF)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber

must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Alyftrek

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 6 years of age; **and**
  - one of the following:
    - for the 4 mg/20 mg/50 mg tablet, requested quantity is ≤ three units/day; **or**
    - for the 10 mg/50 mg/125 mg tablet, requested quantity is ≤ two units/day; **and**
  - baseline BMI; **and**
  - for members > 6 years of age, baseline (ppFEV1).
- For recertification, documentation of positive response to therapy (e.g., improvement in BMI, ppFEV1, decrease in clinical exacerbations) is required.

Bronchitol

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - member has passed the Bronchitol Tolerance Test; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: Pulmozyme, sodium chloride for inhalation; **and**
  - appropriate dosing.

Kalydeco

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ one month of age; **and**
  - requested quantity is ≤ two units/day; **and**
  - baseline body mass index (BMI); **and**
  - for members > six years of age, baseline percent predicted forced expiratory volume in one second (ppFEV1).
- For recertification, documentation of positive response to therapy (e.g., improvement in BMI, ppFEV1, decrease in clinical exacerbations) is required.

Orkambi

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ one year of age; **and**
  - one of the following:
    - for tablets, requested quantity is ≤ four units/day; **or**
    - for granules, requested quantity is ≤ two units/day; **and**
  - baseline BMI; **and**
  - for members > six years of age, baseline ppFEV1.
- For recertification, documentation of positive response to therapy (e.g., improvement in BMI, ppFEV1, decrease in clinical exacerbations) is required.

Symdeko
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - requested quantity is ≤ two units/day; **and**
  - baseline BMI; **and**
  - for members > six years of age, baseline ppFEV1.
- For recertification, documentation of positive response to therapy (e.g., improvement in BMI, ppFEV1, decrease in clinical exacerbations) is required.

Trikafta
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - one of the following:
    - for tablets, requested quantity is ≤ three units/day; **or**
    - for granules, requested quantity is ≤ two units/day; **and**
  - baseline BMI; **and**
  - for members > six years of age, baseline ppFEV1.
- For recertification, documentation of positive response to therapy (e.g., improvement in BMI, ppFEV1, decrease in clinical exacerbations) is required.

MassHealth Evaluation Criteria

Table 22 - Acromegaly, Carcinoid Syndrome, and Cushing's Syndrome Agents

Drug Category: Endocrine/metabolic and Gastrointestinal Agents

Medication Class/Individual Agents: Acromegaly Agents, Carcinoid Syndrome Agents, and Cushing's Syndrome Agents

I. Prior-Authorization Requirements

Acromegaly, Carcinoid Syndrome, and Cushing's Syndrome Agents – Cortisol Synthesis Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
levoketoconazole	Recorlev	PA	
osilodrostat	Isturisa	PA	

Acromegaly, Carcinoid Syndrome, and Cushing's Syndrome Agents – Cortisol Receptor Blocker			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
mifepristone 300 mg	Korlym	PA	A90

Acromegaly, Carcinoid Syndrome, and Cushing's Syndrome Agents – Somatostatin Analogs			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
lanreotide	Somatuline		
lanreotide			
octreotide capsule	Mycapssa	PA	
octreotide injectable suspension	Sandostatin LAR		BP
octreotide injection	Sandostatin		#
pasireotide	Signifor	PA	
pasireotide injectable suspension	Signifor LAR	PA	MB

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Guidelines from Association of Clinical Endocrinologists for the treatment of acromegaly recommend surgery as a primary treatment option for acromegaly and reserve medical therapy for use in members with persistent disease following surgery.[1,2]
- Pharmacologic options for the treatment of acromegaly include: somatostatin analogs, growth hormone receptor antagonists and dopamine analogs.[1,2]
- For additional information regarding the management of dopamine analogs, please see: Table 48 - Antiparkinsonian Agents.
- Guidelines from the Endocrine Society for the treatment of Cushing’s syndrome recommend surgical resection of primary lesions as initial treatment of underlying Cushing’s disease.[3]
- For members with adrenocorticotrophic hormone (ACTH)-dependent Cushing’s syndrome who underwent a noncurative surgery or who were not candidates for surgery, there are several second-line treatment options including: repeat transsphenoidal surgery, radiotherapy, medical therapy, and bilateral adrenalectomy.[3]
- Pharmacologic options for the treatment of Cushing’s syndrome include glucocorticoid receptor-directed agents (e.g. mifepristone), pituitary-directed agents (e.g.

Acromegaly, Carcinoid Syndrome, and Cushing's Syndrome Agents – Growth Hormone Receptor Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
pegvisomant	Somavert	PA	

Acromegaly, Carcinoid Syndrome, and Cushing's Syndrome Agents – Carcinoid Syndrome Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
telotristat ethyl	Xermelo	PA	

Clinical Notes

cabergoline and pasireotide), and steroidogenesis inhibitors (e.g. ketoconazole and mitotane).[3]

[1] Katznelson L, Laws ER Jr, Melmed S, Molitch ME, Murad MH, Utz A, et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014 Nov;99(11):3933-51.

[2] Katznelson L, Atkinson JL, Cook DM, Ezzat SZ, Hamrahian AH, Miller KK et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly–2011 update. Endocr Pract. 2011 Jul-Aug;17 Suppl 4:1-44.

[3]Nieman LK, Biller BM, Findling JW, Murad MH, Newell-Price J, Savage MO, et al; Endocrine Society. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015 Aug;100(8):2807-31.

#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Acromegaly (Mycapssa, Signifor LAR, Somavert)
- Carcinoid syndrome diarrhea (Xermelo)
- Cushing's disease (Isturisa, Signifor, Signifor LAR)
- Hyperglycemia secondary to hypercortisolism in adults with endogenous Cushing’s syndrome who have type 2 diabetes mellitus or glucose intolerance (mifepristone 300 mg)

Note: the above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Isturisa

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - one of the following:
    - member has failed surgical intervention (reoccurrence after surgery or failed tumor removal); **or**
    - surgical interventions are not an option at this time; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: cabergoline, ketoconazole tablet, Lysodren; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Signifor, Signifor LAR.

mifepristone 300 mg

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member has failed surgical intervention (reoccurrence after surgery or failed tumor removal); **or**
    - surgical interventions are not an option at this time; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: cabergoline, ketoconazole tablet, Lysodren; **and**
  - requested quantity is ≤ four tablets/day.

Mycapssa

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is under the care of an endocrinologist; **and**
  - member has responded to and tolerated treatment with octreotide or lanreotide; **and**
  - requested quantity is ≤ four capsules/day.

Recorlev

- Documentation of all of the following is required:

- appropriate diagnosis; **and**
- appropriate dosing; **and**
- one of the following:
  - member has failed surgical intervention (reoccurrence after surgery or failed tumor removal); **or**
  - surgical interventions are not an option at this time; **and**
- inadequate response or adverse reaction to ketoconazole tablet; **and**
- inadequate response or adverse reaction to one or contraindication to both of the following: cabergoline, Lysodren.

Signifor
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member has failed surgical intervention (reoccurrence after surgery or failed tumor removal); **or**
    - surgical interventions are not an option at this time; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: cabergoline, ketoconazole tablet, Lysodren; **and**
  - requested quantity is ≤ two vials/day.

Signifor LAR
- Documentation of all of the following is required for a diagnosis of acromegaly:
  - appropriate diagnosis; **and**
  - member is under the care of an endocrinologist; **and**
  - requested quantity is ≤ one kit or vial/30 days; **and**
  - one of the following:
    - member has persistent or recurring disease following surgery and/or radiation; **or**
    - member is not a candidate for surgery; **and**
  - one of the following:
    - inadequate response or adverse reaction to one somatostatin analog available without PA; **or**
    - contraindication to somatostatin analogs; **and**
  - one of the following:
    - member has moderate-to-severe disease symptoms; **or**
    - member has mild disease and one of the following:
      - inadequate response or adverse reaction to one dopamine analog (e.g., cabergoline, bromocriptine) in combination with a somatostatin analog; **or**
      - adverse reaction to one somatostatin analog available without PA; **or**
      - contraindication to dopamine analogs.

- Documentation of all of the following is required for a diagnosis of Cushing's disease:
  - appropriate diagnosis; **and**
  - one of the following:
    - member has failed surgical intervention (reoccurrence after surgery or failed tumor removal); **or**
    - surgical interventions are not an option at this time; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: cabergoline, ketoconazole tablet, Lysodren; **and**
  - requested quantity is ≤ one kit or vial/30 days.

Somavert
- Documentation of all of the following is required:

- appropriate diagnosis; **and**
- member is under the care of an endocrinologist; **and**
- requested quantity is ≤ one vial/day; **and**
- one of the following:
  - member has persistent or recurring disease following surgery and/or radiation; **or**
  - member is not a candidate for surgery; **and**
- one of the following:
  - inadequate response or adverse reaction to one somatostatin analog available without PA; **or**
  - contraindication to somatostatin analogs; **and**
- one of the following:
  - member has moderate-to-severe disease symptoms; **or**
  - member has mild disease and one of the following:
    - inadequate response or adverse reaction to one dopamine analog (e.g., cabergoline, bromocriptine) in combination with a somatostatin analog; **or**
    - adverse reaction to one somatostatin analog available without PA; **or**
    - contraindication to dopamine analogs.

Xermelo

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to one somatostatin analog therapy; **and**
  - requested agent will be given in combination with somatostatin analog therapy; **and**
  - requested quantity is ≤ three tablets/day.

MassHealth Evaluation Criteria
Table 23 - Respiratory Agents - Inhaled

Drug Category: Respiratory Tract Agents

Medication Class/Individual Agents: Respiratory Inhalants

I. Prior-Authorization Requirements

Inhaled Respiratory Agents – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aclidinium / formoterol	Duaklir	PA	
albuterol / ipratropium inhalation solution			A90
albuterol / ipratropium inhalation spray	Combivent		
albuterol/budesonide	Airsupra	PA	
budesonide / formoterol	Symbicort PD		BP, A90
budesonide / glycopyrrolate / formoterol	Breztri	PA	
fluticasone / salmeterol inhalation powder-Airduo Digihaler	Airduo Digihaler	PA	
fluticasone / salmeterol inhalation powder-Airduo Respiclick	Airduo Respiclick	PA	BP, A90
fluticasone / salmeterol inhalation-Advair	Advair		BP, A90
fluticasone / vilanterol	Breo		BP, A90
fluticasone furoate / umeclidinium / vilanterol	Trelegy	PA	
glycopyrrolate / formoterol	Bevespi	PA	
mometasone / formoterol	Dulera		BP
tiotropium / olodaterol	Stiolto	PA	
umeclidinium / vilanterol	Anoro		A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Quick-relief medications:

- Inhaled short-acting beta$_2$-agonists (SABAs) are no longer recommended as reliever medication for adults and adolescents ≥ 12 years of age.
- Inhaled corticosteroid (ICS)-formoterol is the preferred AIR for adults and adolescents ≥ 12 years of age.
- Alternative option for AIR is to give an ICS whenever as needed SABA is used.
- Overuse of SABAs increases the risk of asthma exacerbations.

Maintenance medications:

Asthma:

- The Global Initiative for Asthma (GINA) guidelines recommend the use of ICS-formoterol as the preferred maintenance treatment for adults and adolescents ≥ 12 years of age.
- GINA recommends the use of low dose ICS for children ≤ 11 years of age. The addition of a leukotriene receptor agonist (LTRA) can be considered for some children.
- For children six to 11 years of age inadequately controlled with low dose ICS or low dose ICS plus

Inhaled Respiratory Agents – Corticosteroids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
beclomethasone inhaler	Qvar Redihaler	PA	
budesonide inhalation powder	Pulmicort		
budesonide inhalation suspension	Pulmicort	PA - ≥ 13 years	# , A90
ciclesonide inhaler	Alvesco	PA	
fluticasone furoate inhalation powder	Arnuity		
fluticasone propionate inhalation aerosol		PA - ≥ 12 years	A90
fluticasone propionate inhalation powder		PA	A90
fluticasone propionate inhalation powder-Armonair Digihaler	Armonair Digihaler	PA	
mometasone inhalation aerosol	Asmanex HFA		
mometasone inhalation powder	Asmanex Twisthaler		

Inhaled Respiratory Agents – Anticholinergics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aclidinium	Tudorza		
ipratropium inhalation aerosol	Atrovent HFA		BP
revefenacin	Yupelri	PA	
tiotropium inhalation powder	Spiriva Handihaler		BP, A90
tiotropium inhalation solution	Spiriva Respimat		
umeclidinium	Incruse		

Inhaled Respiratory Agents – Long-Acting Beta Agonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
arformoterol	Brovana	PA	A90
formoterol	Perforomist	PA	

Clinical Notes

LTRA, consideration can be given to starting low dose ICS-formoterol, increasing ICS to medium dose, or starting very low dose ICS-formoterol.
- GINA also recommends consideration for phenotypic assessment for potential add-on biologics in severe cases of asthma not adequately controlled on maintenance inhalers.

Chronic obstructive pulmonary disease (COPD):
- The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guideline states that inhaled bronchodilators are preferred for the management of COPD.
- Short-acting, as-needed bronchodilators are recommended as a first choice for members with mild or infrequent symptoms.
- For Group B members (i.e., those with moderate-to-severe symptoms and low exacerbation risk), a long-acting muscarinic antagonist (LAMA) plus a long-acting beta agonist (LABA) is recommended as first-line treatment.
- The recommended first choice therapy for Group E members (i.e., those with ≥ two moderate exacerbations or ≥ one leading to hospitalization) is a LABA plus LAMA inhaler. If exacerbations are persistent, or blood eosinophils are ≥ 300, an ICS can be added to the LABA plus LAMA regimen.

The incidence of oral candidiasis with ICS may be reduced by using a spacer/holding chamber and rinsing the mouth with water after inhalation.

Exercise-induced bronchospasm (EIB):
- Inhaled ICS-formoterol, ICS-SABA or SABA can be given prior to or during exercise as needed.

Inhaled Respiratory Agents – Long-Acting Beta Agonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
olodaterol	Striverdi	PA	
salmeterol	Serevent		

Inhaled Respiratory Agents – Phosphodiesterase 3 (PDE3) Inhibitor and Phosphodiesterase 4 (PDE4) Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ensifentrine	Ohtuvayre	PA	

Inhaled Respiratory Agents – Short-Acting Beta Agonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
albuterol inhalation powder-Proair Digihaler	Proair Digihaler	PA	
albuterol inhalation powder-Proair Respiclick	Proair Respiclick		
albuterol inhalation solution			A90
albuterol inhaler		PA	
albuterol inhaler-Ventolin	Ventolin		BP, A90
levalbuterol inhalation solution		PA	A90
levalbuterol inhaler	Xopenex HFA		# , A90

Inhaled Respiratory Agents – Mast Cell Stabilizers			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cromolyn inhalation			A90

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- asthma
- COPD
- EIB

Non-FDA-approved, for example:

- eosinophilic esophagitis (budesonide inhalation suspension, fluticasone priopionate inhalation aerosol)
- chronic sinusitis, pansinusitis, rhinitis, nasal polyposis (budesonide inhalation suspension)
- COPD (budesonide inhalation suspension)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Airduo Digihaler

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: fluticasone/salmeterol inhalation aerosol, powder (generic Advair), fluticasone/salmeterol inhalation powder (generic Airduo Respiclick); **and**
  - requested quantity is ≤ one inhaler/30 days.

Airsupra

- Documentation of the following is required:

- appropriate diagnosis; **and**
- member is ≥ 18 years of age; **and**
- one of the following:
  - inadequate response, adverse reaction, or contraindication to budesonide/formoterol; **or**
  - inadequate response or adverse reaction to the separate agents albuterol and Pulmicort (budesonide inhalation powder) used concomitantly as needed; **or**
  - clinical rationale why the member cannot utilize the combination of the separate agents albuterol and Pulmicort (budesonide inhalation powder) concomitantly as needed.

albuterol inhaler

- Documentation of the following is required:
  - diagnosis of asthma, COPD, or EIB; **and**
  - medical records documenting an inadequate response or adverse reaction to an albuterol product available without PA.

Alvesco, Armonair Digihaler, fluticasone propionate inhalation aerosol ≥ 12 years of age, fluticasone propionate inhalation powder, Qvar Redihaler

- Documentation of the following is required:
  - diagnosis of asthma; **and**
  - inadequate response or adverse reaction to two or contraindication to all inhaled corticosteroids available without PA.

SmartPA: Claims for Alvesco and Qvar Redihaler will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

arformoterol and formoterol

- Documentation of the following is required:
  - diagnosis of COPD; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - member has a recent paid pharmacy claim for a nebulized respiratory product and no recent paid pharmacy claims for inhalers; **or**
    - medical necessity for nebulized formulation; **and**
  - requested quantity is ≤ 120 mL/30 days.

SmartPA: Claims for arformoterol and formoterol will usually process at the pharmacy within the quantity limit of 120 mL/30 days without a PA request if the member (≥ 18 years of age) has a history of MassHealth medical claims for COPD, has a history of paid MassHealth pharmacy claims for a nebulized solution within the last 30 days or has a history of paid MassHealth pharmacy claims for any nebulized solution for ≥ 15 days of therapy within the last 30 days, there is no history of paid MassHealth pharmacy claims for an inhaler within the last 30 days, and there is no history of paid MassHealth pharmacy claims for an inhaler for ≥ 15 days of therapy within the last 30 days.†

Bevespi and Duaklir

- Documentation of the following is required:
  - diagnosis of COPD; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one inhaler/30 days; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Stiolto, umeclidinium/vilanterol.

SmartPA: Claims for Bevespi and Duaklir will usually process at the pharmacy within the quantity limit of one inhaler/30 days without a PA request if the member (≥ 18 years of age) has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

Breztri

- Documentation of the following is required:
  - diagnosis of COPD; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy) or adverse reaction to the separate agents Bevespi and Pulmicort inhalation powder twice daily; **or**
    - clinical rationale why member cannot utilize the combination of the separate agents Bevespi and Pulmicort inhalation powder twice daily; **and**
  - requested quantity is ≤ one inhaler/30 days.

SmartPA: Claims for Breztri will usually process at the pharmacy within the quantity limit of one inhaler/30 days without a PA request if the member (≥ 18 years of age) has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

budesonide inhalation suspension ≥ 13 years of age

- Documentation of the following is required for a diagnosis of asthma:
  - appropriate diagnosis; **and**
  - one of the following:
    - member has a recent paid pharmacy claim for a nebulized respiratory product and no recent paid pharmacy claims for inhalers; **or**
    - medical necessity for nebulized formulation.
- Documentation of the following is required for a diagnosis of eosinophilic esophagitis:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., allergy/immunology, gastroenterology, otolaryngology, rhinology, pulmonology, ENT).
- Documentation of the following is required for a diagnosis of chronic sinusitis, pansinusitis, rhinitis, nasal polyposis:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., allergy/immunology, otolaryngology, rhinology, pulmonology, ENT), **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to one commercially available intranasal steroid, **or**
    - clinical rationale for budesonide irrigation/rinse with suspension formulation.
- Documentation of the following is required for a diagnosis of COPD:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., pulmonology), **and**
  - one of the following:
    - member has a recent claim for a nebulized respiratory product and no recent paid pharmacy claims for inhalers; **or**
    - medical necessity for nebulized formulation.

SmartPA: Claims for budesonide inhalation suspension will usually process at the pharmacy without a PA request if the member is ≥ 13 years of age and has a history of paid MassHealth pharmacy claims for a nebulized solution within the last 30 days or has a history of paid MassHealth pharmacy claims for any nebulized solution for ≥ 15 days of therapy within the last 30 days, there is no history of paid MassHealth pharmacy claims for an inhaler within the last 30 days, and there is no history of paid MassHealth pharmacy claims for an inhaler for ≥ 15 days of therapy within the last 30 days.†

fluticasone propionate inhalation aerosol ≥ 12 years of age

- Documentation of the following is required:
  - diagnosis of eosinophilic esophagitis; **and**
  - prescriber is a specialist (e.g., allergy/immunology, gastroenterology, otolaryngology, rhinology, pulmonology, ENT).

fluticasone/salmeterol inhalation powder (generic Airduo Respiclick)

- Documentation of the following is required:
  - diagnosis of asthma; **and**
  - one of the following:
    - inadequate response or adverse reaction to fluticasone/salmeterol inhalation aerosol, powder (generic Advair); **or**
    - clinical rationale for lower dose of fluticasone/salmeterol; **or**
    - member is already receiving another Respiclick formulation; **and**
  - requested quantity is ≤ one inhaler/30 days.

levalbuterol inhalation solution

- Documentation of the following is required:
  - diagnosis of asthma, COPD, or EIB; **and**
  - inadequate response, adverse reaction, or contraindication to inhaled albuterol solution; **and**
  - one of the following:
    - member is < 13 years of age; **or**
    - medical necessity for nebulized formulation.

Smart PA: Claims for levalbuterol solution will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

Proair Digihaler

- Documentation of the following is required:
  - diagnosis of asthma, COPD, or EIB; **and**
  - inadequate response, adverse reaction, or contraindication to an albuterol product available without prior authorization (Proair Respiclick or Ventolin).

Ohtuvayre

- Documentation of the following is required:
  - diagnosis of moderate to severe COPD; **and**
  - prescriber is a specialist (e.g., allergist, pulmonologist, immunologist) or consult notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) or adverse reaction to one or contraindication to all of the following: Bevespi, Duaklir, Stiolto, umeclidinium/vilanterol; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) or adverse reaction to one or contraindication to both of the following: Breztri, Trelegy; **and**
  - requested quantity is ≤ 150 mL/30 days.
- For recertification, documentation of positive response to therapy (e.g., decreased symptoms, decreased exacerbations, improved quality of life) is required.

Stiolto

- Documentation of the following is required:
  - diagnosis of COPD; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one inhaler/30 days.

SmartPA: Claims for Stiolto will usually process at the pharmacy within the quantity limit of one inhaler/30 days without a PA request if the member (≥ 18 years of age) has a history of MassHealth medical claims for COPD or has a history of paid MassHealth

pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

Striverdi

- Documentation of the following is required:
  - diagnosis of COPD; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one inhaler/30 days.

SmartPA: Claims for Striverdi will usually process at the pharmacy within the quantity limit of one inhaler/30 days without a PA request if the member has a history of MassHealth medical claims for COPD and the member is ≥ 18 years of age.†

Trelegy

- Documentation of the following is required:
  - diagnosis of asthma or COPD; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response (defined as at least 90 days of therapy) or adverse reaction to the separate agents fluticasone/vilanterol and Incruse once daily; **or**
    - inadequate response (defined as at least 90 days of therapy) or adverse reaction to the separate agents Arnuity and umeclidinium/vilanterol once daily; **or**
    - clinical rationale why member cannot utilize the combination of the separate agents fluticasone/vilanterol and Incruse once daily or Arnuity and umeclidinium/vilanterol once daily; **and**
  - requested quantity is ≤ one inhaler/30 days.

SmartPA: Claims for Trelegy will usually process at the pharmacy within the quantity limit of one inhaler/30 days without a PA request if the member (≥ 18 years of age) has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

Yupelri

- Documentation of the following is required:
  - diagnosis of COPD; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - member has a recent paid pharmacy claim for a nebulized respiratory product and no recent paid pharmacy claims for inhalers; **or**
    - medical necessity for nebulized formulation; **and**
  - inadequate response, adverse reaction, or contraindication to ipratropium inhalation nebulizer solution; **and**
  - requested quantity is ≤ 90 mL/30 days.

SmartPA: Claims for Yupelri within the quantity limit of 90 mL/30 days will usually process at the pharmacy without a PA request if the member (≥ 18 years of age) has a history of MassHealth medical claims for COPD, has a history of paid MassHealth pharmacy claims for a nebulized solution within the last 30 days or has a history of paid MassHealth pharmacy claims for any nebulized solution for ≥ 15 days of therapy within the last 30 days, there is no history of paid MassHealth pharmacy claims for an inhaler within the last 30 days, there is no history of paid MassHealth pharmacy claims for an inhaler for ≥ 15 days of therapy within the last 30 days, and has a history of paid MassHealth pharmacy claims for ipratropium inhalation nebulizer solution.†

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 24 - Antipsychotics

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Antipsychotics

I. Prior-Authorization Requirements

Antipsychotics – Second-Generation (Atypical)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aripiprazole extended-release injection	Abilify Asimtufii	PA	
aripiprazole extended-release injection	Abilify Maintena	PA	
aripiprazole film	Opipza	PA	
aripiprazole lauroxil 1,064 mg	Aristada PD	PA - < 10 years and PA > 1 injection/56 days	
aripiprazole lauroxil 441 mg, 662 mg, 882 mg	Aristada PD	PA - < 10 years and PA > 1 injection/28 days	
aripiprazole lauroxil 675 mg	Aristada Initio PD	PA - < 10 years and PA > 1 injection/28 days	
aripiprazole orally disintegrating tablet		PA	A90
aripiprazole solution		PA - < 10 years or ≥ 13 years and PA ≥ 10 mL/day	A90
aripiprazole tablet	Abilify	PA - < 10 years and PA > 2 units/day	# , A90
aripiprazole tablet with sensor	Abilify Mycite	PA	
asenapine sublingual tablet	Saphris	PA	A90
asenapine transdermal	Secuado	PA	
brexpiprazole	Rexulti	PA	
cariprazine	Vraylar PD	PA	
clozapine orally disintegrating tablet		PA	A90
clozapine suspension	Versacloz	PA	A90
clozapine tablet	Clozaril	PA - < 10 years	# , A90
iloperidone	Fanapt	PA	
lumateperone	Caplyta	PA	
lurasidone 20 mg, 40 mg, 60 mg,	Latuda	PA - < 10 years and PA > 1	# , A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Limited scientific data supports the concomitant use of two or more antipsychotics. It is recommended that monotherapy trials be attempted before polypharmacy is used.
- Dissolvable tablets do not have a faster onset of action compared to their conventional oral dosage formulations. They possess the same side effects and have similar pharmacokinetic profiles as the oral tablet. Since dissolvable tablets offer no therapeutic advantage, and they are generally more costly than other oral formulations, all dissolvable tablets will require PA except for olanzapine orally disintegrating tablet and risperidone 0.25 mg, 0.5 mg, 1 mg, and 2 mg orally disintegrating tablet within established quantity limits. Asenapine has minimal-to-no absorption if swallowed and must be dissolved in the mouth to be absorbed via buccal/sublingual sites.
- All second-generation (atypical) antipsychotics have a black-box warning for increased mortality in elderly patients with dementia-related psychosis.
- Second-generation (atypical) antipsychotics have been associated with substantial weight gain. This risk is statistically greater with some products compared to others.

Antipsychotics – Second-Generation (Atypical)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
120 mg		unit/day	
lurasidone 80 mg	Latuda	PA - < 10 years and PA > 2 units/day	# , A90
olanzapine 15 mg orally disintegrating tablet	Zyprexa Zydis	PA - < 10 years and PA > 2 units/day	# , A90
olanzapine 15 mg, 20 mg tablet	Zyprexa	PA - < 10 years and PA > 2 units/day	# , A90
olanzapine 2.5 mg, 5 mg, 7.5 mg, 10 mg tablets	Zyprexa	PA - < 10 years and PA > 3 units/day	# , A90
olanzapine 210 mg, 300 mg extended-release injection	Zyprexa Relprevv	PA - < 10 years and PA > 2 injections/28 days	
olanzapine 405 mg extended-release injection	Zyprexa Relprevv	PA - < 10 years and PA > 1 injection/28 days	
olanzapine 5 mg, 10 mg, 20 mg orally disintegrating tablet	Zyprexa Zydis	PA - < 10 years and PA > 1 unit/day	# , A90
olanzapine injection	Zyprexa		#
paliperidone 1.5 mg, 3 mg, 9 mg tablet	Invega	PA - < 10 years and PA > 1 unit/day	# , A90
paliperidone 6 mg tablet	Invega	PA - < 10 years and PA > 2 units/day	# , A90
paliperidone extended-release 1-month injection	Invega Sustenna PD	PA - < 10 years, PA > 2 injections/28 days within the first 28 days of therapy and PA > 1 injection/28 days after 28 days of therapy	
paliperidone extended-release 1-month injection -Erzofri	Erzofri	PA	
paliperidone extended-release 3-month injection	Invega Trinza PD	PA - < 10 years and PA > 1 injection/84 days	
paliperidone extended-release 6-month injection	Invega Hafyera PD	PA - < 10 years and PA > 1 injection/168 days	
pimavanserin	Nuplazid	PA	
quetiapine	Seroquel	PA - < 10 years and PA > 3 units/day	# , A90

Clinical Notes

- In November 2003, the FDA mandated that the following information be added to the WARNINGS section of all second-generation (atypical) antipsychotic drug labeling. "Hyperglycemia in extreme progressing to ketoacidosis, hyperosmolar coma and/or death has been reported for this class of drugs. Fasting glucose should be obtained at the beginning of treatment and periodically. Patients with established diagnosis of diabetes mellitus should be monitored for worsening of glycemic control (for complete details see package insert)."
- A consensus statement issued by the APA, ADA, and others suggested a scheduled monitoring of the following members on these drugs: weight/BMI, waist circumference, blood pressure, fasting glucose, and fasting lipid profile.[1]
- Antipsychotic-induced metabolic complications such as weight increases, glucose increases, and triglyceride increases are more pronounced in children and adolescents compared to the adult population.

[1] *American Diabetes Association; American Psychiatric Association; American Association of Clinical Endocrinologists; North American Association for the Study of Obesity. Consensus development conference on antipsychotic drugs and obesity and diabetes. J Clin Psych 2004;65(2):267-72.*

Please see the following link to find out more information regarding Second-Generation (Atypical) Antipsychotics. https://www.mass.gov/lists/second-generation-antipsychotics-also-known-as-atypical-antipsychotics

Antipsychotics – Second-Generation (Atypical)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
quetiapine extended-release	Seroquel XR	PA - < 10 years and PA > 2 units/day	# , A90
risperidone 0.25 mg, 0.5 mg, 1 mg, 2 mg orally disintegrating tablet		PA - < 10 years and PA > 2 units/day	A90
risperidone 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg tablets	Risperdal	PA - < 10 years and PA > 3 units/day	# , A90
risperidone 12.5 mg, 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection-Risperdal Consta	Risperdal Consta	PA - < 10 years and PA > 2 injections/28 days	BP
risperidone 150 mg, 200 mg, 250 mg extended-release subcutaneous injection	Uzedy PD	PA - < 10 years and PA > 1 injection/56 days	
risperidone 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection-Rykindo	Rykindo	PA	
risperidone 3 mg, 4 mg orally disintegrating tablet		PA	A90
risperidone 4 mg tablet	Risperdal	PA - < 10 years and PA > 4 units/day	# , A90
risperidone 50 mg, 75 mg, 100 mg, 125 mg extended-release subcutaneous injection	Uzedy PD	PA - < 10 years and PA > 1 injection/28 days	
risperidone 90 mg, 120 mg extended-release subcutaneous injection	Perseris PD	PA - < 10 years and > 1 injection/28 days	
risperidone solution	Risperdal	PA - < 10 years and PA > 16 mL/day	# , A90
ziprasidone capsule	Geodon	PA - < 10 years and PA > 2 units/day	# , A90
ziprasidone injection	Geodon		#

Antipsychotics - Muscarinic Agonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
xanomeline / trospium	Cobenfy	PA	

Antipsychotics – First-Generation (Typical)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amitriptyline / perphenazine		PA	A90
chlorpromazine		PA - < 10 years	A90
fluphenazine		PA - < 10 years	A90
haloperidol	Haldol	PA - < 10 years	# , A90
loxapine capsule	Loxitane	PA - < 10 years	# , A90
molindone		PA - < 10 years	A90
perphenazine		PA - < 10 years	A90
pimozide	Orap	PA - < 10 years	# , A90
thioridazine		PA - < 10 years	A90
thiothixene	Navane	PA - < 10 years	# , A90
trifluoperazine		PA - < 10 years	A90

Antipsychotics – Second-Generation (Atypical) Antipsychotic and Opioid Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
olanzapine / samidorphan	Lybalvi	PA	

Antipsychotics – Second-Generation (Atypical) Antipsychotic and Selective Serotonin Reuptake Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
olanzapine / fluoxetine	Symbyax	PA	A90

#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Agitation associated with dementia due to Alzheimer’s Disease
- Bipolar disorder
- Hallucinations/delusions associated with Parkinson's Disease Psychosis
- Irritability associated with autistic disorder
- Major depressive disorder
- Schizoaffective disorder
- Schizophrenia
- Tourette syndrome

non-FDA-approved, for example:

- Autism spectrum disorders
- Bipolar disorder
- Schizoaffective disorder
- Schizophrenia
- Tourette syndrome

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member’s condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member’s current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Abilify Asimtufii

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to Aristada; **and**

- requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits and polypharmacy requirements for Abilify Asimtufii will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

Abilify Maintena

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to Aristada; **or**
    - member refuses gluteal injections and requires a dose of Aristada that must be administered gluteally only (> 441 mg); **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits and polypharmacy requirements for Abilify Maintena will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

Abilify Mycite

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Abilify Maintena and Aristada; **and**
  - medical necessity for monitoring member's ingestion of oral aripiprazole as noted by one of the following:
    - requirement of witnessed or recorded medication ingestion; **or**
    - alternative medication adherence methods were insufficient, including all of the following: medication alarms or reminders, pill boxes, pill counts, refill frequency assessment; **and**
  - member has been trained to use the Abilify Mycite (aripiprazole tablet with sensor) system; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- For recertification, documentation of continued medical necessity for use instead of alternatives is required.

aripiprazole ODT

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the orally disintegrating formulation as noted by one of the following:
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - need for witnessed administration; **and**
  - one of the following:
    - requested quantity does not exceed established quantity limits (please refer to the reference table below); **or**
    - clinical rationale why the dose cannot be consolidated; **or**
    - clinical rationale why the member requires dosing at intervals exceeding the quantity limit.

aripiprazole solution for members ≥ 13 years of age and ≥ ten mL/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the solution formulation as noted by one of the following:
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - need for witnessed administration; **and**
  - one of the following:
    - requested quantity does not exceed established quantity limits (please refer to the reference table below); **or**

- requested quantity is ≥ ten mL/day and inadequate response, adverse reaction, or contraindication to aripiprazole ODT (at an equivalent dose to the requested dose).

asenapine sublingual tablet

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all second-generation (atypical) antipsychotics; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits and polypharmacy requirements for asenapine sublingual tablet will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two second-generation (atypical) antipsychotics or of the requested agent for 90 days out of the last 120 days.†

Caplyta

- Documentation of all of the following is required for all members with a diagnosis of bipolar depression:
  - appropriate diagnosis; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below); **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to both of the following: olanzapine monotherapy or in combination with fluoxetine, quetiapine immediate-release or extended-release; **or**
    - inadequate response or adverse reaction to two different or contraindication to all second-generation (atypical) antipsychotics; **and**
  - one of the following:
    - request is for Caplyta 42 mg capsule; **or**
    - for Caplyta 10.5 mg or 21 mg capsule, one of the following:
      - member has hepatic impairment; **or**
      - member is utilizing a CYP3A4 inhibitor; **or**
      - member experienced side effects with the 42 mg dose; **or**
      - member has high sensitivity to antipsychotic medications and needs to be initiated on a lower dose.
- Documentation of all of the following is required for members < 18 years of age with a psychiatric diagnosis not listed above:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, ziprasidone; **and**
  - inadequate response or adverse reaction to two different or contraindication to all atypical and typical antipsychotics; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below); and
  - one of the following:
    - request is for Caplyta 42 mg capsule; **or**
    - for Caplyta 10.5 mg or 21 mg capsule, one of the following:
      - member has hepatic impairment; **or**
      - member is utilizing a CYP3A4 inhibitor; **or**
      - member experienced side effects with the 42 mg dose; **or**
      - member has high sensitivity to antipsychotic medications and needs to be initiated on a lower dose.
- Documentation of all of the following is required for members ≥ 18 years of age with a psychiatric diagnosis not listed above:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all second-generation (atypical) antipsychotics; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
  - one of the following:
    - request is for the 42 mg capsule; **or**
    - for Caplyta 10.5 mg or 21 mg capsule, one of the following:

- member has hepatic impairment; **or**
- member is utilizing a CYP3A4 inhibitor; **or**
- member experienced side effects with the 42 mg dose; **or**
- member has high sensitivity to antipsychotic medications and needs to be initiated on a lower dose.

SmartPA: Claims within quantity limits and polypharmacy requirements for Caplyta will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days. Claims within quantity limits and polypharmacy requirements for Caplyta 42 mg for members < 18 years of age will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of one of the following second-generation (atypical) antipsychotics available without PA: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, or ziprasidone, and any two other atypical or typical antipsychotics. Claims within quantity limits and polypharmacy requirements for Caplyta 42 mg for members ≥ 18 years of age will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two second-generation (atypical) antipsychotics.†

clozapine ODT, risperidone ODT 3 mg and ODT 4 mg

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - medical necessity for the orally disintegrating formulation as noted by one of the following:
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - need for witnessed administration; **or**
    - intolerance to other formulations of the requested agent; **and**
  - for risperidone ODT 3 mg or ODT 4 mg, requested quantity does not exceed established quantity limits (please refer to reference table below).

Cobenfy

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - Cobenfy will be used as monotherapy; **or**
    - documentation of cross-taper plan if currently on antipsychotic therapy; **and**
  - one of the following:
    - member is at high risk for extrapyramidal side effects (EPS)/tardive dyskinesia (TD) with at least one of the following:
      - member is ≥ 55 years of age; **or**
      - history of EPS/TD with prior second-generation (atypical) antipsychotic use; **or**
    - all of the following:
      - member is at high risk for metabolic disease; **and**
      - inadequate response or adverse reaction to one or contraindication to all of the following: aripiprazole, lurasidone, ziprasidone; **and**
      - inadequate response or adverse reaction to one additional second generation (atypical) antipsychotic or contraindication to all second generation (atypical) antipsychotics; **or**
    - inadequate response or adverse reaction to two or contraindication to all second-generation (atypical) antipsychotics; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

Erzofri

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to Invega Sustenna; **and**
  - inadequate response, adverse reaction, or contraindication to one other long-acting injectable antipsychotic; **and**

- requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits for Erzofri will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

Fanapt

- Documentation of all of the following is required for members < 18 years of age:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, ziprasidone; **and**
  - inadequate response or adverse reaction to two different or contraindication to all atypical and typical antipsychotics; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- Documentation of all of the following is required for members ≥ 18 years of age:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all second-generation (atypical) antipsychotics; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits and polypharmacy requirements for Fanapt for members < 18 years of age will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of one of the following second-generation (atypical) antipsychotics available without PA: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, or ziprasidone, and any two other atypical or typical antipsychotics, or of the requested agent for at least 90 days out of the last 120 days. Claims within quantity limits and polypharmacy requirements for Fanapt for members ≥ 18 years of age will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two second-generation (atypical) antipsychotics or of the requested agent for at least 90 days out of the last 120 days.†

Lybalvi

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all second-generation (atypical) antipsychotics; **and**
  - both of the following:
    - member is not being treated with an opioid; **and**
    - member is not being treated for acute opioid withdrawal; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within specified quantity limits and polypharmacy requirements will usually process and pay at the pharmacy without PA if the member has a history of paid claims for the reference agent for at least 90 out of the last 120 days.†

Nuplazid

- Documentation of all the following is required for all members:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist (including neurology nurse practitioners or physician assistants) or consult notes (dated within one year) from a specialist are provided; **and**
  - for Nuplazid 10 mg tablet, requested medication will be used in combination with a strong CYP3A4 inhibitor; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

Opipza

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the orally disintegrating formulation as noted by one of the following:
    - member has a swallowing disorder or condition affecting ability to swallow; **or**

- need for witnessed administration; **and**
- inadequate response, adverse reaction, or contraindication to both of the following: aripiprazole ODT, aripiprazole solution; **and**
- one of the following:
  - requested quantity does not exceed established quantity limits (please refer to the reference table below); **or**
  - clinical rationale why the dose cannot be consolidated; **or**
  - clinical rationale why the member requires dosing at intervals exceeding the quantity limit.

perphenazine/amitriptyline and olanzapine/fluoxetine

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents.

SmartPA: Claims for perphenazine/amitriptyline will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days of therapy out of the last 120 days.†

Rexulti

- Documentation of all of the following is required for all members with a diagnosis of major depressive disorder (MDD) or treatment -resistant depression:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all antidepressants (either alone or in combination); **and**
  - Rexulti will be used as adjunctive antidepressant therapy; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- Documentation of all of the following is required for all members with a psychiatric diagnosis not listed above:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all second-generation (atypical) antipsychotics; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits and polypharmacy requirements for Rexulti will usually process at the pharmacy without a PA request if the member has a diagnosis of major depressive disorder, a history of paid MassHealth pharmacy claims for any two antidepressants, and a history of paid MassHealth pharmacy claims for an antidepressant in the last 30 days. Claims within quantity limits and polypharmacy requirements for Rexulti will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two second-generation (atypical) antipsychotics or of the requested agent for at least 90 days out of the last 120 days.†

Rykindo

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: risperidone extended-release intramuscular injection (generic Risperdal Consta), Perseris, Uzedy; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within specified quantity limits will usually process and pay at the pharmacy without PA if the member has a history of paid claims for the reference agent for at least 90 days out of the last 120 days.†

Secuado

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two second-generation (atypical) antipsychotics; **and**
  - one of the following:
    - inadequate response or adverse reaction to asenapine sublingual; **or**

- medical necessity for the transdermal formulation; **and**
- requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within specified quantity limits and polypharmacy requirements will usually process and pay at the pharmacy without PA if the member has a history of paid claims for the reference agent for at least 90 days out of the last 120 days.†

Versacloz

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - medical necessity for the oral suspension formulation as noted by one of the following:
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - need for witnessed administration; **or**
    - intolerance to other clozapine formulations.

Vraylar

- Documentation of all of the following is required for all members for adjunctive treatment for MDD or treatment-resistant depression:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all antidepressants (either alone or in combination); **and**
  - Vraylar will be used as adjunctive antidepressant therapy; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- Documentation of all of the following is required for all members with a diagnosis of bipolar depression:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: olanzapine monotherapy or in combination with fluoxetine, quetiapine immediate-release or extended-release; **or**
    - inadequate response or adverse reaction to one different or contraindication to all second-generation (atypical) antipsychotics; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- Documentation of all of the following is required for all members with a psychiatric diagnosis not listed above:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, ziprasidone; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits and polypharmacy requirements for Vraylar will usually process at the pharmacy without a PA request if the member has a diagnosis of major depressive disorder, a history of paid MassHealth pharmacy claims for any one antidepressant, and a history of paid MassHealth pharmacy claims for an antidepressant in the last 30 days. Claims within quantity limits and polypharmacy requirements for Vraylar will usually process and pay at the pharmacy without prior authorization if the member has a history of a paid claim for the reference agent for at least 90 out of 120 days. Claims for Vraylar will usually also process and pay without prior authorization for members who have a history of paid claims for one of the following: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, or ziprasidone in all claims history.†

Exceeding quantity limits (for all agents except aripiprazole ODT and solution, and Opipza)

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - one of the following:
    - clinical rationale why the dose cannot be consolidated; **or**
    - clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA.

Polypharmacy ***(overlapping pharmacy claims for two or more antipsychotics [includes first-generation and/or second-generation***

antipsychotics, except clozapine, Cobenfy, Nuplazid, and injectable formulations] for at least 60 days within a 90-day period) for members ≥ 18 years of age

- Documentation of all of the following is required:
  - psychiatric diagnosis including treatment-resistant conditions; **and**
  - treatment plan including names of current antipsychotics and corresponding diagnoses; **and**
  - prescriber is a specialist (e.g., psychiatrist, neurologist [including psychiatric/neurological nurse practitioners or physician assistants]) or consult notes (dated within one year) from a specialist are provided; **and**
  - one of the following:
    - inadequate response or adverse reaction to two monotherapy trials as clinically appropriate; **or**
    - member had a recent psychiatric hospitalization and was discharged on the current regimen; **or**
    - cross-titration/taper of antipsychotic therapy; **or**
    - member is stable on the current regimen.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy (*pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, viloxazine, and xanomeline/trospium] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period*) for members < 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist,

pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
- if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation; **and**
- one of the following:
  - member has a seizure diagnosis only; **or**
  - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
  - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
  - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and** one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Antipsychotic Polypharmacy (*overlapping pharmacy claims for 2 or more antipsychotics [includes first-generation and/or second-generation antipsychotics, except short-acting injectable formulations] for at least 60 days within a 90-day period*) for members < 18 years of age
- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - treatment plan including name, dose, and frequency of all current behavioral health medications, associated target symptom(s), and behavioral health diagnoses; **and**
    - a comprehensive behavioral health plan (i.e., non-pharmacologic interventions) is in place; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - stage of treatment is acute, maintenance, or discontinuation; **and**
    - one of the following:
      - for acute stage (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects), one of the following:
        - cross-titration/taper of antipsychotic therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials as clinically appropriate; **or**
      - for maintenance stage (response to antipsychotic treatment with goal of remission or recovery), all of the following:
        - regimen is effective, therapy benefits outweigh risks, and appropriate monitoring is in place; **and**
        - if member has been on the antipsychotic regimen for the last 12 months, clinical rationale for extended therapy including at least one of the following: previous efforts to reduce/simplify the antipsychotic regimen in the last 24 months resulted in symptom exacerbation; or family/caregiver does not support the antipsychotic regimen change at this time due to risk of exacerbation; or other significant barrier for antipsychotic therapy discontinuation; **or**

- for discontinuation stage (clinically indicated that the antipsychotic regimen can likely be successfully tapered), cross-titration/taper of antipsychotic therapy.

Antipsychotic for members < ten years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - for requests for aripiprazole or risperidone for members ≥ six years of age and < ten years of age, a diagnosis of autism spectrum disorder (ASD); **or**
  - all of the following:
    - complete medication treatment plan including name, dose, and frequency of all current behavioral health medications, associated target symptom(s), and behavioral health diagnoses; **and**
    - a comprehensive behavioral health treatment plan (i.e., non-pharmacological interventions) is in place; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatry [including psychiatric nurse practitioners], neurologist, pediatric neurology, developmental and behavioral pediatrics) or consult is provided; **and**
    - one of the following:
      - member is in acute stage of treatment (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects); **or**
      - all of the following:
        - member is in maintenance stage of treatment (response to antipsychotic treatment with goal of remission or recovery); **and**
        - regimen is effective, therapy benefits outweigh risks, and appropriate monitoring is in place; **and**
        - if member has been on the antipsychotic regimen for the last 12 months, clinical rationale for extended therapy including at least one of the following: previous efforts to reduce/simplify the antipsychotic regimen in the last 12 months resulted in symptom exacerbation; or family/caregiver does not support the antipsychotic regimen change at this time due to risk of exacerbation; or other significant barrier for antipsychotic therapy discontinuation; **or**
      - all of the following:
        - member is in discontinuation stage of treatment (clinically indicated that the antipsychotic regimen can likely be successfully tapered); **and**
        - cross-titration/taper of antipsychotic therapy.

Cobenfy for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

Reference Table:

Drug	Quantity Limits
Abilify (aripiprazole tablet)	2 units/day
Abilify Asimtufii (aripiprazole extended-release injection)	1 injection/56 days
Abilify Maintena (aripiprazole extended-release injection)	1 injection/28 days
Abilify Mycite (aripiprazole tablet with sensor)	1 unit/day
aripiprazole orally disintegrating tablet	1 unit/day
aripiprazole solution	< 10 mL/day
Aristada (aripiprazole lauroxil 441 mg, 662 mg, 882 mg)	1 injection/28 days
Aristada (aripiprazole lauroxil 1,064 mg)	1 injection/56 days
Aristada Initio (aripiprazole lauroxil 675 mg)	1 injection/28 days
Caplyta (lumateperone)	1 unit/day
Cobenfy (xanomeline/trospium)	2 units/day
Erzofri (paliperidone IM)	1 injection/28 days
Fanapt (iloperidone)	2 units/day
Geodon (ziprasidone)	2 units/day
Invega (paliperidone tablet) 1.5 mg, 3 mg, 9 mg	1 unit/day
Invega (paliperidone tablet) 6 mg	2 units/day
Invega Hafyera (paliperidone IM)	1 injection/168 days
Invega Sustenna (paliperidone IM)	2 injections within first 28 days, 1 injection/28 days thereafter
Invega Trinza (paliperidone IM)	1 injection/84 days
Latuda (lurasidone) 20 mg, 40 mg, 60 mg, 120 mg	1 unit/day
Latuda (lurasidone) 80 mg	2 units/day
Lybalvi (olanzapine/samidorphan)	1 unit/day
Nuplazid (pimavanserin)	1 unit/day
Opipza (aripiprazole film)	1 unit/day
Perseris (risperidone 90 mg, 120 mg extended-release subcutaneous injection)	1 injection/28 days
Rexulti (brexpiprazole)	1 unit/day
Risperdal (risperidone tablet) 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg	3 units/day
Risperdal (risperidone tablet) 4 mg	4 units/day
Risperdal (risperidone solution)	16 mL/day (480 mL/30 days)
Risperdal Consta (risperidone intramuscular injection)	2 injections/28 days
risperidone orally disintegrating tablet 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg	2 units/day
Rykindo (risperidone intramusuclar injection)	2 injections/28 days
Saphris (asenapine sublingual tablet)	2 units/day
Secuado (asenapine transdermal)	1 unit/day
Seroquel (quetiapine)	3 units/day

Seroquel XR (quetiapine extended-release) 50 mg,150 mg, 200 mg, 300 mg, 400 mg	2 units/day
Uzedy (risperidone 50 mg, 75 mg, 100 mg, 125 mg extended-release subcutaneous injection)	1 injection/28 days
Uzedy (risperidone 150 mg, 200 mg, 250 mg extended-release subcutaneous injection)	1 injection/56 days
Vraylar (cariprazine)	1 unit/day
Zyprexa (olanzapine tablet) 2.5 mg, 5 mg, 7.5 mg, 10 mg	3 units/day
Zyprexa (olanzapine tablet) 15 mg, 20 mg	2 units/day
Zyprexa Relprevv (olanzapine pamoate long-acting injection) 210 mg, 300 mg	2 injections/28 days
Zyprexa Relprevv (olanzapine pamoate long-acting injection) 405 mg	1 injection/28 days
Zyprexa Zydis (olanzapine orally disintegrating tablet) 5 mg, 10 mg, 20 mg	1 unit/day
Zyprexa Zydis (olanzapine orally disintegrating tablet) 15 mg	2 units/day

† **Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.**

Please see the following link to find out more information regarding Second-Generation (Atypical) Antipsychotics: https://www.mass.gov/lists/second-generation-antipsychotics-also-known-as-atypical-antipsychotics.

MassHealth Evaluation Criteria
Table 25 - Corticosteroids - Intranasal

Drug Category: Cough, Cold and Allergy

Medication Class/Individual Agents: Intranasal Steroids

I. Prior-Authorization Requirements

Intranasal Corticosteroids				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** • Intranasal corticosteroids are effective in managing symptoms of itching, nasal congestion, rhinorrhea, and sneezing associated with perennial and seasonal rhinitis. • Symptoms may begin to improve in two to three days but full benefit may not be achieved for two to three weeks. • Dosage may be reduced after a response has been achieved. • At the recommended doses, side effects are usually minimal and include stinging, sneezing, headache, and epistaxis. • Please see the MassHealth Over-the-Counter Drug List for additional information.
azelastine / fluticasone propionate	Dymista		BP, M90	
beclomethasone nasal aerosol	Qnasl	PA		
budesonide OTC nasal spray		PA - > 1 inhaler/30 days	M90	
ciclesonide 37 mcg nasal aerosol	Zetonna	PA - > 1 inhaler/30 days		
ciclesonide 50 mcg nasal spray	Omnaris	PA - > 1 inhaler/30 days		
flunisolide nasal spray		PA	M90	
fluticasone propionate 50 mcg nasal spray		PA - > 1 inhaler/30 days	M90	
fluticasone propionate 93 mcg nasal spray	Xhance	PA		
mometasone nasal spray		PA	M90	
mometasone sinus implant	Sinuva	PA		
olopatadine / mometasone	Ryaltris	PA		
triamcinolone OTC nasal spray		PA - > 1 inhaler/30 days	M90	

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

M90 Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Allergic rhinitis

- Chronic rhinosinusitis with or without nasal polyps
- Nasal polyps
- Nasal polyps and a history of ethmoid sinus surgery
- Non-allergic rhinitis

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Flonase Sensimist

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - medical necessity for the requested formulation instead of the formulations available without PA within quantity limits.

flunisolide nasal spray (one inhaler/30 days), mometasone nasal spray (one inhaler/30 days), and Qnasl (one inhaler/30 days) for members six years of age and older

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as at least 14 days of therapy), adverse reaction, or contraindication to budesonide OTC, fluticasone propionate 50 mcg, and triamcinolone OTC nasal sprays.

SmartPA: Claims for flunisolide nasal spray, mometasone nasal spray, and Qnasl for members ≥ six years will usually process at the pharmacy without a PA request if the claim is for ≥ one inhaler/30 days and the member has a history of paid MassHealth pharmacy claims for budesonide OTC, fluticasone propionate 50 mcg, and triamcinolone OTC nasal sprays.†

flunisolide nasal spray (one inhaler/30 days), mometasone nasal spray (one inhaler/30 days), and Qnasl (one inhaler/30 days), for members four and five years of age

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**

- inadequate response (defined as at least 14 days of therapy), adverse reaction, or contraindication to fluticasone propionate 50 mcg and triamcinolone OTC nasal sprays.

Smart PA: Claims for flunisolide nasal spray, mometasone nasal spray, and Qnasl for members ages four or five years of age will usually process at the pharmacy without a PA request if the claim is for ≥ one inhaler/30 days and the member has a history of paid MassHealth pharmacy claims for fluticasone propionate 50 mcg and triamcinolone OTC nasal sprays.†

flunisolide nasal spray (one inhaler/30 days), mometasone nasal spray (one inhaler/30 days), and Qnasl (one inhaler/30 days) for members less than four years of age

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as at least 14 days of therapy), adverse reaction or contraindication to triamcinolone OTC nasal spray.

Smart PA: Claims for flunisolide nasal spray, mometasone nasal spray, and Qnasl for members < four years of age will usually process at the pharmacy without a PA request if the claim is for ≥ one inhaler/30 days and the member has a history of paid MassHealth pharmacy claims for triamcinolone OTC nasal spray.†

flunisolide nasal spray (> one inhaler/30 days), mometasone nasal spray (> one inhaler/30 days), Qnasl (> one inhaler/30 days), Ryaltris (> one inhaler/30 days), and Xhance (> one inhaler/30 days)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - individual drug PA criteria must be met first where applicable; **and**
  - medical records demonstrating an inadequate response to an adequate trial of the manufacturer's recommended doses; **and**
  - inadequate response (defined as at least 14 days of therapy) or adverse reaction to two or contraindication to all of the following: azelastine, cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine, olopatadine.

fluticasone propionate 50 mcg (> one inhaler/30 days), Omnaris (> one inhaler/30 days), and Zetonna (> one inhaler/30 days)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records demonstrating an inadequate response to an adequate trial of the manufacturer's recommended doses; **and**
  - inadequate response (defined as at least 14 days of therapy) or adverse reaction to two or contraindication to all of the following: azelastine, cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine, olopatadine.

Ryaltris (one inhaler/30 days)

- Documentation of all of the following is required:
  - member is ≥ 12 years of age; **and**
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as at least 14 days of therapy) or adverse reaction to one intranasal corticosteroid agent used in combination with one intranasal antihistamine agent; **or**
    - inadequate response (defined by at least 14 days of therapy), adverse reaction, or contraindication to azelastine/fluticasone propionate nasal spray.

Sinuva

- Documentation of all of the following is required:
  - member is ≥ 18 years of age; **and**
  - appropriate diagnosis; **and**
  - prescriber is an otolaryngologist; **and**
  - appropriate dosing; **and**

- one of the following:
  - inadequate response or adverse reaction to an oral corticosteroid and an inadequate response (defined as at least 14 days of therapy) or adverse reaction to an intranasal corticosteroid; **or**
  - contraindication to oral corticosteroids and an inadequate response (defined as at least 14 days of therapy) or adverse reaction to two intranasal corticosteroids.

Xhance (one inhaler/30 days)

- Documentation of all of the following is required:
  - member is ≥ 18 years of age; **and**
  - appropriate diagnosis; **and**
  - medical necessity for use of Xhance instead of all other intranasal corticosteroids.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 26 - Antidiabetic Agents

Drug Category: Endocrine/Metabolic

Medication Class/Individual Agents: Antidiabetic Agents

I. Prior-Authorization Requirements

Antidiabetic Agents – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alogliptin / metformin	Kazano	PA	M90
alogliptin / pioglitazone	Oseni	PA	M90
canagliflozin / metformin	Invokamet	PA	
canagliflozin / metformin extended-release	Invokamet XR	PA	
dapagliflozin / metformin extended-release	Xigduo XR		BP, M90
dapagliflozin / saxagliptin	Qtern	PA	
empagliflozin / linagliptin	Glyxambi	PA	
empagliflozin / linagliptin / metformin extended-release	Trijardy XR	PA	
empagliflozin / metformin	Synjardy		
empagliflozin / metformin extended-release	Synjardy XR		
ertugliflozin / metformin	Segluromet	PA	
ertugliflozin / sitagliptin	Steglujan	PA	
glimepiride / pioglitazone	Duetact	PA	BP, M90
glipizide / metformin			M90
glyburide / metformin			M90
linagliptin / metformin	Jentadueto		BP
linagliptin / metformin extended-release	Jentadueto XR		BP
pioglitazone / metformin	Actoplus Met		# , M90
repaglinide /		PA	M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Please note: anti-obesity agents and/or drugs used for the treatment of obesity are not payable for Health Safety Net patients for weight loss.

Alpha-glucosidase inhibitors:

- If hypoglycemia occurs, treat with oral glucose (dextrose) and not cane sugar (sucrose).
- Contraindications include inflammatory bowel disease, colon ulcerations, and intestinal obstruction.

Biguanides:

- Hold metformin therapy for 48 hours after receiving iodinated contrast and reinstitute only after confirming normal renal function.
- May cause lactic acidosis; contraindicated in members predisposed to acidosis (e.g., major surgery, congestive heart failure, hepatic failure).
- Contraindicated in females and males with renal disease or dysfunction (e.g., serum creatinine greater than or equal to 1.4 mg/dL and 1.5 mg/dL, respectively).

Insulin:

- Rapid-acting: aspart, glulisine, lispro

Antidiabetic Agents – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
metformin			
saxagliptin / metformin extended-release	Kombiglyze XR	PA	M90
sitagliptin / metformin			M90
sitagliptin / metformin - Janumet	Janumet		
sitagliptin / metformin - Zituvimet	Zituvimet	PA	
sitagliptin / metformin extended-release	Janumet XR		
sitagliptin / metformin extended-release - Zituvimet XR	Zituvimet XR	PA	

Antidiabetic Agents – Thiazolidinediones			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
pioglitazone	Actos		# , M90

Antidiabetic Agents – Insulin			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
insulin aspart	Fiasp	PA	
insulin aspart	Novolog	PA	
insulin aspart 70/30			
insulin aspart 70/30-Novolog	Novolog	PA	
insulin degludec	Tresiba		BP
insulin detemir	Levemir		
insulin glargine-aglr	Rezvoglar	PA	
insulin glargine-Basaglar	Basaglar	PA	
insulin glargine-Basaglar	Basaglar Tempo	PA	
insulin glargine-Lantus	Lantus PD		BP
insulin glargine-Toujeo	Toujeo		BP
insulin glargine-yfgn	Semglee	PA	
insulin glulisine	Apidra	PA	
insulin human	Afrezza	PA	

Clinical Notes

  - onset: 15-30 minutes
  - duration: three-five hours
- Short-acting: regular
  - onset: 30-60 minutes
  - duration: five-eight hours
- Intermediate-acting: NPH
  - onset: one-three hours
  - duration: 12-16 hours
- Long-acting: degludec, detemir, glargine
  - onset: one-two hours
  - duration: 20-42 hours

Meglitinides:

- Take before meals; hold dose if meal is missed.
- Use with caution in members with moderate-to-severe hepatic impairment.

Sulfonylureas:

- Use with caution in elderly members and in members with renal or hepatic impairment.

Thiazolidinediones:

- Use with caution in members with edema.
- Contraindicated in members with NYHA class III or IV cardiac status.
- Not recommended for members with abnormal liver function tests.
- May cause resumption of ovulation and increase risk of pregnancy in premenopausal anovulatory women with insulin resistance.

Pregnancy/lactation:

- Insulin is the agent of choice during pregnancy and lactation.

Phentermine Contraindication

The following are acceptable contraindications to phentermine:

- Allergy to phentermine or any of the excipients
- Arrhythmia
- Bipolar disorder with mania
- Concomitant use of stimulants
- Congestive heart failure
- Concomitant use of monoamine oxidase inhibitor (MAOI)
- Coronary artery disease
- Glaucoma
- History of myocardial infarction (MI)

Antidiabetic Agents – Insulin			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
inhalation powder			
insulin lispro 100 units/mL cartridge	Humalog		
insulin lispro 100 units/mL prefilled syringe, vial			
insulin lispro 100 units/mL prefilled syringe, vial-Humalog	Humalog	PA	
insulin lispro 100 units/mL prefilled syringe-Humalog Tempo	Humalog Tempo	PA	
insulin lispro 200 units/mL	Humalog		
insulin lispro 50/50	Humalog		
insulin lispro 75/25 prefilled syringe			
insulin lispro 75/25 prefilled syringe-Humalog	Humalog	PA	
insulin lispro 75/25 vial	Humalog		
insulin lispro-aabc	Lyumjev	PA	
insulin lispro-aabc	Lyumjev Tempo	PA	
insulin lispro-Admelog	Admelog	PA	
insulin NPH	Humulin N	PA	
insulin NPH	Novolin N		
insulin NPH / regular insulin 70/30	Humulin		
insulin NPH / regular insulin 70/30	Novolin		
insulin regular	Humulin R		
insulin regular	Novolin R		

Antidiabetic Agents – Glucagon Like Peptide (GLP)-1 Agonists and GLP-1 Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dulaglutide	Trulicity PD	PA - > 2 mL/28 days	
exenatide 10 mcg injection	Byetta	PA - > 2.4 mL/30 days	BP

Clinical Notes

- History of psychosis
- History of stroke
- Hyperthyroidism
- Pregnancy or lactation
- Substance use disorder (SUD), opioid use disorder (OUD), alcohol use disorder, stimulant use disorder
- Symptomatic peripheral artery disease (PAD)
- Uncontrolled anxiety despite pharmacotherapy
- Uncontrolled hypertension defined as average blood pressure of ≥ 140/90 mm Hg despite pharmacotherapy

Antidiabetic Agents – Glucagon Like Peptide (GLP)-1 Agonists and GLP-1 Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
exenatide 5 mcg injection	Byetta	PA - > 1.2 mL/30 days	BP
exenatide extended-release auto-injection	Bydureon Bcise	PA	
insulin degludec / liraglutide	Xultophy	PA	
insulin glargine / lixisenatide	Soliqua	PA	
liraglutide-Victoza	Victoza	PA - >9 mL/30 days	BP
semaglutide injection-Ozempic	Ozempic	PA	
semaglutide tablet	Rybelsus	PA	

Antidiabetic Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bromocriptine 0.8 mg tablet	Cycloset		
colesevelam	Welchol		# , M90
pramlintide	Symlinpen		

Antidiabetic Agents – Sodium Glucose Cotransporter (SGLT)-2 Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
canagliflozin	Invokana	PA	
dapagliflozin	Farxiga		BP, M90
empagliflozin	Jardiance		
ertugliflozin	Steglatro	PA	
sotagliflozin	Inpefa	PA	

Antidiabetic Agents – Sulfonylureas - Second Generation			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
glimepiride 1 mg, 2 mg, 4 mg			M90
glimepiride 3 mg		PA	M90
glipizide			M90
glipizide extended -release	Glucotrol XL		# , M90
glyburide			M90

Antidiabetic Agents – Sulfonylureas - Second Generation			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
glyburide, micronized	Glynase		# , M90

Antidiabetic Agents – Biguanides			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
metformin extended-release suspension	Riomet ER	PA	
metformin extended-release, gastric tablet	Glumetza	PA	M90
metformin extended-release, osmotic tablet		PA	M90
metformin extended-release, XR tablet			M90
metformin immediate-release 500 mg, 850 mg, 1,000 mg tablet			M90
metformin immediate-release 625 mg tablet		PA	M90
metformin immediate-release solution	Riomet	PA - ≥ 13 years	# , M90

Antidiabetic Agents – Dipeptidyl Peptidase (DPP)-4 Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alogliptin	Nesina	PA	M90
linagliptin	Tradjenta		BP
saxagliptin	Onglyza	PA	M90
sitagliptin-Januvia	Januvia		
sitagliptin-Zituvio	Zituvio	PA	BP, M90

Antidiabetic Agents – Glucose-Dependent Insulinotropic Polypeptide (GIP) and Glucagon Like Peptide (GLP)-1 Agonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
tirzepatide-Mounjaro	Mounjaro	PA	

Antidiabetic Agents – Alpha-Glucosidase Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acarbose	Precose		# , M90
miglitol		PA	M90

Antidiabetic Agents - Anti-CD3 antibodies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
teplizumab-mzwv	Tzield	PA	

Antidiabetic Agents – Meglitinides			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
nateglinide			M90
repaglinide			M90

#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Diabetes mellitus (Admelog, Afrezza, Basaglar, Basaglar Tempo, Fiasp, Humalog Tempo, Humulin N, insulin aspart [generic Novolog], Lyumjev, Lyumjev Tempo)
- Heart failure (Inpefa)
- Type 1 diabetes mellitus, Stage 2 (Tzield)
- Type 2 diabetes mellitus (alogliptin, alogliptin/metformin, alogliptin/pioglitazone, Bydureon Bcise, glimepiride/pioglitazone, Glyxambi, Invokana, Invokamet, Invokamet XR, metformin extended-release, gastric tablet (generic Glumetza), metformin extended-release, osmotic tablet (generic Fortamet), metformin immediate-release 625 mg tablet, metformin immediate-release solution, miglitol, Mounjaro, Onglyza, Ozempic, Qtern, repaglinide/metformin, Riomet ER, Rybelsus, saxagliptin/metformin extended-release, Segluromet, sitagliptin (generic Zituvio), Soliqua, Steglatro, Steglujan, Trijardy XR, Xultophy), Zituvimet, Zituvimet XR
- Type 2 diabetes mellitus and chronic kidney disease (Inpefa)
- Type 2 diabetes mellitus and diabetic nephropathy with albuminuria (Invokana)

non-FDA-approved, for example:

- Gestational diabetes (metformin extended-release, gastric tablet (generic Glumetza), metformin extended-release, osmotic tablet (generic Fortamet), metformin immediate-release solution, Riomet ER)

- Obesity (Bydureon Bcise, liraglutide [generic Victoza], Mounjaro, Ozempic, Rybelsus)
- Oligomenorrhea related to polycystic ovarian syndrome (PCOS) (metformin extended-release, gastric tablet [generic Glumetza], metformin extended-release, osmotic tablet [generic Fortamet], metformin immediate-release solution, Riomet ER)
- Overweight (Bydureon Bcise, liraglutide [generic Victoza], Mounjaro, Ozempic, Rybelsus)
- Prediabetes (Bydureon Bcise, metformin extended-release, gastric tablet [generic Glumetza], metformin extended-release, osmotic tablet [generic Fortamet], metformin immediate-release solution, Ozempic, Riomet ER, Rybelsus)
- Prevention of diabetes related to PCOS (metformin extended-release, gastric tablet [generic Glumetza], metformin extended-release, osmotic tablet [generic Fortamet], metformin immediate-release solution, Riomet ER)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Admelog, Apidra, Fiasp, insulin aspart (generic Novolog), Lyumjev, and Lyumjev Tempo

- Documentation of both of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 90 days of therapy within a 180-day time period), adverse reaction, or contraindication to insulin lispro (Humalog or therapeutically equivalent generic); **and**
  - for Lyumjev Tempo, medical necessity for use of Tempo pen formulation instead of Kwikpen formulation (i.e., documentation that member has access to the Tempo smart button and accompanying app).

Afrezza

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical necessity for the use of an inhaled insulin product instead of an injectable or prefilled insulin syringe.

alogliptin, saxagliptin, and sitagliptin (generic Zituvio)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with Januvia or Tradjenta; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to Januvia or Tradjenta; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to Januvia or Tradjenta; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to Januvia and Tradjenta; **and**
  - one of the following:
    - requested quantity is ≤ one tablet/day; **or**
    - clinical rationale for exceeding FDA-approved dosing.

SmartPA: Claims for alogliptin, saxagliptin, and sitagliptin (generic Zituvio) within the quantity limit (described above) will usually process at the pharmacy without a PA request if the member has a history of type 2 diabetes mellitus and paid MassHealth pharmacy claims for metformin and Januvia or Tradjenta for at least 90 days within the last 120-day time period.†

alogliptin/metformin, alogliptin/pioglitazone, glimepiride/pioglitazone, Glyxambi, Invokamet, Invokamet XR, Qtern, repaglinide/metformin, saxagliptin/metformin extended-release, Segluromet, Steglujan, Trijardy XR, Zituvimet*, and Zituvimet XR**

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to combination therapy with metformin used in combination with at least one of the non-metformin agents in the requested combination; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to at least one of the non-metformin agents in the requested combination; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to at least one of the non-metformin agents in the requested combination; **and**
  - for Trijardy XR, medical necessity for use of the combination product instead of the commercially available separate agents.

*** Please note, sitagliptin/metformin (generic Zituvimet) is available without PA.

Basaglar and Basaglar Tempo

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 90 days of therapy within a 180-day time period) or adverse reaction to insulin glargine prefilled syringe or vial (branded or unbranded Lantus solostar or Lantus vial); **and**
  - inadequate response (defined as ≥ 90 days of therapy within a 180-day time period) or adverse reaction to one of the following: insulin glargine-yfgn prefilled syringe or vial, Rezvoglar prefilled syringe; **and**
  - for Basaglar Tempo, medical necessity for use of Tempo pen formulation instead of Kwikpen formulation (i.e., documentation that member has access to the Tempo smart button and accompanying app).

Bydureon Bcise, Ozempic, Rybelsus

- Documentation of all of the following is required for the diagnosis of prediabetes or type 2 diabetes:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with Byetta, liraglutide (generic Victoza), or Trulicity; **or**

- adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
- inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
- inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to Byetta, liraglutide (generic Victoza), or Trulicity; **and**

- if requested quantity exceeds quantity limits, clinical rationale why dose cannot be consolidated or for exceeding FDA-approved dosing; **and**
- requested agent will not be used in combination with another GLP-1 receptor agonist.

- Documentation of all of the following is required for diagnosis of obesity or overweight:
  - appropriate diagnosis; **and**
  - one of the following:
    - for Ozempic and Rybelsus, member is ≥ 18 years of age; **or**
    - for Bydureon Bcise, member is ≥ 12 years of age; **and**
  - member weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity); **and**
  - member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
  - if requested quantity exceeds quantity limits, clinical rationale why dose cannot be consolidated or for exceeding FDA-approved dosing; **and**
  - the requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
  - one of the following*:
    - inadequate response to phentermine with or without topiramate defined as all of the following:
      - member is adherent to phentermine (defined as ≥ 90 days out of 120 days)**; **and**
      - one of the following:
        - insufficient clinical response defined as < 5% reduction in bodyweight from baseline despite initial trial of ≥ three months of treatment with the maximally tolerated dose of phentermine; **or**
        - plateaued clinical response defined as no weight loss for at least ≥ three months of treatment with the maximally tolerated dose of phentermine; **and**
      - member's current BMI is ≥ 27 kg/m^2 (dated within the 90 days prior to treatment initiation of requested agent); **or**
    - medical records documenting adverse reaction to phentermine that is allergic in nature or cannot be expected or managed as part of weight loss therapy; **or**
    - medical records documenting contraindication to phentermine; **and**
  - one of the following:
    - member BMI is ≥ 30 kg/m^2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity); **or**
    - for Bydureon Bcise, both of the following:
      - member is ≥ 12 years of age and <17 years of age; **and**
      - BMI is in the 95th percentile or greater (dated within the 90 days prior to initiation of pharmacotherapy for obesity); **or**
    - both of the following:
      - member BMI is ≥ 27 kg/m^2 (dated within the last 90 days prior to initiation of pharmacotherapy for obesity); **and**
      - one of the following weight-related comorbid conditions:
        - coronary heart disease or other atherosclerotic disease; **or**
        - dyslipidemia; **or**
        - hypertension; **or**
        - non-alcoholic steatohepatitis (NASH); **or**
        - obstructive sleep apnea; **or**
        - polycystic ovarian syndrome; **or**
        - prediabetes; **or**
        - systemic osteoarthritis; **or**

        - type 2 diabetes mellitus.
- For recertification for the diagnosis of obesity or overweight, documentation of all of the following is required:
  - member weight (dated within the last 90 days); **and**
  - one of the following:
    - weight loss of ≥ 5% from baseline body weight; **or**
    - both of the following:
      - improvement in secondary measures; **and**
      - attestation that the improvement in secondary measure is believed to be related to anti-obesity therapy despite lack of reduction in body weight.
- Please note for the quantity limits listed above:
  - a 28-day supply should consist of:
    - one carton of four 2 mg autoinjectors (Bydureon Bcise)
    - one prefilled pen (Ozempic)
    - one tablet per day (Rybelsus)

*Please note, members who have paid MassHealth pharmacy claims for a GLP-1 agonist within the last 90 days may bypass the phentermine trial. For all other members, documentation of clinical rationale why the member is not new to GLP-1 therapy is required to bypass the phentermine trial.
**Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to these agents.

SmartPA: Claims for Bydureon Bcise, Ozempic, and Rybelsus within the quantity limit (as described above) will usually process at the pharmacy without a PA request if the member has a history of type 2 diabetes mellitus and paid MassHealth pharmacy claims for metformin and Byetta, liraglutide (generic Victoza), or Trulicity for at least 90 days within the last 120-day time period.†

Byetta and Trulicity exceeding quantity limits
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale why dose cannot be consolidated or for exceeding FDA-approved dosing; **and**
  - requested agent will not be used in combination with another GLP-1 receptor agonist.

glimepiride 3 mg tablet
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation intstead of glimepiride tables available without prior authorization.

Humalog 100 units/mL prefilled syringe, Humalog 100 units/mL vial, Humalog 75/25 prefilled syringe, Novolog, and Novolog 70/30
- Documentation of both of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to the therapeutically equivalent generic formulation.

Humalog Tempo
- Documentation of both of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for use of Tempo pen formulation instead of Kwikpen formulation (i.e., documentation that member has access to the Tempo smart button and accompanying app).

Humulin N

- Documentation of both of the following is required:
  - appropriate diagnosis: **and**
  - inadequate response (defined as ≥ 90 days of therapy within a 180-day time period) or adverse reaction to Novolin N prefilled syringe or vial.

Inpefa
- Documentation of all of the following is required for heart failure:
  - indication of reduction of risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to both dapagliflozin and Jardiance; **and**
  - requested quantity is ≤ one tablet/day.
- Documentation of all of the following is required for type 2 diabetes and chronic kidney disease:
  - indication of reduction of risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in type 2 diabetes mellitus and chronic kidney disease with other cardiovascular risk factors; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: dapagliflozin, Invokana, Jardiance; **and**
  - requested quantity is ≤ one tablet/day.

Invokana
- Documentation of all of the following is required for the diagnosis of diabetic nephropathy with albuminuria:
  - indication of risk reduction of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one tablet/day.
- Documentation of all of the following is required for the diagnosis of type 2 diabetes:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with dapagliflozin or Jardiance; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to dapagliflozin or Jardiance; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to dapagliflozin or Jardiance; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to dapagliflozin and Jardiance; **and**
  - one of the following:
    - requested quantity is ≤ one tablet/day; **or**
    - clinical rationale for exceeding FDA-approved dosing.

SmartPA: Claims for Invokana within the quantity limit (described above) will usually process at the pharmacy without a PA request if the member has a history of type 2 diabetes mellitus and paid MassHealth pharmacy claims for metformin and dapagliflozin or Jardiance for at least 90 days within the last 120-day time period.†

liraglutide (generic Victoza) exceeding quantity limits
- Documentation of all of the following is required for the diagnosis of type 2 diabetes or prediabetes:
  - appropriate diagnosis; **and**
  - clinical rationale why dose cannot be consolidated or for exceeding FDA-approved dosing; **and**
  - requested agent will not be used in combination with another GLP-1 receptor agonist.
- Documentation of all of the following is required for the diagnosis of obesity or overweight:

- appropriate diagnosis; **and**
- member is ≥ 12 years of age; **and**
- member weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity); **and**
- member will be counseled to continue reduced-calorie diet and increased physical activity; **and**
- requested quantity is ≤ five pens/30 days; **and**
- the requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
- one of the following*:
  - inadequate response to phentermine with or without topiramate defined as all of the following:
    - member is adherent to phentermine (defined as ≥ 90 days out of 120 days)**; **and**
    - one of the following:
      - insufficient clinical response defined as < 5% reduction in bodyweight from baseline despite initial trial of ≥ three months of treatment with the maximally tolerated dose of phentermine; **or**
      - plateaued clinical response defined as no weight loss for at least ≥ three months of treatment with the maximally tolerated dose of phentermine; **and**
    - member's current BMI is ≥ 27 kg/m^2 (dated within the 90 days prior to initiation of requested agent); **or**
  - medical records documenting adverse reaction to phentermine that is allergic in nature or cannot be expected or managed as part of weight loss therapy; **or**
  - medical records documenting contraindication to phentermine; **and**
- one of the following:
  - member BMI is ≥ 30 kg/m^2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity); **or**
  - both of the following:
    - member is ≥ 12 years of age and < 18 years of age; **and**
    - member BMI is in the 95th percentile or greater (dated within the 90 days prior to initiation of pharmacotherapy for obesity); **or**
  - both of the following:
    - member BMI is ≥ 27 kg/m^2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity); **and**
    - one of the following weight-related comorbid conditions:
      - coronary heart disease or other atherosclerotic disease; **or**
      - dyslipidemia; **or**
      - hypertension; **or**
      - non-alcoholic steatohepatitis (NASH); **or**
      - obstructive sleep apnea; **or**
      - polycystic ovarian syndrome; **or**
      - prediabetes; **or**
      - systemic osteoarthritis; **or**
      - type 2 diabetes mellitus.
- For recertification for the diagnosis of obesity or overweight, documentation of all of the following is required:
  - member weight (dated within the last 90 days); **and**
  - one of the following:
    - weight loss of ≥ 5% from baseline body weight; **or**
    - both of the following:
      - improvement in secondary measures; **and**
      - attestation that the improvement in secondary measure is believed to be related to anti-obesity therapy despite lack of reduction in body weight.

*Please note, members who have paid MassHealth pharmacy claims for a GLP-1 agonist within the last 90 days may bypass the phentermine trial. For all other members, documentation of clinical rationale why the member is not new to GLP-1 therapy is required to bypass the phentermine trial.

**Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing

adherence to these agents.

metformin extended-release, gastric tablet (generic Glumetza) and metformin extended-release, osmotic tablet (generic Fortamet)

- Documentation of all of the following is required for type 2 diabetes, or prevention of diabetes related to PCOS:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response (defined as ≥ 90 days of therapy) or adverse reaction, at the requested dose, to the metformin extended-release, XR tablet formulation available without PA; **and**
  - for metformin extended-release, gastric tablet, medical necessity for the use of requested product instead of metformin formulations available without PA.
- Documentation of all of the following is required for gestational diabetes:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response (defined as ≥ 90 days of therapy) or adverse reaction, at the requested dose, to the metformin extended-release, XR tablet formulation available without PA; **and**
  - for metformin extended-release, gastric tablet, medical necessity for the use of requested product instead of metformin formulations available without PA; **and**
  - inadequate response, adverse reaction, or contraindication to insulin therapy.
- Documentation of all of the following is required for oligomenorrhea related to PCOS:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response (defined as ≥ 90 days of therapy) or adverse reaction, at the requested dose, to the metformin extended-release, XR tablet formulation available without PA; **and**
  - for metformin extended-release, gastric tablet, medical necessity for the use of requested product instead of metformin formulations available without PA; **and**
  - inadequate response, adverse reaction, or contraindication to combined oral contraceptives.

metformin immediate-release 625 mg tablet

- Documentation of both of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation instead of metformin tablets available without prior authorization.

metformin immediate-release solution ≥ 13 years of age and Riomet ER

- Documentation of all of the following is required for type 2 diabetes, prediabetes, or prevention of diabetes related to PCOS:
  - appropriate diagnosis; **and**
  - one of the following:
    - medical necessity for the use of a liquid formulation; **or**
    - medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin tablet formulation, or allergic reaction or adverse reaction to the metformin tablet formulation that is not class specific (i.e., nausea, diarrhea); **and**
  - for Riomet ER, medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin immediate-release solution formulation.
- Documentation of all of the following is required for gestational diabetes:
  - appropriate diagnosis; **and**
  - one of the following:
    - medical necessity for the use of a liquid formulation; **or**
    - medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin tablet formulation, or allergic reaction or adverse reaction to the metformin tablet formulation that is not class specific (i.e., nausea, diarrhea); **and**
  - for Riomet ER, medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin immediate-release solution formulation; **and**
  - inadequate response, adverse reaction, or contraindication to insulin therapy.
- Documentation of all of the following is required for oligomenorrhea related to PCOS:

- appropriate diagnosis; **and**
- one of the following:
  - medical necessity for the use of a liquid formulation; **or**
  - medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin tablet formulation, or allergic reaction or adverse reaction to the metformin tablet formulation that is not class specific (i.e., nausea, diarrhea); **and**
- for Riomet ER, medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin immediate-release solution formulation; **and**
- inadequate response, adverse reaction, or contraindication to combined oral contraceptives.

miglitol

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with acarbose; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to acarbose; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to acarbose; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to acarbose; **and**
  - one of the following:
    - requested quantity is ≤ three tablets/day; **or**
    - clinical rationale for exceeding FDA-approved dosing.

SmartPA: Claims for miglitol within the quantity limit (as described above) will usually process at the pharmacy without a PA request if the member has a history of type 2 diabetes mellitus and paid MassHealth pharmacy claims for metformin and acarbose for at least 90 days within the last 120-day time period.†

Mounjaro

- Documentation of all of the following is required for the diagnosis of type 2 diabetes:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with Byetta, liraglutide (generic Victoza), or Trulicity; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to Byetta, liraglutide (generic Victoza), or Trulicity; **and**
  - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to Ozempic; **and**
  - the requested agent will not be used in combination with a GLP-1 receptor agonist; **and**
  - if requested quantity exceeds quantity limits, clinical rationale why dose cannot be consolidated or for exceeding FDA-approved dosing.

- Documentation of all of the following is required for diagnosis of obesity or overweight:
  - appropriate diagnosis; **and**

- member is ≥ 18 years of age; **and**
- member weight (dated within the 90 days prior to treatment initiation); **and**
- member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
- medical necessity for the requested agent instead of Zepbound; **and**
- the requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
- if requested quantity exceeds quantity limits, clinical rationale why dose cannot be consolidated or for exceeding FDA-approved dosing; **and**
- one of the following*:
  - inadequate response to phentermine with or without topiramate as defined as all of the following:
    - member is adherent to phentermine (defined as ≥ 90 days out of 120 days)**; **and**
    - one of the following:
      - insufficient clinical response defined as < 5% reduction in bodyweight from baseline despite initial trial of ≥ three months of treatment with the maximally tolerated dose of phentermine; **or**
      - plateaued clinical response defined as no weight loss for at least ≥ three months of treatment with the maximally tolerated dose of phentermine; **and**
    - member's current BMI is ≥ 27 kg/m^2 (dated within the 90 days prior to treatment initiation); **or**
  - medical records documenting adverse reaction to phentermine that is allergic in nature or cannot be expected or managed as part of weight loss therapy; **or**
  - medical records documenting contraindication to phentermine; **and**
- one of the following:
  - member BMI ≥ 30 kg/m^2 (dated within the 90 days prior to treatment initiation); **or**
  - both of the following:
    - member BMI is ≥ 27 kg/m^2 (dated within the 90 days prior to treatment initiation); **and**
    - one of the following weight-related comorbid conditions:
      - coronary heart disease or other atherosclerotic disease; **or**
      - dyslipidemia; **or**
      - hypertension; **or**
      - non-alcoholic steatohepatitis (NASH); **or**
      - obstructive sleep apnea; **or**
      - polycystic ovarian syndrome; **or**
      - prediabetes; **or**
      - systemic osteoarthritis; **or**
      - type 2 diabetes mellitus.
- For recertification for the diagnosis of obesity or overweight, documentation of all of the following is required:
  - member weight (dated within the last 90 days); **and**
  - one of the following:
    - weight loss of ≥ 5% from baseline body weight; **or**
    - both of the following:
      - improvement in secondary measures; **and**
      - attestation that the improvement in secondary measure is believed to be related to anti-obesity therapy despite lack of reduction in body weight.
- Please note for the quantity limits listed above:
  - a 30 day supply should consist of one carton of four prefilled pens.

*Please note, members who have paid MassHealth pharmacy claims for a GLP-1 agonist within the last 90 days may bypass the phentermine trial. For all other members, documentation of clinical rationale why the member is not new to GLP-1 therapy is required to bypass the phentermine trial.

**Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to these agents.

Rezvoglar and Semglee

- Documentation of both of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 90 days of therapy within a 180-day time period) or adverse reaction with insulin glargine prefilled syringe or vial (branded or unbranded Lantus solostar or Lantus vial).

Soliqua and Xultophy

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with Byetta, liraglutide (generic Victoza), or Trulicity; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to Byetta, liraglutide (generic Victoza), or Trulicity; **and**
  - requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
  - if requested quantity exceeds quantity limits, clinical rationale why dose cannot be consolidated or for exceeding FDA-approved dosing.
  - please note for the quantity limits listed above:
    - a 30-day supply should consist of:
      - six prefilled pens (Soliqua)
      - one carton of five prefilled pens (Xultophy)

SmartPA: Claims for Soliqua and Xultophy within the quantity limit (as described above) will usually process at the pharmacy without a PA request if the member has a history of type 2 diabetes mellitus and paid MassHealth pharmacy claims for metformin and Byetta, liraglutide (generic Victoza), or Trulicity for at least 90 days within the last 120-day time period.†

Steglatro

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with dapagliflozin or Jardiance; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to dapagliflozin or Jardiance; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to dapagliflozin or Jardiance; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to dapagliflozin and Jardiance; **and**
  - one of the following:
    - requested quantity is ≤ one tablet/day; **or**
    - clinical rationale for exceeding FDA-approved dosing.

SmartPA: Claims for Steglatro within the quantity limit (described above) will usually process at the pharmacy without a PA request if the member has a history of type 2 diabetes mellitus and paid MassHealth pharmacy claims for metformin and dapagliflozin or Jardiance for at least 90 days within the last 120-day time period.†

Tzield

- Documentation of all of the following is required for stage 2 type 1 diabetes mellitus:
  - appropriate diagnosis; **and**
  - member is ≥ eight years of age; **and**
  - appropriate dosing; **and**
  - prescriber is an endocrinologist or consult notes from a specialist are provided; **and**
  - lab results documenting ≥ two islet autoantibodies; **and**
  - member has not been previously treated with Tzield; **and**
  - one of the following within the last three months:
    - fasting plasma glucose (FPG): 100 to 125 mg/dL; **or**
    - 2-hour plasma glucose (2-h PG): 140 to 199 mg/dL; **or**
    - A1C: 5.7% to 6.4%; **or**
    - both of the following:
      - 10% increase in A1C in ≤12 months; **and**
      - A1C is ≤ 6.4%.

GLP-1 and GIP/GLP-1 Agonist Polypharmacy

- Documentation of all of the following is required:
  - individual drug prior authorization criteria must be met first where applicable; **and**
  - member is transitioning from one GLP-1 or GIP/GLP-1 agonist to another, and prior GLP-1 or GIP/GLP-1 agonist use will be discontinued.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 27 - Antiemetics, Appetite Stimulants, and Anabolics

Drug Category: Gastrointestinal

Medication Class/Individual Agents: Antiemetics/5-HT3 Receptor Antagonists, Appetite Stimulants, and Anabolics

I. Prior-Authorization Requirements

Antiemetics, Appetite Stimulants, and Anabolics – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aprepitant 125 mg powder for oral suspension	Emend	PA - > 6 units/28 days	A90
aprepitant 40 mg, 125 mg capsule		PA - > 2 units/28 days	A90
aprepitant 80 mg	Emend	PA - > 4 units/28 days	# , A90
aprepitant injectable emulsion	Cinvanti	PA	
aprepitant trifold pack	Emend	PA - > 2 packs/28 days	A90
doxylamine / pyridoxine delayed-release	Diclegis	PA	BP, A90
doxylamine / pyridoxine extended-release	Bonjesta	PA	
dronabinol	Marinol	PA - > 2 units/day	#
fosaprepitant injection-Emend	Emend	PA - > 2 units/28 days	#
fosaprepitant injection-Focinvez	Focinvez	PA	
fosnetupitant / palonosetron injection	Akynzeo	PA - > 2 units/28 days	
megestrol 40 mg/mL suspension			A90
megestrol 625 mg/5 mL suspension		PA	A90
netupitant / palonosetron capsule	Akynzeo	PA - > 2 units/28 days	
scopolamine transdermal patch	Transderm-Scop		BP, A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Granisetron oral formulations are FDA approved for the prevention/treatment of chemotherapy-induced and radiation-induced nausea and vomiting.
- Ondansetron is FDA approved for the prevention/treatment of postoperative, chemotherapy-induced, and radiation-induced nausea and vomiting.
- Netupitant/palonosetron is FDA approved for prevention of acute and delayed chemotherapy-induced nausea and vomiting (CINV).
- Rolapitant is FDA approved in combination with other antiemetic agents for prevention of delayed CINV.
- Dronabinol is an orally active cannabinoid that is FDA approved for the treatment of cancer chemotherapy induced nausea and vomiting in members with an inadequate response to conventional antiemetic treatments.
- Dronabinol is also FDA approved for the management of anorexia associated with weight loss in members with acquired immune deficiency syndrome (AIDS).
- Orally active cannabinoids are recommended by the National Comprehensive Cancer Network (NCCN) as an option for the treatment of breakthrough nausea and vomiting as an addition to the appropriate prophylactic regimen of conventional antiemetics that is based upon

Antiemetics, Appetite Stimulants, and Anabolics – 5-HT3 Receptor Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dolasetron	Anzemet	PA	
granisetron extended-release injection	Sustol	PA - > 2 units/28 days	
granisetron injection			
granisetron tablet		PA - > 2 units/28 days	A90
granisetron transdermal system	Sancuso	PA	BP
ondansetron 16 mg orally disintegrating tablet		PA	A90
ondansetron 4 mg, 8 mg orally disintegrating tablet			A90
ondansetron injection			
ondansetron solution		PA - ≥ 13 years	A90
ondansetron tablet	Zofran		# , A90
palonosetron 0.25 mg/2 mL injection		PA - > 2 units/28 days	A90
palonosetron 0.25 mg/5 mL injection		PA - > 2 units/28 days	

Clinical Notes

emetogenicity of the chemotherapy regimen. The NCCN recommends that consideration can be given to the use of a cannabinoid in palliative care members; however, the NCCN recognizes that the use of cannabinoids in members with cancer-related anorexia has limited data to support this use.

- For the treatment of nausea and vomiting of pregnancy, initial pharmacotherapy includes pyridoxine. The combination of doxylamine and pyridoxine could be used when pyridoxine monotherapy fails to improve symptoms.

#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- AIDS-associated anorexia, cachexia, or weight loss
- Chemotherapy-induced nausea and vomiting (CINV)
- Nausea and vomiting of pregnancy (NVP)
- Osteoporosis-related bone pain
- Postoperative nausea and vomiting (PONV)
- Prevent weight loss/promote weight gain

- Radiation-induced nausea and vomiting (RINV)

Non-FDA-approved, for example:

- Anorexia of non-AIDS-related etiology or require appetite stimulation
- Appetite stimulation or relief from nausea/vomiting associated with a comorbid cancer diagnosis
- Nausea/vomiting of any etiology (not associated with chemotherapy or cyclic vomitting)
- PONV
- RINV
- Severe thermal burns

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Akynzeo, fosaprepitant injection, palonosetron, and Sustol injection > 2 units/28 days

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limit.

Anzemet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to to both of the following: granisetron tablet, ondansetron tablet or ODT.

aprepitant 40 mg capsule, 125 mg capsule, and trifold pack > 2 units/28 days

- Documentation of the following is required for the diagnosis of CINV:
  - appropriate diagnosis.
- Documentation of the following is required for the diagnosis of PONV:
  - appropriate diagnosis; **and**

- medical necessity for exceeding the quantity limit.

aprepitant 80 mg capsule > 4 units/28 days

- Documentation of the following is required for the diagnosis of CINV:
  - appropriate diagnosis.
- Documentation of the following is required for the diagnosis of PONV:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limit.

SmartPA: Claims for aprepitant (40 mg, 80 mg, 125 mg, trifold pack) above the established quantity limits will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims history of an antineoplastic medication in the last 60 days **or** has MassHealth medical claims for a CPT code for chemotherapy administration in the last 60 days.†

Bonjesta and doxylamine/pyridoxine delayed-release

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to combination therapy with doxylamine and pyridoxine; **and**
  - for Bonjesta, inadequate response or adverse reaction to doxylamine/pyridoxine delayed-release.

Cinvanti

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to oral aprepitant or fosaprepitant injection (Emend).

dronabinol capsule > 2 units/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limit.

Emend 125 mg powder for oral suspension > 6 units/28 days

- Documentation of the following is required for the diagnosis of CINV:
  - appropriate diagnosis.
- Documentation of the following is required for the diagnosis of PONV:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limit.

SmartPA: Claims for Emend 125 mg powder for oral suspension above the established quantity limits will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims history of an antineoplastic medication in the last 60 days **or** has MassHealth medical claims for a CPT code for chemotherapy administration in the last 60 days.†

Focinvez

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale for the use of the requested agent instead of fosaprepitant injection (Emend); **and**
  - requested quantity is ≤ 2 units/28 days.

granisetron tablet > 2 units/day

- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - CINV; **or**

- RINV; **and**
- one of the following:
  - medical necessity for exceeding the quantity limit; **or**
  - inadequate response, adverse reaction, or contraindication to ondansetron oral tablets or ODT and one of the following:
    - anti-cancer treatment regiment includes an oral agent; **or**
    - member requires additional breakthrough treatment for CINV and is already on an antiemetic agents from a different therapeutic class.

megestrol 625 mg/5 mL suspension

- Documentation of all of the following is required:
  - diagnosis of AIDS-associated anorexia, cachexia, or weight loss; **and**
  - medical records documenting an inadequate response or adverse reaction to one or contraindication to both of the following: megestrol 40 mg/mL suspension, megestrol tablet.
- For recertification, documentation of the following is required:
  - positive response to therapy including weight gain or no net weight loss from baseline; **or**
  - clinical rationale for continued therapy despite weight loss.

ondansetron 16 mg ODT

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale for use of the requested formulation instead of ondansetron ODT at an equivalent dose that is available without PA.

ondansetron solution for members ≥ 13 years of age

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the use of the solution formulation as noted by one of the following:
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - clinical rationale why conventional formulations cannot be used; **or**
    - provider notes the appropriate dose cannot be achieved without splitting a tablet.

Sancuso

- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - CINV; **or**
    - PONV; **or**
    - RINV; **and**
  - inadequate response, adverse reaction, or contraindication to ondansetron ODT.

IV. Pediatric Members

- ondansetron (Zofran) is FDA-approved for chemotherapy-associated nausea and vomiting in children ≥ four years of of age; however weight based dosing (I.V. product) is available for pediatric members ≥ six months of age.
- promethazine and prochlorperazine are FDA-approved for use in pediatric members ≥ two years of age.

Conventional Antiemetics (not all inclusive)			
Antihistamines	**Prokinetic**	**Phenothiazines**	**Anticholinergics**

dimenhydrinate diphenhydramine hydroxyzine meclizine	metoclopramide	prochlorperazine promethazine	scopolamine trimethobenzamide

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 28 - Antifungal Agents - Topical

Drug Category: Dermatological

Medication Class/Individual Agents: Antifungal

I. Prior-Authorization Requirements

Antifungal Agents: Topical – Imidazoles			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
clotrimazole			*, A90
clotrimazole / betamethasone cream			A90
clotrimazole / betamethasone lotion		PA	A90
econazole 1% cream			A90
efinaconazole	Jublia	PA	
ketoconazole cream, shampoo			A90
ketoconazole foam	Extina	PA	A90
luliconazole	Luzu	PA	A90
miconazole			*, A90
miconazole / zinc oxide ointment	Vusion		BP, A90
oxiconazole cream		PA	A90
oxiconazole lotion	Oxistat	PA	
sertaconazole	Ertaczo	PA	

Antifungal Agents: Topical – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ciclopirox 0.77% cream	Loprox		# , A90
ciclopirox 0.77% suspension	Loprox	PA	A90
ciclopirox 1% shampoo, 0.77% gel		PA	A90
ciclopirox 8% nail lacquer			A90
tavaborole		PA	A90
tolnaftate cream, powder			*, A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Dermatophyte infections routinely affect otherwise healthy individuals.
- Immunocompromised members are particularly susceptible to fungal infections.
- Topical antifungals are considered first-line therapy for most dermatophyte infections.
- Products are usually applied once or twice daily for two to four weeks (depending on the location).
- Combination products may prolong treatment and delay disease resolution.
- Onychomycosis requires 48 weeks of topical ciclopirox treatment.
- Ciclopirox nail lacquer demonstrates a minimally better cure rate versus placebo.

Antifungal Agents: Topical – Benzylamine			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
butenafine	Mentax		

Antifungal Agents: Topical – Allymines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
naftifine	Naftin	PA	A90
terbinafine 1% cream			*, A90

Antifungal Agents: Topical – Polyenes			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
nystatin / triamcinolone cream, ointment			A90
nystatin cream, ointment, 100,000 powder			A90

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Onychomycosis – Jublia and tavaborole
- Seborrheic dermatitis – ciclopirox and ketoconazole
- Superficial tinea or candida (fungal) infections
- Vulvovaginal candidiasis – vaginal formulations only

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to

satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

ciclopirox 0.77% gel

- Documentation of all of the following is required for a diagnosis of seborrheic dermatitis of the scalp:
  - appropriate diagnosis; **and**
  - inadequate response (within the last 90 days), adverse reaction, or contraindication to both of the following:
    - ciclopirox 1% shampoo; **and**
    - ketoconazole shampoo.
- Documentation of all of the following is required for a diagnosis of tinea corporis or tinea pedis:
  - appropriate diagnosis; **and**
  - inadequate response (within the last 90 days), adverse reaction, or contraindication to ciclopirox 0.77% cream; **and**
  - inadequate response (within the last 90 days) or adverse reaction to one or contraindication to all of the following available without PA:
    - topical allylamine (e.g., terbinafine, tolnaftate); **or**
    - topical azole antifungal (e.g., clotrimazole, econazole, ketoconazole, miconazole); **or**
    - topical butenafine.

ciclopirox 1% shampoo

- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - seborrheic dermatitis of the scalp; **or**
    - tinea capitis; **and**
  - inadequate response (within the last 90 days), adverse reaction, or contraindication to ketoconazole shampoo.

SmartPA: Claims for ciclopirox 1% shampoo will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for ketoconazole shampoo within the last 90 days.†

ciclopirox 0.77% suspension

- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - cutaneous candidiasis; **or**
    - tinea corporis; **or**
    - tinea cruris; **or**
    - tinea pedis; **or**
    - tinea versicolor; **and**
  - inadequate response (within the last 90 days), adverse reaction, or contraindication to ciclopirox 0.77% cream.

SmartPA: Claims for ciclopirox 0.77% suspension will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for ciclopirox 0.77% cream within the last 90 days.†

clotrimazole/betamethasone lotion

- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - tinea corporis; **or**
    - tinea cruris; **or**
    - tinea pedis; **and**
  - inadequate response (within the last 90 days), adverse reaction, or contraindication to clotrimazole/betamethasone cream.

SmartPA: Claims for clotrimazole/betamethasone lotion will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for clotrimazole/betamethasone cream within the last 90 days.†

Jublia, tavaborole

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to itraconazole or terbinafine oral tablets; **or**
    - medical necessity for topical formulation **and** inadequate response to 24 consecutive weeks of therapy or adverse reaction to ciclopirox nail solution; **or**
    - contraindication to all of the following: ciclopirox nail solution, itraconazole oral therapy and terbinafine oral tablets; **and**
  - for tavaborole, medical records documenting inadequate response to 48 weeks of therapy, adverse reaction, or contraindication to Jublia.

ketoconazole foam

- Documentation of all of the following is required for a diagnosis of seborrheic dermatitis of the scalp:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response (within the last 90 days) or adverse reaction to one or contraindication to both of the following:
    - ciclopirox gel; **or**
    - ciclopirox shampoo; **and**
  - inadequate response (within the last 90 days), adverse reaction, or contraindication to ketoconazole shampoo.
- Documentation of all of the following is required for a diagnosis of non-scalp seborrheic dermatitis:
  - appropriate diagnosis; **and**
  - inadequate response (within the last 90 days), adverse reaction, or contraindication to both of the following:
    - one topical azole antifungal available without PA; **or**
    - ciclopirox cream.

luliconazole, naftifine cream, Naftin 1% gel, oxiconazole

- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - tinea corporis; **or**
    - tinea cruris; **or**
    - tinea pedis; **and**
  - inadequate response (within the last 90 days) or adverse reaction to two or contraindication to all of the following available without PA:
    - topical allylamine (e.g., terbinafine, tolnaftate); **or**
    - topical azole antifungal (e.g., clotrimazole, econazole, ketoconazole, miconazole); **or**

- topical butenafine; **or**
- topical ciclopirox.

SmartPA: Claims for luliconazole, naftifine cream, Naftin 1% gel, and oxiconazole will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two of the following available without PA within the last 90 days: topical allylamine (e.g., terbinafine, tolnaftate), topical azole antifungal (e.g., clotrimazole, econazole, ketoconazole, miconazole), topical butenafine, topical ciclopirox.†

naftifine 2% gel

- Documentation of all of the following is required:
  - diagnosis of interdigital tinea pedis infection; **and**
  - inadequate response (within the last 90 days) or adverse reaction to two or contraindication to all of the following available without PA:
    - topical allylamine (e.g., terbinafine, tolnaftate); **or**
    - topical azole antifungal (e.g., clotrimazole, econazole, ketoconazole, miconazole); **or**
    - topical butenafine; **or**
    - topical ciclopirox.

SmartPA: Claims for naftifine 2% gel will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two of the following available without PA within the last 90 days: topical allylamine (e.g., terbinafine, tolnaftate), topical azole antifungal (e.g., clotrimazole, econazole, ketoconazole, miconazole), topical butenafine, topical ciclopirox.†

tolnaftate liquid

- Documentation of the following is required:
  - diagnosis of one of the following:
    - tinea corporis; **or**
    - tinea cruris; **or**
    - tinea pedis; **and**
  - inadequate response (within the last 90 days) or adverse reaction to two or contraindication to all of the following available without PA:
    - topical azole antifungal (e.g., clotrimazole, econazole, ketoconazole, miconazole); **or**
    - topical butenafine; **or**
    - topical ciclopirox; **and**
  - inadequate response (within the last 90 days), adverse reaction, or contraindication to tolnaftate powder.

SmartPA: Claims for tolnaftate liquid will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for tolnaftate powder and two of the following available without PA within the last 90 days: topical azole antifungal (e.g., clotrimazole, econazole, ketoconazole, miconazole), topical butenafine, topical ciclopirox.†

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria

Table 29 - Anti-Allergy and Anti-Inflammatory Agents - Ophthalmic

Drug Category: Anti-Allergy and Anti-Inflammatory Agents - Ophthalmic

Medication Class/Individual Agents: Anti-Allergy and Anti-Inflammatory Agents - Ophthalmic

I. Prior-Authorization Requirements

Ophthalmic Anti-Allergy and Anti-Inflammatory Agents – NSAIDs			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bromfenac 0.07%	Prolensa		BP, A90
bromfenac 0.075%	Bromsite	PA	A90
bromfenac 0.09%		PA	A90
diclofenac ophthalmic solution			A90
flurbiprofen ophthalmic solution			A90
ketorolac 0.4% ophthalmic solution	Acular LS		# , A90
ketorolac 0.45% ophthalmic solution	Acuvail		
ketorolac 0.5% ophthalmic solution	Acular		# , A90
nepafenac 0.1% ophthalmic suspension	Nevanac		
nepafenac 0.3% ophthalmic suspension	Ilevro	PA	

Ophthalmic Anti-Allergy and Anti-Inflammatory Agents – Mast Cell Stabilizers			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cromolyn ophthalmic			A90
lodoxamide	Alomide		

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Nonpharmacologic treatments, such as allergen avoidance, cold compress, and lubrication to remove the allergen, may provide relief.
- Products containing vasoconstrictors may cause rebound redness if used more frequently than the recommended treatment duration.
- The dropper tip should not touch the eye in order to prevent contaminating the bottle.
- Remove contact lenses before instilling eye drops as some preservatives in ocular products may be absorbed by soft contact lenses.
- *FDA-approved ages:*
  - ≥ 18 years of age: bromfenac, cyclosporine 0.09%, dexamethasone, diclofenac, difluprednate, flurbiprofen, hydroxypropyl cellulose ophthalmic insert, loteprednol, prednisolone
  - ≥ 17 years of age: lifitegrast
  - ≥ 16 years of age: cyclosporine 0.05%
  - ≥ ten years of age: nepafenac
  - ≥ three years of age: azelastine, ketotifen, ketorolac tromethamine 0.4%, nedocromil
  - ≥ two years of age: alcaftadine, bepotastine, cetirizine, epinastine, fluorometholone, ketorolac tromethamine 0.5%, lodoxamide, olopatadine

Ophthalmic Anti-Allergy and Anti-Inflammatory Agents – Corticosteroids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dexamethasone intravitreal implant	Ozurdex		MB
dexamethasone ophthalmic insert	Dextenza		MB
dexamethasone ophthalmic suspension	Maxidex		
dexamethasone sodium phosphate ophthalmic solution			A90
difluprednate	Durezol		# , A90
fluorometholone	FML		# , A90
fluorometholone acetate	Flarex		
loteprednol 0.2%	Alrex		# , A90
loteprednol 0.25% suspension	Eysuvis	PA	
loteprednol 0.38% gel	Lotemax SM	PA	
loteprednol 0.5%	Lotemax		BP, A90
loteprednol 1% suspension	Inveltys	PA	
prednisolone acetate 0.12% ophthalmic suspension	Pred Mild		
prednisolone acetate 1% ophthalmic suspension	Pred Forte		# , A90
prednisolone sodium phosphate ophthalmic solution			A90

Ophthalmic Anti-Allergy and Anti-Inflammatory Agents – Antihistamines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alcaftadine			A90
bepotastine	Bepreve		BP, A90
cetirizine ophthalmic solution	Zerviate	PA	
ketotifen			*, A90

Clinical Notes

Pregnancy:

alcaftadine, cetirizine, lodoxamide, and nedocromil are pregnancy category B; the rest of the ophthalmic anti-allergy agents are pregnancy category C.

Ophthalmic Anti-Allergy and Anti-Inflammatory Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
artificial tears			*, A90
cyclosporine 0.05% ophthalmic emulsion	Restasis		BP, A90
cyclosporine 0.09% ophthalmic solution	Cequa	PA	
cyclosporine 0.1% ophthalmic emulsion	Verkazia	PA	
cyclosporine 0.1% ophthalmic solution	Vevye	PA	
cyclosporine multidose 0.05% ophthalmic emulsion	Restasis Multidose	PA	
hydroxypropyl cellulose ophthalmic insert	Lacrisert		
lifitegrast	Xiidra	PA	
lotilaner	Xdemvy	PA	
naphazoline			*
naphazoline / pheniramine	Naphcon-A		A90
naphazoline / pheniramine	Opcon-A		A90
perfluorohexyloctane	Miebo	PA	
varenicline nasal spray	Tyrvaya	PA	

Ophthalmic Anti-Allergy and Anti-Inflammatory Agents – Mast Cell Stabilizer /Antihistamine			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
azelastine ophthalmic solution			A90
epinastine			A90
olopatadine ophthalmic solution			A90

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Perennial (chronic) or seasonal (short term) allergic conjunctivitis (Zerviate)
- Postoperative pain and inflammation following ocular surgery (bromfenac 0.09%, Bromsite, Ilevro, Inveltys, Lotemax SM)
- Keratoconjunctivitis sicca (KCS)/dry eyes (Cequa, Eysuvis, Miebo, Restasis Multidose, Tyrvaya, Vevye, Xdemvy, Xiidra)
- Vernal keratoconjunctivitis (Verkazia)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

bromfenac 0.09% and Bromsite

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- member is ≥ 18 years of age; **and**
- inadequate response or adverse reaction to bromfenac 0.07% opthalmic solution.

Cequa
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to cyclosporine 0.05% ophthalmic emulsion; **and**
  - requested quantity is ≤ two units/day.

SmartPA: Claims for Cequa will usually process at the pharmacy without a PA request for a quantity of ≤ two units/day if the member is ≥ 18 years of age and there is a history of paid MassHealth pharmacy claims for at least 90 out of the last 120 days for Cequa **or** if there is a history of paid claims for cyclosporine 0.05% ophthalmic solution in the last 90 days.†

Eysuvis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all topical corticosteroids for ophthalmic use available without PA; **and**
  - inadequate response, adverse reaction, or contraindication to cyclosporine 0.05% ophthalmic emulsion; **and**
  - requested duration is ≤ two weeks.

Ilevro
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ ten years of age; **and**
  - inadequate response or adverse reaction to nepafenac 0.1% ophthalmic suspension.

Inveltys and Lotemax SM (for postoperative pain and inflammation)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to loteprednol 0.5% ophthalmic gel, ointment, or suspension.

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Miebo and Tyrvaya
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: cyclosporine 0.05% ophthalmic emulsion and Xiidra; **and**
  - one of the following:
    - for Miebo, requested quantity is ≤ three mL/30 days; **or**
    - for Tyrvaya, requested quantity is ≤ 8.4 mL/30 days.

Restasis Multidose

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 16 years of age; **and**
  - medical necessity for use of multidose formulation instead of cyclosporine 0.05% ophthalmic emulsion (single use vial formulation); **and**
  - requested quantity is ≤ one unit/28 days.

Verkazia
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ four years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: azelastine ophthalmic solution, epinastine, ketotifen, olopatadine ophthalmic solution; **and**
  - inadequate response or adverse reaction to one or contraindication to all topical corticosteroids for ophthalmic use; **and**
  - requested quantity is ≤ four units/day.

Vevye
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: cyclosporine 0.05% ophthalmic emulsion, cyclosporine 0.09% ophthalmic emulsion, Xiidra, and Tyraya; **and**
  - requested quantity is ≤ two mL/50 days.

Xdemvy
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is an ophthalmologist or optometrist or consult notes from an ophthalmologist or optometrist are provided; **and**
  - requested quantity is ≤ ten mL for one course of therapy.

Xiidra
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 17 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to cyclosporine 0.05% ophthalmic emulsion; **and**
  - requested quantity is ≤ two units/day.

SmartPA: Claims for Xiidra will usually process at the pharmacy without a PA request for a quantity of ≤ two units/day if the member is ≥ 17 years of age and there is a history of paid MassHealth pharmacy claims for at least 90 out of the last 120 days for Xiidra **or** if there is a history of paid MassHealth pharmacy claims for cyclosporine 0.05% ophthalmic solution in the last 90 days.†

Zerviate for members ≥ three years of age
- Documentation of the following is required:
  - an appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to two or contraindication to all of the following: alcaftadine, Alomide, azelastine ophthalmic solution, bepotastine, epinastine, ketotifen, olopatadine ophthalmic solution; **or**
    - both of the following:

- diagnosis of vernal keratoconjunctivitis or atopic keratoconjunctivitis; **and**
- inadequate response or adverse reaction to one or contraindication to all of the following: azelastine ophthalmic solution, epinastine, ketotifen, olopatadine ophthalmic solution.

Zerviate for members ≥ two to < three years of age

- Documentation of the following is required:
  - an appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to two or contraindication to all of the following: alcaftadine, Alomide, bepotastine, epinastine, olopatadine ophthalmic solution; **or**
    - both of the following:
      - diagnosis of vernal keratoconjunctivitis or atopic keratoconjunctivitis; **and**
      - inadequate response or adverse reaction to one or contraindication to all of the following: bepotastine, epinastine, olopatadine ophthalmic solution.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 30 - Neuromuscular Blocker Agents

Drug Category: Muscle

Medication Class/Individual Agents: Neuromuscular Blockers

I. Prior-Authorization Requirements

Botulinum Toxins (Types A and B)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
abobotulinumtoxinA	Dysport	PA	
daxibotulinumtoxinA-lanm	Daxxify	PA	
incobotulinumtoxinA	Xeomin	PA	
onabotulinumtoxinA	Botox	PA	
rimabotulinumtoxinB	Myobloc	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Additional information:

- Due to the formation of antibodies, patients may develop resistance to Type A after repeated use. In these cases, Type B may be an alternative because antibodies to Type A and B do not cross-react.
- Units of biological activity cannot be directly converted between Botulinum Types A and B.
- There is also a difference in relative potencies between products distributed in North America and elsewhere.

Contraindications:

- Infection at the proposed injection site

Warnings:

- Recommended dose and frequency should not be exceeded. Risks with higher doses are unknown.
- Hypersensitivity reactions
- Preexisting neuromuscular disorders
- Dysphagia
- Human albumin (both products contain albumin)

II. Therapeutic Uses

FDA-approved, for example:

- Blepharospasm–Botox, Xeomin

- Cervical dystonia–Botox, Daxxify, Dysport, Myobloc, Xeomin
- Lower limb spasticity–Botox, Dysport
- Migraine prophylaxis–Botox
- Neurogenic detrusor overactivity–Botox
- Overactive bladder–Botox
- Severe primary axillary hyperhidrosis in adults–Botox
- Sialorrhea–Myobloc, Xeomin
- Strabismus–Botox
- Upper limb spasticity–Botox, Dysport, Xeomin
- Urinary incontinence associated with neurologic conditions–Botox

non-FDA-approved, for example:

- Achalasia or esophageal dysphagia–Botox, Dysport
- Anal fissures–Botox, Dysport, Myobloc, Xeomin
- Anal stenosis, chronic constipation, or encopresis–Botox
- Gastroparesis–Botox, Dysport, Myobloc, Xeomin
- Migraine prophylaxis (concomitant therapy with a CGRP inhibitor)–Botox
- Migraine prophylaxis (dosing frequency every ten weeks)–Botox
- Myofascial pain syndrome–Botox
- Myofascial pelvic pain syndrome–Botox
- Severe craniofacial hyperhidrosis–Botox
- Severe primary axillary hyperhidrosis in pediatrics–Botox
- Severe palmar or plantar hyperhidrosis–Botox
- Sialorrhea–Botox
- Raynaud's phenomenon–Botox
- Trigeminal neuralgia–Botox

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member’s condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member’s current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Botox

- Documentation of all of the following is required for achalasia or esophageal dysphagia:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - one of the following:
    - member has failed a surgical option; **or**
    - member is not a surgical candidate or is unwilling to undergo surgical procedure; **and**
  - initial requested dose is ≤ 100 units no more frequently than every six months.
- Documentation of all of the following is required for anal fissures:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: topical nifedipine, topical nitroglycerin.
- Documentation of all of the following is required for anal stenosis, chronic constipation, or encopresis:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response or adverse reaction to two or contraindication to all laxatives; **and**
  - inadequate response to dietary changes (e.g., increased intake of fluids and fiber) and/or behavior modification (e.g., biofeedback training, toilet training); and
  - initial requested dose is ≤ 100 units no more frequently than every three months.
- Documentation of all of the following is required for blepharospasm associated with dystonia, cervical dystonia, limb spasticity, and strabismus:
  - appropriate diagnosis; **and**
  - appropriate dosing for requested indication (for pediatric members, child's weight must be provided).
- Documentation of all of the following is required for gastroparesis:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response, adverse reaction, or contraindication to metoclopramide; **and**
  - inadequate response or adverse reaction to one or contraindication to all antiemetics.
- Documentation of all of the following is required for migraine prophylaxis:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist, pain medicine/anesthesiology physician, or physical medicine/rehabilitation physician, or consult notes from a specialist are provided; **and**
  - migraine headache frequency of ≥ 15 days/30 days; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: atenolol, metoprolol, nadolol, propranolol, timolol; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: amitriptyline, topiramate, valproic acid, venlafaxine; **and**
  - appropriate dosing for requested indication; **and**
  - for a dosing frequency of every ten weeks, both of the following:
    - member received initial positive response to therapy; **and**
    - member is experiencing a "wearing-off" or efficacy after a dose increase to 195 units; **and**
  - for concomitant therapy with a CGRP inhibitor, a partial, but incomplete, response to a CGRP inhibitor.
- Documentation of all of the following is required for myofascial pain syndrome:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: cyclobenzaprine, gabapentin or pregabalin, local anesthetic, SNRI, TCA agent; **and**

    - approriate dosing (up to a total dose of 200 units).
- Documentation of all of the following is required for myofascial pelvic pain syndrome:
    - appropriate diagnosis; **and**
    - inadequate response or adverse reaction to two or contraindication to all of the following: gabapentin or pregabalin, muscle relaxant, SNRI, TCA agent, vaginal diazepam; **and**
    - approriate dosing (up to a total dose of 300 units).
- Documentation of all of the following is required for neurogenic bladder dysfunction or neurogenic detrusor overactivity in adults:
    - appropriate diagnosis; **and**
    - prescriber is a urologist or consult notes from a urologist are provided; **and**
    - inadequate response or adverse reaction to one or contraindication to all of the following classes:
        - two anticholinergic medications; **or**
        - one anticholinergic medication and one cholinergic agent; **or**
        - one anticholinergic medication and one alpha blocker; **or**
    - appropriate dosing for requested indication.
- Documentation of all of the following is required for neurogenic bladder dysfunction or neurogenic detrusor overactivity in pediatrics:
    - appropriate diagnosis; **and**
    - prescriber is a urologist or consult notes from a urologist are provided; **and**
    - inadequate response or adverse reaction to one or contraindication to both of the following classes:
        - one anticholinergic medication; **or**
        - one beta-3 adrenergic receptor agonist; **and**
    - appropriate dosing for requested indication.
- Documentation of all of the following is required for overactive bladder (including urinary urgency with or without incontinence, nocturia, or urinary frequency):
    - appropriate diagnosis; **and**
    - prescriber is a urologist or consult notes from a urologist are provided; **and**
    - inadequate response or adverse reaction to one or contraindication to both of the following: two anticholinergic medications or one anticholinergic medication and one beta-3 adreneric receptor agonist; **and**
    - appropriate dosing for requested indication.
- Documentation of all of the following is required for Raynaud's Phenomenon:
    - appropriate diagnosis; **and**
    - inadequate response or adverse reaction to three or contraindication to all of the following: a calcium channel blocker (amlodipine or nifedipine), fluoxetine, losartan, a PDE type 5 inhibitor, a topical nitrate; **and**
    - requested dose is ≤ 200 units/90 days.
- Documentation of all of the following is required for severe craniofacial hyperhidrosis:
    - appropriate diagnosis; **and**
    - prescriber is a dermatologist or neurologist or consult notes from a dermatologist or neurologist are provided; **and**
    - inadequate response or adverse reaction to one or contraindication to all of the following: aluminum chloride solution, oral glycopyrrolate, oral oxybutynin; **and**
    - appropriate dosing (areas to be injected must be provided).
- Documentation of all of the following is required for severe primary axillary hyperhidrosis in adults:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - prescriber is a dermatologist or neurologist or consult notes from a dermatologist or neurologist are provided; **and**
    - inadequate response, adverse reaction, or contraindication to aluminum chloride solution; **and**
    - appropriate dosing for requested indication.
- Documentation of all of the following is required for severe primary axillary hyperhidrosis in pediatrics:
    - appropriate diagnosis; **and**

- member is 12 to ≤ 18 years of age; **and**
- prescriber is a dermatologist or neurologist or consult notes from a dermatologist or neurologist are provided; **and**
- inadequate response, adverse reaction, or contraindication to aluminum chloride solution; **and**
- appropriate dosing for requested indication.

- Documentation of all of the following is required for escalated dosing in severe axillary hyperhidrosis:
  - appropriate diagnosis; and
  - prescriber is a dermatologist or neurologist or consult notes from a dermatologist or neurologist are provided; and
  - inadequate response to FDA-approved dosing of 50 units per axilla; and
  - requested dose is ≤ 200 units per axilla.
- Documentation of all of the following is required for severe palmar or plantar hyperhidrosis:
  - appropriate diagnosis; **and**
  - prescriber is a dermatologist or neurologist or consult notes from a dermatologist or neurologist are provided; **and**
  - inadequate response, adverse reaction, or contraindication to aluminum chloride solution; **and**
  - appropriate dosing for requested indication.
- Documentation of all of the following is required for sialorrhea:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: atropine, glycopyrrolate, hyoscyamine, scopolamine, a tricyclic antidepressant; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: Myobloc, Xeomin; **and**
  - appropriate dosing (40 to 100 units every three to six months).
- Documentation of all of the following is required for trigeminal neuralgia:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or physical medicine/rehabilitation physician or consult notes from a specialist are provided; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: baclofen, carbamazepine, gabapentin, lamotrigine, oxcarbazepine, tizanidine, topiramate; **and**
  - appropriate dosing.

SmartPA: Claims for Botox ≤ 600 units will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for cerebral palsy and if MassHealth pharmacy claims indicate at least 70 days have passed since the last paid claim for Botox.†

Daxxify

- Documentation of all of the following is required for cervical dystonia/spasmodic torticollis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing.

Dysport

- Documentation of all of the following is required for achalasia or esophageal dysphagia:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - one of the following:
    - member has failed a surgical option; **or**
    - member is not a surgical candidate or is unwilling to undergo surgical procedure; **and**
  - initial requested dose is ≤ 250 units no more frequently than every six months.
- Documentation of all of the following is required for anal fissures:
  - appropriate diagnosis; **and**

- prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
- inadequate response or adverse reaction to one or contraindication to both of the following: topical nifedipine, topical nitroglycerin.

- Documentation of all of the following is required for cervical dystonia:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing for requested indication.
- Documentation of all of the following is required for gastroparesis:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response, adverse reaction, or contraindication to metoclopramide; **and**
  - inadequate response or adverse reaction to one or contraindication to all antiemetics.
- Documentation of all of the following is required for upper limb spasticity and lower limb spasticity:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - appropriate dosing for requested indication (for pediatric members, child's weight must be provided).

Myobloc

- Documentation of all of the following is required for anal fissures:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: topical nifedipine, topical nitroglycerin.
- Documentation of all of the following is required for cervical dystonia:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing for requested indication.
- Documentation of all of the following is required for gastroparesis:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response, adverse reaction, or contraindication to metoclopramide; **and**
  - inadequate response or adverse reaction to one or contraindication to all antiemetics.
- Documentation of all of the following is required for sialorrhea:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: atropine, glycopyrrolate, hyoscyamine, scopolamine, a TCA agent; **and**
  - appropriate dosing for requested indication.

Xeomin

- Documentation of all of the following is required for anal fissures:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: topical nifedipine, topical nitroglycerin.
- Documentation of all of the following is required for blepharospasm and cervical dystonia:
  - an appropriate diagnosis; **and**

- member is ≥ 18 years of age; **and**
- appropriate dosing for requested indication.

- Documentation of all of the following is required for gastroparesis:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response, adverse reaction, or contraindication to metoclopramide; **and**
  - inadequate response or adverse reaction to one or contraindication to all antiemetics.
- Documentation of all of the following is required for sialorrhea:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: atropine, glycopyrrolate, hyoscyamine, scopolamine, a TCA agent; **and**
  - appropriate dosing for requested indication (for pediatric members, child's weight must be provided).
- Documentation of all of the following is required for upper limb spasticity:
  - an appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - if member is <18 years of age, spasticity is not caused by cerebral palsy; **and**
  - appropriate dosing for requested indication (for pediatric members, child's weight must be provided).

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 31 - Cerebral Stimulants and Miscellaneous Agents

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Cerebral Stimulant

I. Prior-Authorization Requirements

Cerebral Stimulants and Miscellaneous Agents – Short-and Intermediate-Acting Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amphetamine salts	Adderall	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#
amphetamine sulfate		PA	
amphetamine sulfate orally disintegrating tablet	Evekeo ODT	PA	
dexmethylphenidate	Focalin	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#
dextroamphetamine 2.5 mg, 7.5 mg, 15 mg, 20 mg, 30 mg tablet		PA	
dextroamphetamine 5 mg, 10 mg tablet		PA - < 3 years or ≥ 21 years and PA > 3 units/day	
dextroamphetamine 5 mg, 10 mg, 15 mg capsule	Dexedrine Spansule	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#
dextroamphetamine solution		PA - < 3 years or ≥ 21 years and PA > 40 mL/day	
methamphetamine	Desoxyn	PA	
methylphenidate chewable tablet		PA - < 3 years or ≥ 21 years and PA > 3 units/day	
methylphenidate oral solution	Methylin oral solution	PA - < 3 years or ≥ 21 years and PA > 30 mL/day	#
methylphenidate sustained-release tablet		PA - < 3 years or ≥ 21 years and PA > 3 units/day	
methylphenidate-Ritalin	Ritalin	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Concurrent therapy with long-acting agents will require PA for quantities > two units/day (all agents combined). Concurrent therapy with a short- or intermediate-acting agent and a long-acting agent will also require PA for quantities > three units/day (all agents combined). Cerebral stimulant solutions will require PA for quantities > 40 mL/day (all agents combined). Individual drug quantity limits may also apply (see reference table below for individual drug quantity limits and dose consolidation options).

FDA-approved indications:

- Attention Deficit Hyperactivity Disorder (ADHD)
- Narcolepsy
- Binge-eating disorder (lisdexamfetamine)

Approved medications for ADHD according to age:

- ≥ six years of age: all cerebral stimulants, atomoxetine, clonidine extended-release 0.1 mg tablet, guanfacine extended-release, viloxazine
- ≥ three to < six years of age: short-acting dextroamphetamine/amphetamine, short- and

Cerebral Stimulants and Miscellaneous Agents – Long-Acting Amphetamine Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amphetamine extended-release 1.25 mg/mL oral suspension		PA	
amphetamine extended-release 2.5 mg/mL oral suspension	Dyanavel XR	PA	
amphetamine extended-release chewable tablet	Dyanavel XR	PA	
amphetamine extended-release orally disintegrating tablet	Adzenys XR-ODT	PA	BP
amphetamine salts extended-release-Adderall XR	Adderall XR PD	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
amphetamine salts extended-release-Mydayis	Mydayis	PA	
dextroamphetamine transdermal	Xelstrym	PA	
lisdexamfetamine capsule	Vyvanse	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
lisdexamfetamine chewable tablet	Vyvanse	PA	BP

Cerebral Stimulants and Miscellaneous Agents – Long-Acting Methylphenidate Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dexmethylphenidate extended-release	Focalin XR	PA - < 3 years or ≥ 21 years and PA > 2 units/day	#
methylphenidate extended-release 72 mg tablet		PA	
methylphenidate extended-release chewable tablet	Quillichew ER	PA	
methylphenidate extended-release oral suspension	Quillivant XR	PA	
methylphenidate extended-release orally disintegrating tablet	Cotempla XR-ODT	PA	

Clinical Notes

intermediate-acting mixed amphetamine salts, dextroamphetamine and amphetamine sulfate

Approved medications for narcolepsy:

- Short- or intermediate-acting mixed amphetamine salts, dextroamphetamine, and methylphenidate
- modafinil
- solriamfetol
- pitolisant

Precautionary use in:

- advanced arteriosclerosis, symptomatic cardiovascular disease, moderate-to-severe hypertension, hyperthyroidism, glaucoma, motor tics, Tourette syndrome, and seizure disorders
- psychologically agitated states, history of drug abuse
- MAO inhibitor use within 14 days

The American Academy of Pediatrics (AAP) suggests evidence is particularly strong for stimulant medications for elementary and school-aged children and adolescents. Adjunctive therapies (guanfacine extended-release and clonidine extended-release 0.1 mg tablet) may be considered if stimulant therapy is not fully effective or limited by side effects. Atomoxetine has also demonstrated efficacy in reducing core symptoms among school-aged children and adolescents (AAP, 2019).

Cerebral Stimulants and Miscellaneous Agents – Long-Acting Methylphenidate Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
methylphenidate extended-release, CD		PA	
methylphenidate extended-release-Aptensio XR	Aptensio XR	PA	
methylphenidate extended-release-Concerta	Concerta	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
methylphenidate extended-release-Jornay PM	Jornay PM	PA	
methylphenidate extended-release-Relexxii	Relexxii	PA	
methylphenidate transdermal	Daytrana	PA - < 3 years or ≥ 21 years and PA > 1 unit/day	BP
methylphenidate-Ritalin LA	Ritalin LA	PA	
serdexmethylphenidate / dexmethylphenidate	Azstarys	PA	

Cerebral Stimulants and Miscellaneous Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
atomoxetine	Strattera	PA - < 6 years	# , A90
clonidine extended-release 0.1 mg tablet		PA - < 3 years and PA > 4 units/day	A90
clonidine extended-release suspension	Onyda XR	PA	
guanfacine extended-release	Intuniv	PA - < 3 years	# , A90
viloxazine	Qelbree	PA	

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Attention Deficit Hyperactivity Disorder (ADHD)
- Narcolepsy
- Binge-eating disorder (lisdexamfetamine)

Non-FDA-approved, for example:

- Autism spectrum disorder
- Binge-eating disorder (all other cerebral stimulant agents)
- Depressive condition (as adjunctive treatment)
- Excessive sleepiness or fatigue associated with a chronic medical condition such as: cancer-related fatigue, multiple sclerosis, Parkinson's disease
- Sleep disorder (hypersomnia, obstructive sleep apnea, shift work disorder)
- Traumatic brain injury

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency for all stimulants prescribed.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member’s condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member’s current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

All requests for cerebral stimulants at quantities above established quantity limits (per day)

- Documentation of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - medical necessity for an increased dosage that results in requiring quantities that exceed the determined limits (see reference table below for individual drug quantity limits and dose consolidation options)

All requests for cerebral stimulants in members ≥ 21 years of age (new to therapy)

- Documentation of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - individual drug quantity limits must be met first where applicable; **and**
  - clinically appropriate diagnosis including:
    - ADHD; **or**
    - autism spectrum disorder; **or**
    - binge eating disorder; **or**
    - depressive condition (as adjunctive treatment); **or**
    - excessive sleepiness or fatigue associated with a chronic medical condition such as: cancer-related fatigue, multiple sclerosis, Parkinson's disease; **or**
    - narcolepsy; **or**
    - sleep disorder (hypersomnia, obstructive sleep apnea, shift work disorder); **or**
    - traumatic brain injury.

Please note, three-month provisional approval may be allowed for members who were stabilized on the requested medication during a recent hospitalization.

SmartPA: Claims for amphetamine salts, amphetamine salts ER, Daytrana, dextroamphetamine (5 mg and 10 mg tablet, 5 mg, 10 mg, and 15 mg capsule, or solution), dexmethylphenidate, dexmethylphenidate ER, lisdexamfetamine capsule, methylphenidate (Ritalin), methylphenidate ER (Concerta), methylphenidate oral solution, methylphenidate SR, and methylphenidate chewable tablet within quantity limits will usually process at the pharmacy without a PA request if the member is ≥ 21 years of age and has a history of a paid MassHealth pharmacy claims for a CNS stimulant within the last 90 days, or if the member is ≥ 21 years of age and has an appropriate diagnosis in history.†

Adzenys XR-ODT, amphetamine extended-release 1.25 mg/mL oral suspension, amphetamine salts extended-release (generic Mydayis), Dyanavel XR, lisdexamfetamine chewable tablet, Xelstrym

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - for amphetamine salts extended-release (generic Mydayis), member is ≥ 13 years of age; **and**
  - clinical rationale for use of the requested agent instead of amphetamine salts extended-release (generic Adderall XR); **and**
  - clinical rationale for use of the requested agent instead of lisdexamfetamine capsule; **and**
  - for Dyanavel XR suspension, one of the following:
    - requested quantity is ≤8 mL (20 mg)/day; **or**
    - clinical rationale for exceeding the FDA approved maximum dose.

amphetamine sulfate

- Documentation of the following is required for diagnosis of ADHD:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ seven days of therapy) or adverse reaction to one amphetamine immediate-release product available without PA; **or**
    - clinical rationale for use of the requested agent instead of amphetamine immediate-release products available without PA.
- Documentation of the following is required for diagnosis of narcolepsy:
  - appropriate diagnosis; **and**
  - medical records documenting the results of the sleep study used to confirm narcolepsy [polysomnogram (PSG) or Multiple Sleep Latency Test (MSLT)]; **and**
  - one of the following:
    - inadequate response (defined as ≥ seven days of therapy) or adverse reaction to one amphetamine immediate-release product available without PA; **or**

- clinical rationale for use of the requested agent instead of amphetamine immediate-release products available without PA.

Azstarys, Cotempla XR-ODT, Jornay PM, methylphenidate extended-release (generic Aptensio XR), Quillichew ER, Quillivant XR

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale for use of the requested agent instead of dexmethylphenidate extended-release; **and**
  - clinical rationale for use of the requested agent instead of methylphenidate transdermal; **and**
  - one of the following:
    - medical necessity for requested formulation instead of solid oral formulations as noted by one of the following:
      - member utilizes tube feeding (G-tube/J-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
      - member is < 13 years of age; **or**
    - clinical rationale for use of the requested agent instead of methylphenidate extended-release (generic Concerta); **and**
  - for Quillivant XR, one of the following:
    - requested quantity is ≤ 12 mL (60 mg)/day; **or**
    - clinical rationale for exceeding the FDA approved maximum dose.

Please note, six-month provisional approval may be allowed for members who are stabilized on the requested medication and there is severe risk of harm.

clonidine extended-release 0.1 mg tablet exceeding quantity limits

- Documentation of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - medical necessity for an increased dosage that results in requiring quantities that exceed the determined limits

dextroamphetamine 2.5 mg, 7.5 mg, 15 mg, 20 mg, 30 mg tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for requested strength instead of dextroamphetamine 5 mg and 10 mg tablets available without PA.

Evekeo ODT

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for requested formulation instead of solid oral formulations as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age.

methamphetamine

- Documentation of the following is required:
  - diagnosis of ADHD; **and**
  - medical records documenting an inadequate response (defined as ≥ seven days of therapy) or adverse reaction to all other stimulant and non-stimulant medications.

methylphenidate extended-release 72 mg tablet and Relexxii

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for the 45 mg, 63 mg and 72 mg tablets, clinical rationale for use of the requested agent instead of all of the following:
    - two methylphenidate extended-release (generic Concerta) tablets to achieve the requested dose (i.e., 27 mg and 18 mg, 27 mg

and 36 mg, or 36 mg and 36 mg); **and**
    - dexmethylphenidate extended-release; **and**
    - methylphenidate transdermal; **and**
- for the 18 mg, 27 mg, 36 mg, and 54 mg tablets clinical rationale for use of the requested agent instead of all of the following:
    - dexmethylphenidate extended-release; **and**
    - methylphenidate extended-release tablets (generic Concerta); **and**
    - methylphenidate transdermal.

methylphenidate extended-release (generic Ritalin LA) and methylphenidate extended-release CD

- Documentation of the following is required:
    - appropriate diagnosis; **and**
    - clinical rationale for use of the requested agent instead of dexmethylphenidate extended-release; **and**
    - one of the following:
        - medical necessity for requested formulation instead of solid oral formulations as noted by one of the following:
            - member utilizes tube feeding (G-tube/J-tube); **or**
            - member has a swallowing disorder or condition affecting ability to swallow; **or**
            - member is < 13 years of age; **or**
        - clinical rationale for use of the requested agent instead of methylphenidate extended-release (generic Concerta).

Please note, six-month provisional approval may be allowed for members who are stabilized on the requested medication and there is severe risk of harm.

Onyda XR

- Documentation of the following is required:
    - appropriate diagnosis; **and**
    - inadequate response (defined as ≥ 30 days of therapy), adverse reaction, or contraindication to clonidine immediate-release tablets; **and**
    - inadequate response (defined as ≥ 30 days of therapy), adverse reaction, or contraindication to clonidine patches; **and**
    - requested quantity is ≤ four mL/day; **and**
    - one of the following:
        - inadequate response (defined as ≥ seven days of therapy) to one liquid stimulant (amphetamine or methylphenidate product) available without prior authorization; **or**
        - adverse reaction to one stimulant which would be expected of either class; **or**
        - contraindication to all stimulants; **and**
    - one of the following:
        - inadequate response (defined as ≥ 30 days of therapy), adverse reaction, or contraindication to clonidine extended-release tablets; **or**
        - medical necessity for requested formulation instead of solid oral formulations as noted by one of the following:
            - member utilizes tube feeding (G-tube/J-tube); **or**
            - member has a swallowing disorder or condition affecting ability to swallow; **or**
            - member is < 13 years of age.

Qelbree

- Documentation of the following is required:
    - appropriate diagnosis; **and**
    - member is ≥ six years of age; **and**
    - inadequate response (defined as ≥ 30 days of therapy), adverse reaction, or contraindication to atomoxetine; **and**
    - appropriate dosing; **and**
    - one of the following:

- for members < 18 years of age, one of the following:
  - for 100 mg capsule, requested quantity is ≤ one unit/day; **or**
  - for 150 mg and 200 mg capsule, requested quantity is ≤ two units/day; **or**
- for members ≥ 18 years of age, one of the following:
  - for 100 mg capsule, requested quantity is ≤ one unit/day; **or**
  - for 150 mg and 200 mg capsule, requested quantity is ≤ three units/day.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions. Please note, one-month provisional approval may be allowed for members who are stabilized on the requested medication to avoid risk of destabilization.

Behavioral Health Medication Polypharmacy ***(pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, viloxazine, and xanomeline/trospium] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**

- other significant barrier for therapy discontinuation; **and**
- one of the following:
  - member has a seizure diagnosis only; **or**
  - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
  - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
  - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and** one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Cerebral Stimulant Polypharmacy ***(overlapping pharmacy claims for 2 or more cerebral stimulants [immediate-release and extended-release formulations of the same chemical entity are not included in this restriction and are counted as one cerebral stimulant agent] for at least 60 days within a 90-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current cerebral stimulants and corresponding diagnoses; **and**
    - inadequate response (defined as > seven days of therapy), adverse reaction, or contraindication to monotherapy trial with a methylphenidate product; **and**
    - inadequate response (defined as > seven days of therapy), adverse reaction, or contraindication to monotherapy trial with an amphetamine product; **and**
    - clinical rationale for cerebral stimulant polypharmacy.

Alpha$_2$ Agonist or Cerebral Stimulant for members < three years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - for an alpha$_2$ agonist, member has a cardiovascular diagnosis only; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - treatment plan including names of current alpha$_2$ agonist(s) and cerebral stimulant(s) and corresponding diagnoses; **and**
    - clinical rationale for use of alpha$_2$ agonist or cerebral stimulant in member < three years of age; **and**
    - for requests for an amphetamine product, inadequate response (defined as > seven days of therapy), adverse reaction, or

contraindication to a methylphenidate product.

atomoxetine or viloxazine for members < six years of age

- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - if member is < three years of age, prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided.

Reference Table:

Please note in addition to individual drug quantity limits, concurrent therapy quantity limits may also apply

Drug Name	Availability	Individual Drug Quantity Limits
Short- and Intermediate-Acting Agents		
amphetamine sulfate	Tablet: 5, 10 mg	Three units/day
amphetamine sulfate (Evekeo ODT)	Tablet: 5, 10, 15, 20 mg	Three units/day
dexmethylphenidate (Focalin)	Tablet: 2.5, 5, 10 mg	Three units/day
dextroamphetamine	Tablet: 2.5, 5, 7.5, 10, 15, 20, 30 mg	Three units/day
dextroamphetamine (Dexedrine Spansule)	Capsule: 5, 10, 15 mg	Three units/day
dextroamphetamine oral solution	Solution: 5 mg/5 mL	40 mL/day
methamphetamine (Desoxyn)	Tablet: 5 mg	N/A
methylphenidate chewable tablet	Chewable Tablet: 2.5, 5, 10 mg	Three units/day
methylphenidate sustained-release tablet	Tablet: 10, 20 mg	Three units/day
methylphenidate (Ritalin)	Tablet: 5, 10, 20 mg	Three units/day
methylphenidate oral solution (Methylin)	Solution: 5 mg/5 mL, 10 mg/5 mL	30 mL/day
mixed amphetamine salts (Adderall)	Tablet: 5, 7.5, 10, 12.5, 15, 20, 30 mg	Three units/day
Long-Acting Agents		
amphetamine (Adzenys XR-ODT)	Tablet: 3.1, 6.3, 9.4, 12.5, 15.7, 18.8 mg	One unit/day
amphetamine (Dyanavel XR)	Suspension: 2.5 mg/mL	8 mL/day
amphetamine (Dyanavel XR)	Tablet: 5, 10, 15, 20 mg	One unit/day
dexmethylphenidate (Focalin XR)	Capsule: 5, 10, 15, 20, 25, 30, 35, 40 mg	Two units/day
dextroamphetamine (Xelstrym)	Patch: 4.5, 9, 13.5, 18 mg	One unit/day
lisdexamfetamine (Vyvanse)	Capsule: 10, 20, 30, 40, 50, 60, 70 mg Chewable Tablet: 10, 20, 30, 40, 50, 60 mg	Two units/day
methylphenidate (Aptensio XR)	Capsule: 10, 15, 20, 30, 40, 50, 60 mg	One unit/day
methylphenidate (Concerta)	Tablet: 18, 27, 36, 54 mg	Two units/day
methylphenidate	Tablet: 72 mg	One unit/day
methylphenidate, CD	Capsule: 10, 20, 30, 40, 50, 60 mg	Two units/day
methylphenidate (Jornay PM)	Capsule: 20, 40, 60, 80, 100 mg	One unit/day

methylphenidate (Cotempla XR-ODT)	Tablet: 8.6, 17.3 mg Tablet: 25.9 mg	One unit/day Two units/day
methylphenidate (Quillichew ER)	Tablet: 20, 30, 40 mg	Two units/day
methylphenidate (Quillivant XR)	Suspension: 25 mg/5 mL	12 mL/day
methylphenidate (Relexxii)	Tablet: 45, 63 mg	One unit/day
methylphenidate (Ritalin LA)	Capsule: 10, 20, 30, 40, 60 mg	Two units/day
methylphenidate transdermal (Daytrana)	Patch: 10, 15, 20, 30 mg	One unit/day
mixed amphetamine salts (Adderall XR)	Capsule: 5, 10, 15, 20, 25, 30 mg	Two units/day
mixed amphetamine salts (Mydayis)	Capsule: 12.5, 25, 37.5, 50 mg	One unit/day
serdexmethylphenidate/dexmethylphenidate (Azstarys)	Capsule: 26.1/5.2, 39.2/7.8, 52.3/10.4 mg	One unit/day

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 32 - Serums, Toxoids, and Vaccines

Drug Category: Serums, Toxoids, and Vaccines

Medication Class/Individual Agents: Serums, Toxoids, and Vaccines

I. Prior-Authorization Requirements

Serums, Toxoids, and Vaccines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
adenovirus live vaccine delayed-release oral tablets			
BCG live vaccine	BCG Vaccine		
BCG live, intravesical			MB
chikungunya virus vaccine, live	Ixchiq		
chikungunya virus vaccine, recombinant	Vimkunya		
cholera vaccine, live, oral	Vaxchora		
COVID-19 vaccine, adjuvanted	Novavax		1
dengue tetravalent vaccine, live	Dengvaxia		
diphtheria / tetanus / acellular pertussis / poliovirus inactivated / haemophilus B conjugate / hepatitis B vaccine	Vaxelis		
diphtheria / tetanus / acellular pertussis / poliovirus inactivated / haemophilus B conjugate vaccine	Pentacel		1
diphtheria / tetanus toxoids / acellular pertussis / hepatitis B, recombinant / poliovirus, inactivated vaccine	Pediarix		1
diphtheria / tetanus toxoids / acellular	Kinrix		1

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Administrative Schedule:

- PA requirements exist to ensure appropriate dosing of vaccines given in a series to adult members. The pharmacy may contact the MassHealth Drug Utilization Review program for review of the claim in the event that a dose is required that is not consistent with the current Advisory Council on Immunization Practices (ACIP) recommendations.
- For vaccinations that require a series of doses, the time interval between each dose can be increased from the recommended schedule but should not be decreased. The immunization series does not need to be restarted, regardless of the length of time from the last dose (exception: oral typhoid).
- If two live vaccines are administered separately, there should be an interval of at least 28 days in between
- Multiple inactivated vaccines can be administered at any time in relation to another

Side Effects:

- Usually minor (e.g., slight fever, rash, or soreness at the site of injection)
- Serious reactions are extremely rare

Serums, Toxoids, and Vaccines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
pertussis / poliovirus, inactivated vaccine			
diphtheria / tetanus toxoids / acellular pertussis vaccine	Daptacel		1
diphtheria / tetanus toxoids / acellular pertussis vaccine	Infanrix		1
diphtheria / tetanus toxoids vaccine			1
haemophilus B conjugate vaccine-Acthib	Acthib		1
haemophilus B conjugate vaccine-Hiberix	Hiberix		1
haemophilus B conjugate vaccine-Pedvaxhib	Pedvaxhib		1
hepatitis A vaccine, inactivated - Havrix	Havrix		1
hepatitis A vaccine, inactivated-Vaqta	Vaqta		1
hepatitis A, inactivated / hepatitis B recombinant	Twinrix		1
hepatitis B recombinant vaccine	Engerix-B		1
hepatitis B recombinant vaccine	Prehevbrio		1
hepatitis B recombinant vaccine	Recombivax HB		1
hepatitis B recombinant vaccine, adjuvanted	Heplisav-B		1
human papillomavirus 9-valent vaccine	Gardasil 9	PA - < 9 years and PA ≥ 46 years	1
influenza virus vaccine, adjuvanted	Fluad	PA - < 65 years	1
influenza virus vaccine, high dose	Fluzone	PA - < 65 years	1
influenza virus vaccine-Afluria	Afluria		1

Clinical Notes

Safety:

- Thimerosal has been removed or reduced to trace amounts in almost all of the vaccines routinely recommended for children six years of age and younger
- Current scientific evidence does not support the hypothesis that vaccines have a causal link to autism

Contraindications:

- Serious allergic reaction to previous dose of vaccine or vaccine component

Not Contraindications:

- Mild acute illness with or without fever
- Current antimicrobial therapy
- Mild to moderate local reaction (e.g., swelling, redness, soreness)
- Low-grade or moderate fever after previous dose
- Convalescent phase of illness
- Premature birth

Precautions:

- Moderate or severe acute illness with or without fever

Live Virus Vaccines (e.g., measles, mumps, rubella, varicella):

- Avoid use in immunocompromised members
- Administration should be deferred in the presence of active infections or inactive, untreated tuberculosis
- Pregnancy should be avoided for three months following vaccination

Report unexpected events after vaccinations to the Vaccine Adverse Event Reporting System (VAERS) at (800) 822-7967.

Serums, Toxoids, and Vaccines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
influenza virus vaccine-Fluarix	Fluarix		1
influenza virus vaccine-Flublok	Flublok		1
influenza virus vaccine-Flucelvax	Flucelvax		1
influenza virus vaccine-Flulaval	Flulaval		1
influenza virus vaccine-Flumist	Flumist		1
influenza virus vaccine-Fluzone	Fluzone		1
japanese encephalitis vaccine	Ixiaro		
measles / mumps / rubella / varicella virus vaccine	Proquad		1
measles / mumps / rubella vaccine	M-M-R II Vaccine		1
measles / mumps / rubella vaccine	Priorix		
meningococcal group B vaccine-Bexsero	Bexsero		1
meningococcal group B vaccine-Trumenba	Trumenba		1
Moderna COVID-19 vaccine, mRNA	Spikevax		1
pentavalent meningococcal groups A, B, C, W and Y vaccine	Penbraya		
Pfizer-BioNTech COVID-19 vaccine, mRNA	Comirnaty		1
pneumococcal 13-valent conjugate vaccine	Prevnar 13		1
pneumococcal 15-valent conjugate vaccine	Vaxneuvance		
pneumococcal 20-valent conjugate vaccine	Prevnar 20		
pneumococcal 21-valent conjugate vaccine	Capvaxive		
pneumococcal 23-valent polysaccharide vaccine	Pneumovax		1
poliovirus vaccine,	Ipol		1

Serums, Toxoids, and Vaccines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
inactivated			
quadrivalent meningococcal conjugate vaccine-Menquadfi	Menquadfi		1
quadrivalent meningococcal conjugate vaccine-Menveo	Menveo		1
rabies virus vaccine-Imovax Rabies	Imovax Rabies		
rabies virus vaccine-Rabavert	Rabavert		
respiratory syncytial virus vaccine	Abrysvo	PA - < 18 years	1
respiratory syncytial virus vaccine suspension	Mresvia	PA - < 60 years	
respiratory syncytial virus vaccine, adjuvanted	Arexvy	PA - < 50 years	
rotavirus vaccine, live, oral	Rotarix		1
rotavirus vaccine, live, oral, pentavalent	Rotateq		1
smallpox / monkeypox vaccine, live	Jynneos		1
tetanus toxoid / diphtheria vaccine	Tenivac		1
tetanus toxoids / diphtheria / acellular pertussis / inactivated poliovirus vaccine	Quadracel		
tetanus toxoids / diphtheria / acellular pertussis vaccine	Adacel		1
tetanus toxoids / diphtheria / acellular pertussis vaccine	Boostrix		1
tick-borne encephalitis vaccine	Ticovac		
typhoid vaccine capsule	Vivotif Berna		

Serums, Toxoids, and Vaccines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
typhoid vaccine injection	Typhim VI		
varicella virus vaccine	Varivax		1
varicella zoster immune globulin, human	Varizig		
yellow fever vaccine	YF-Vax		
yellow fever vaccine, live	Stamaril		
zoster vaccine recombinant, adjuvanted	Shingrix	PA - < 50 years	

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

1 Product may be available through the Massachusetts Department of Public Health (DPH). Please check with DPH for availability. MassHealth does not pay for immunizing biologicals (i.e., vaccines) and tubercular (TB) drugs that are available free of charge through local boards of public health or through the Massachusetts Department of Public Health without PA (130 CMR 406.413(C)). In cases where free vaccines are available to providers for specific populations (e.g. children, high risk, etc.), MassHealth will reimburse the provider only for individuals not eligible for the free vaccines. Notwithstanding the above, MassHealth will pay pharmacies for seasonal flu vaccine serum without PA, if the vaccine is administered in the pharmacy.

II. Therapeutic Uses

FDA-approved, for example:

- Maternal use for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through six months of age – Abrysvo
- Prevention of diseases caused by human papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52, and 58 – Gardasil-9
- Prevention of herpes zoster – Shingrix
- Prevention of influenza – Fluad and Fluzone High-Dose
- Prevention of LRTD caused by RSV in individuals ≥ 50 years of age – Arexvy
- Prevention of LRTD caused by RSV in individuals ≥ 60 years of age – Abrysvo
- Prevention of LRTD caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV – Abrysvo

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name

Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Herpes zoster vaccine (Shingrix)

- Documentation of the following is required:
  - appropriate indication; **and**
  - one of the following:
    - member is ≥ 50 years of age; **or**
    - member is ≥ 18 years of age and is at increased risk of herpes zoster due to immunodeficiency or immunosuppression caused by known disease or therapy.

SmartPA: Claims for Shingrix for ≤ two doses in all MassHealth pharmacy claims history will usually process at the pharmacy without a PA request if the member is ≥ 18 years of age, has a history of MassHealth medical claims indicative of immunodeficiency or immunosuppression (including history of autologous hematopoietic stem cell transplant, hematologic malignancy, renal transplant, solid tumor receiving chemotherapy, HIV-infection).†

Human papillomavirus 9-valent vaccine (Gardasil-9)

- Documentation of the following is required:
  - appropriate indication; **and**
  - member is ≥ 9 and < 46 years of age; **or**
  - member is ≥ 46 years of age who has already begun the sequence while within the appropriate age range.

Inactivated influenza virus vaccine, high-dose (Fluzone High-Dose), and influenza virus vaccine, adjuvanted (Fluad) in members < 65 years of age

- Documentation of the following is required:
  - appropriate indication; **and**
  - requested quantity of one dose/season; **and**
  - medical necessity for high-dose instead of standard formulation in members < 65 years of age.

Respiratory syncytial virus vaccine (Abrysvo) in members < 18 years of age

- Documentation of the following is required for prevention of LRTD caused by RSV in members < 18 years of age:
  - appropriate indication; **and**
  - medical necessity for the requested agent in members < 18 years of age.
- Documentation of the following is required for maternal use in members < 18 years of age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through six months of age:

- appropriate indication; **and**
- vaccine will be administered between weeks 32 and 36 of pregnancy.

Respiratory syncytial virus vaccine, adjuvanted (Arexvy) in members < 50 years of age

- Documentation of the following is required:
  - appropriate indication; **and**
  - medical necessity for the requested agent in members < 50 years of age.

Respiratory syncytial virus vaccine suspension (Mresvia) in members < 60 years of age

- Documentation of the following is required:
  - appropriate indication; **and**
  - medical necessity for the requested agent in members < 60 years of age.

†Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 33 - Inflammatory Bowel Disease Agents

Drug Category: Inflammatory Bowel Disease Agents

Medication Class/Individual Agents: Inflammatory Bowel Disease Agents

I. Prior-Authorization Requirements

Inflammatory Bowel Disease Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
balsalazide	Colazal		# , A90
budesonide 3 mg delayed-release capsule			A90
budesonide extended-release capsule	Ortikos	PA	
budesonide extended-release tablet	Uceris		BP, A90
budesonide rectal foam	Uceris	PA	A90
hydrocortisone enema	Cortenema		# , A90
hydrocortisone foam	Cortifoam		
hydrocortisone hemorrhoidal cream	Anusol-HC		# , A90
mesalamine 0.375 gram extended-release capsule	Apriso		BP, A90
mesalamine 1.2 gram delayed-release tablet	Lialda	PA	A90
mesalamine 250 mg, 500 mg controlled-release capsule	Pentasa		BP, A90
mesalamine 400 mg delayed-release capsule	Delzicol DR	PA	A90
mesalamine 800 mg delayed-release tablet		PA	A90
mesalamine enema	Rowasa		# , A90
mesalamine kit	Rowasa Kit	PA	A90
mesalamine suppository	Canasa		# , A90
olsalazine	Dipentum		
sulfasalazine	Azulfidine		# , A90
sulfasalazine delayed-release	Azulfidine EN-Tabs		# , A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Crohn's disease
- Ulcerative colitis

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

budesonide rectal foam

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response (defined by at least three weeks of therapy) or adverse reaction to one or contraindication to both of the following: hydrocortisone enema, hydrocortisone foam.

SmartPA: Claims for budesonide rectal foam will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 60 days out of the last 90 days.†

mesalamine 400 mg delayed-release capsule

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 5 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all mesalamine oral formulations available without PA; **and**
  - appropriate dosing.

SmartPA: Claims for mesalamine 400 mg delayed-release capsule will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 60 days out of the last 90 days.†

mesalamine 800 mg delayed-release tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all mesalamine oral formulations available without PA; **and**
  - appropriate dosing.

SmartPA: Claims for mesalamine 800 mg delayed-release tablet will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 60 days out of the last 90 days.†

mesalamine 1.2 gram delayed-release tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member's current weight is ≥ 24 kg; **and**
  - inadequate response or adverse reaction to one or contraindication to all mesalamine oral formulations available without PA; **and**
  - appropriate dosing.

SmartPA: Claims for mesalamine 1.2 gram delayed-release tablet will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 60 days out of the last 90 days.†

mesalamine enema kit

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to mesalamine enema and mesalamine suppository.

SmartPA: Claims for mesalamine enema kit will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 60 days out of the last 90 days.†

Ortikos

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all budesonide oral formulations available without PA; **and**
  - one of the following:
    - member is ≥ 18 years of age; **or**
    - both of the following:
      - member is ≥ eight years of age; **and**
      - agent will be used for treatment of active Crohn’s disease.

SmartPA: Claims for Ortikos will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 60 days out of the last 90 days.†

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 34 - Antibiotics - Ophthalmic

Drug Category: Ophthalmic

Medication Class/Individual Agents: Antibacterial Agents

I. Prior-Authorization Requirements

Antibiotics: Ophthalmic			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
azithromycin ophthalmic solution	Azasite		BP
bacitracin ophthalmic ointment		PA	A90
besifloxacin ophthalmic suspension	Besivance		
ciprofloxacin ophthalmic ointment, solution	Ciloxan		# , A90
erythromycin ophthalmic ointment			A90
gatifloxacin ophthalmic solution			A90
gentamicin ophthalmic solution			A90
levofloxacin ophthalmic solution		PA	A90
moxifloxacin ophthalmic solution, twice daily		PA	A90
moxifloxacin ophthalmic solution-Vigamox	Vigamox		# , A90
natamycin	Natacyn		
ofloxacin ophthalmic solution	Ocuflox		# , A90
sulfacetamide ophthalmic ointment, solution			A90
tobramycin ophthalmic ointment, solution	Tobrex		# , A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Mild bacterial conjunctivitis may be self-limiting and resolve spontaneously in immune-competent adults.
- Most ophthalmic antibiotics contain the preservative benzalkonium chloride. Certain patients may have an allergic reaction or experience dose limiting ocular irritation when using agents containing preservatives. Moxifloxacin ophthalmic solutions are preservative free.
- Treatment should last five to seven days for bacterial conjunctivitis, five days for corneal ulcers, and a few weeks for blepharitis.
- Systemic antibiotic treatment should be utilized for conjunctivitis due to Neisseria gonorrhoeae or Chlamydia trachomatis.
- Ointment may blur vision for up to 20 minutes but are preferred for corneal ulcers because it acts as a lubricant.
- Contact lens wearers may require a flouroquinolone due to the high incidence of pseudomonas infection.

Antibiotics: Ophthalmic – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bacitracin / polymyxin B ophthalmic ointment			A90
neomycin / bacitracin / polymyxin B / hydrocortisone ophthalmic ointment			A90
neomycin / bacitracin / polymyxin B ophthalmic ointment			A90
neomycin / polymyxin B / dexamethasone ophthalmic ointment, suspension	Maxitrol		# , A90
neomycin / polymyxin B / gramicidin			A90
neomycin / polymyxin B / hydrocortisone ophthalmic suspension		PA	A90
sulfacetamide / prednisolone sodium phosphate ophthalmic solution			A90
tobramycin / loteprednol ophthalmic suspension	Zylet		
tobramycin 0.3% / dexamethasone 0.05%, ophthalmic suspension	Tobradex ST		
tobramycin 0.3% / dexamethasone 0.1%, ophthalmic ointment, suspension	Tobradex		# , A90
trimethoprim / polymyxin B ophthalmic solution			A90

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Ocular infections involving the conjunctiva and/or cornea
  - bacterial conjunctivitis
  - bacterial keratitis/corneal ulcers
  - blepharitis/blepharoconjunctivitis
  - surgical prophylaxis

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

moxifloxacin ophthalmic solution, twice daily

Documentation of the following is required:

- appropriate diagnosis; **and**
- inadequate response or adverse reaction to moxifloxacin ophthalmic solution (Vigamox).

SmartPA: Claims for moxifloxacin ophthalmic solution, twice daily will usually process at the pharmacy without a PA request if the prescriber is an ophthalmologist.†

Single-entity agent: bacitracin ophthalmic ointment

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all single-entity or combination ophthalmic antibiotic(s) products available without prior authorization.

Combination antibiotic/corticosteroid product: neomycin/polymyxin B/hydrocortisone ophthalmic suspension

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to an ophthalmic antibiotic/corticosteroid combination product available without prior authorization; **or**
    - inadequate response, adverse reaction, or contraindication to an opthalmic antibiotic agent used in combination with an ophthalmic corticosteroid agent available without prior authorization.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 35 - Antibiotics and Anti-Infectives - Oral and Inhaled

Drug Category: Infectious Disease Agents

Medication Class/Individual Agents: Antibiotics and Anti-Infectives

I. Prior-Authorization Requirements

Anti-Infectives: Oral and Inhaled – Not Otherwise Classified

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
albendazole			A90	• Metronidazole is available in 125 mg, 250 mg and 500 mg tablets, and 375 mg capsules. Due to a considerable cost difference, metronidazole 125 mg tablets and metronidazole 375 mg capsules require prior authorization (PA). • Linezolid is FDA-approved for the treatment of gram-positive coccal infections including methicillin-resistant *Staphylococcus aureus* (MRSA). The Centers for Disease Control and Prevention (CDC) recommends that clinicians reserve linezolid for more severe infections after consultation with an infectious disease specialist or for those patients who have not responded to other antibiotics. Community-acquired MRSA has responded to a number of other antibiotics, including doxycycline, clindamycin, minocycline, and TMP/sulfamethoxazole. Vancomycin continues to be first-line treatment for hospital-acquired MRSA infections. Due to a considerable cost difference, linezolid suspension requires PA.
artemether / lumefantrine	Coartem	PA - > 24 units/365 days		
atovaquone	Mepron		# , A90	
benznidazole				
clindamycin capsule, injection, oral solution	Cleocin		# , A90	
dapsone tablet			A90	
fidaxomicin	Dificid	PA		
fosfomycin			A90	
hydroxychloroquine			A90	
hydroxychloroquine-Sovuna	Sovuna	PA		
ivermectin tablet	Stromectol		#	
linezolid suspension	Zyvox	PA	BP, A90	
linezolid tablet	Zyvox		# , A90	
mebendazole		PA	A90	
methenamine	Hiprex		# , A90	
metronidazole 125 mg tablet		PA		
metronidazole 250 mg, 500 mg tablet			A90	
metronidazole 375 mg capsule	Flagyl	PA	A90	
metronidazole suspension	Likmez	PA		
nifurtimox	Lampit	PA		
nitazoxanide	Alinia	PA		
nitrofurantoin 25 mg/5 mL suspension	Furadantin	PA	A90	
nitrofurantoin 50 mg/5 mL suspension		PA	A90	
nitrofurantoin macrocrystals	Macrodantin		# , A90	
nitrofurantoin monohydrate /	Macrobid		# , A90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
macrocrystals			
praziquantel	Biltricide		# , A90
pyrantel pamoate	Reese's Pinworm		
pyrimethamine		PA	A90
quinine	Qualaquin		# , A90
rifamycin	Aemcolo	PA	
rifaximin 200 mg	Xifaxan		
rifaximin 550 mg	Xifaxan	PA	
secnidazole	Solosec	PA	
tafenoquine	Krintafel	PA - > 2 units/365 days	
tedizolid tablet	Sivextro	PA	
tinidazole			A90
triclabendazole	Egaten	PA	
trimethoprim tablet			A90
vancomycin capsule	Vancocin		# , A90
vancomycin oral solution	Firvanq		BP, A90

Antibiotics: Oral and Inhaled – Aminoglycosides

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amikacin liposome inhalation	Arikayce	PA		
neomycin			*, A90	
paromomycin			A90	
tobramycin inhalation powder	Tobi Podhaler	PA		
tobramycin inhalation solution-Bethkis	Bethkis	PA	BP, A90	
tobramycin inhalation solution-Kitabis Pak	Kitabis Pak	PA	BP, A90	
tobramycin inhalation solution-Tobi	Tobi		# , A90	

Antibiotics: Oral and Inhaled – Penicillins

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amoxicillin			A90	• Amoxicillin/clavulanate is available as immediate-release and extended-release formulations. The extended-release formulation requires PA. In addition, amoxicillin/clavulanate 125/31.25 mg/5 mL suspension requires PA. The immediate-release tablets, chewable tablets, and select strengths of suspension are available without PA.
amoxicillin / clavulanate 125/31.25 mg/5 mL suspension	Augmentin	PA		
amoxicillin / clavulanate chewable tablet, 200/28.5, 250/62.5, 400/57,	Augmentin		# , A90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
600/42.9 mg/5 mL suspension, tablet			
amoxicillin / clavulanate extended-release	Augmentin XR	PA	A90
ampicillin			A90
dicloxacillin			A90
penicillin V			A90

Antibiotics: Oral and Inhaled – Sulfonamides

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
sulfadiazine			A90	
sulfamethoxazole / trimethoprim suspension	Sulfatrim		# , A90	
sulfamethoxazole / trimethoprim tablet	Bactrim		#	

Antibiotics: Oral and Inhaled – Fluoroquinolones

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
ciprofloxacin 100 mg tablet		PA	A90	• Ciprofloxacin tablets are available in 100 mg, 250 mg, 500 mg, and 750 mg strengths. The 250 mg, 500 mg, and 750 mg strengths are significantly less costly. PA is required for ciprofloxacin 100 mg tablets.
ciprofloxacin injection, suspension, 250 mg, 500 mg, 750 mg tablet	Cipro		# , A90	
delafloxacin tablet	Baxdela	PA		
levofloxacin			A90	
moxifloxacin tablet			A90	
ofloxacin tablet		PA	A90	

Antibiotics: Oral and Inhaled – Tetracyclines

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
demeclocycline			A90	*Oral antibiotics for the treatment of acne or rosacea:* • Moderate acne can be managed with topical retinoids in combination with oral antibiotics and/or benzoyl peroxide. • Oral tetracyclines may be used for the management of papulopustular rosacea. • These agents are most useful for improving inflammatory papules and pustules, and may also reduce erythema.
doxycycline hyclate 100 mg capsule	Vibramycin		# , A90	
doxycycline hyclate 100 mg tablet pack	Lymepak	PA		
doxycycline hyclate 20 mg, 100 mg tablet			A90	
doxycycline hyclate 50 mg capsule			A90	
doxycycline		PA	A90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
hyclate 50 mg tablet			
doxycycline hyclate 75 mg, 150 mg tablet		PA	A90
doxycycline hyclate delayed-release 50 mg, 75 mg, 100 mg, 150 mg tablet		PA	A90
doxycycline hyclate delayed-release 60 mg, 80 mg, 200 mg tablet	Doryx	PA	A90
doxycycline monohydrate 150 mg capsule		PA	A90
doxycycline monohydrate 150 mg tablet		PA	A90
doxycycline monohydrate 40 mg capsule	Oracea	PA	A90
doxycycline monohydrate 50 mg, 100 mg capsule			A90
doxycycline monohydrate 50 mg, 75 mg, 100 mg tablet			A90
doxycycline monohydrate 75 mg capsule		PA	A90
doxycycline monohydrate suspension			A90
minocycline capsule			A90
minocycline extended-release 45 mg, 90 mg, 135 mg tablet		PA	A90
minocycline extended-release 55 mg, 65 mg, 80 mg, 105 mg, 115 mg tablet	Solodyn		# , A90
minocycline tablet		PA	A90
omadacycline tablet	Nuzyra	PA	
tetracycline capsule			A90
tetracycline tablet		PA	A90

Antibiotics: Oral and Inhaled – Macrolides

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
azithromycin injection, suspension, tablet	Zithromax		# , A90	• Azithromycin is available as 250 mg and 500 mg tablets, 100 mg/5mL and 200 mg/5mL suspensions, and one gram powder packets. The tablet and suspension formulations are significantly less costly. PA is required for the one gram powder packet. • Clarithromycin is available in extended-release and immediate-release formulations. The immediate-release formulation is available without PA.
azithromycin powder packet	Zithromax	PA	A90	
clarithromycin			A90	
clarithromycin extended-release		PA	A90	
erythromycin delayed-release capsule, tablet			A90	
erythromycin ethylsuccinate suspension	Eryped		# , A90	
erythromycin stearate tablet			A90	
erythromycin tablet			A90	

Antibiotics: Oral and Inhaled – Antitubercular Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
bedaquiline	Sirturo	PA		
cycloserine			A90	
ethambutol	Myambutol		# , A90	
ethionamide	Trecator			
isoniazid			A90	
pretomanid			A90	
pyrazinamide			A90	
rifabutin	Mycobutin		# , A90	
rifampin	Rifadin		# , A90	
rifapentine	Priftin			

Antibiotics: Oral and Inhaled – Cephalosporins

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
cefaclor capsule			A90	• Cefadroxil tablet requires PA. Cefadroxil capsule and suspension are less-costly alternatives and are available without PA. • Cefaclor is available as extended-release and immediate-release formulations. The immediate-release formulation is available without PA. • Cefpodoxime suspension requires PA. Cefpodoxime tablets are less costly and available without PA. Cefdinir, another third-generation cephalosporin, comes in a suspension formulation that is available without PA. • Cephalexin capsules are available in 250 mg, 500 mg, and 750 mg strengths. The 250 mg and 500 mg capsules are significantly less costly. PA is required for cephalexin
cefaclor extended-release		PA	A90	
cefaclor suspension		PA	A90	
cefadroxil capsule, suspension			A90	
cefadroxil tablet		PA	A90	
cefdinir			A90	
cefixime		PA	A90	
cefpodoxime suspension		PA	A90	
cefpodoxime tablet			A90	
cefprozil			A90	
cefuroxime axetil			A90	
cephalexin 250			A90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
mg, 500 mg capsule, suspension				750 mg capsules.
cephalexin 750 mg capsule		PA	A90	

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Infections (site and location vary by indication for requested agent)

Non-FDA-approved, for example:

- Infections (site and location vary by indication for requested agent)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Aemcolo

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response or adverse reaction to one of the following: ciprofloxacin, levofloxacin; **or**
    - inadequate response, adverse reaction, or contraindication to azithromycin; **or**
    - contraindication to fluoroquinolones and azithromycin; and
  - inadequate response, adverse reaction, or contraindication to Xifaxan (rifaximin) 200 mg
  - requested quantity is ≤ 12 tablets/three days.

amoxicillin/clavulanate extended-release, azithromycin powder packet, cefaclor extended-release, cefaclor suspension, cefadroxil tablet, cefpodoxime suspension, cephalexin 750 mg capsule, ciprofloxacin 100 mg tablet, clarithromycin extended-release, metronidazole 375 mg capsule, and tetracycline tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to one other clinically appropriate, less-costly antibiotic; **and**
  - medical necessity for the requested formulation instead of formulations available without PA.

Alinia suspension

- Documentation of all of the following is required for a diagnosis of giardiasis:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member is ≥ one year of age; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: metronidazole, tinidazole.
- Documentation of all of the following is required for a diagnosis of cryptosporidiosis:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member is ≥ one year of age.
- Documentation of all of the following is required for a diagnosis of Helicobacter pylori:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following:
    - clarithromycin-based triple therapy containing metronidazole: proton pump inhibitor, clarithromycin, and metronidazole; **and**
    - bismuth quadruple therapy: proton pump inhibitor, bismuth subsalicylate, metronidazole, and tertracycline.

Arikayce

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - member has completed a minimum of six consecutive months of a multidrug background regimen therapy; **and**
  - requested agent will be used as part of a combination antibacterial drug regimen to treat nontuberculous mycobacteria (*Mycobacterium avium* complex) lung disease; **and**
  - prescriber is a specialist (e.g., pulmonologist, infectious disease specialist) or consult notes from a specialist are provided.

Augmentin 125/31.25 mg/5mL suspension

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member is < 12 weeks of age; **or**

- requested dose is too difficult to measure using the 250/62.5 mg/5 mL formulation.

Baxdela tablet and Nuzyra tablet, for non-MRSA community acquired bacterial pneumonia (CABP)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: amoxicillin, amoxicillin/clavulanate, ampicillin/sulbactam, azithromycin, cefotaxime, cefpodoxime, ceftriaxone, cefuroxime, clarithromycin, doxycycline, levofloxacin, moxifloxacin.

Baxdela tablet and Nuzyra tablet for suspected or confirmed MRSA acute bacterial skin and skin structure infection (ABSSSI) or suspected or confirmed mixed pathogen (including MRSA) ABSSSI

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - culture is positive for MRSA and inadequate response or adverse reaction to one or contraindication to all of the following: sulfamethoxazole-trimethoprim, clindamycin, vancomycin IV, linezolid, doxycycline, minocycline; **or**
    - member has a history of past MRSA infection and inadequate response or adverse reaction to two or contraindication to all of the following: sulfamethoxazole-trimethoprim, clindamycin, vancomycin IV, linezolid, doxycycline, minocycline; **and**
  - for suspected or confirmed mixed pathogen infections (including MRSA), inadequate response, adverse reaction, or contraindication to one other antibiotic with gram negative coverage available without PA.

Baxdela tablet and Nuzyra tablet for suspected or confirmed mixed pathogen non-MRSA ABSSSI

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all antibiotics with appropriate coverage for pathogens available without PA.

cefixime

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., genitourinary tract infections, respiratory tract infections, skin and skin structure infections); **and**
  - for suspension, one of the following:
    - member is < 13 years of age; **or**
    - medical necessity for use of suspension formulation instead of the capsule formulation; **and**
  - for capsules, requested quantity is ≤ one unit/day; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication (e.g., culture not susceptible) to both of the following: cefdinir, cefpodoxime; **or**
    - member is completing a course of therapy which was initiated while a hospital inpatient.

SmartPA: Claims for cefixime capsule will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for a diagnosis of genitourinary tract infections, respiratory tract infections, or skin and skin structure infections, there is a history of at least one paid MassHealth pharmacy claim for cefdinir or cefpodoxime in the last 90 days and the current claim plus history ≤ one unit/day.†

SmartPA: Claims for cefixime suspension will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for a diagnosis of genitourinary tract infections, respiratory tract infections, or skin and skin structure infections, member's age < 13 years of age, and there is a history of at least one paid MassHealth pharmacy claim for cefdinir or

cefpodoxime in the last 90 days.†

Coartem > 24 units/365 days

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limit.

Dificid

- Documentation of all of the following is required:
  - diagnosis of clostridium difficile-associated diarrhea (CDAD) that is not considered to be fulminant disease; **and**
  - member is ≥ six months of age; **and**
  - appropriate dosing.

Doryx (doxycycline hyclate delayed-release 60 mg tablet), doxycycline hyclate 50 mg, 75 mg, and 150 mg tablet, doxycycline hyclate delayed-release 50 mg, 75 mg, 80 mg, 100 mg, 150 mg, and 200 mg tablet, doxycycline monohydrate 40 mg and 75 mg capsule, and doxycycline monohydrate 150 mg capsule and tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to one doxycycline hyclate or monohydrate formulation available without PA; **and**
  - medical necessity for the requested formulation instead of doxycycline formulations available without PA.

Egaten

- Documentation of all of the following is required:
  - diagnosis of Fascioliasis; **and**
  - member is ≥ six years of age; **and**
  - prescriber is an infectious disease specialist or consult notes from an infectious disease specialist regarding the use of the agent are provided; **and**
  - appropriate dosing.

Krintafel > 2 units/365 days

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is receiving the requested agent in combination with chloroquine therapy; **and**
  - medical necessity for exceeding the quantity limit.

Lampit

- Documentation of all of the following is required for pediatric members:
  - appropriate diagnosis; **and**
  - member is < 18 years of age; **and**
  - appropriate dosing based on member weight; **and**
  - requested duration is ≤ 60 days; **and**
  - for members ≥ two to < 13 years of age, inadequate response, adverse reaction, or contraindication to benznidazole.
- Documentation of all of the following is required for adult members:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing based on member weight; **and**
  - requested duration is ≤ 90 days; **and**
  - inadequate response, adverse reaction, or contraindication to benznidazole.

- For recertification, documentation of medical necessity for duration of therapy exceeding 60 days in pediatric members or 90 days in adult members.

Likmez
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member is < 13 years of age; **or**
    - inadequate response, adverse reaction, or contraindication to metronidazole tablets; **or**
    - medical necessity for use of the suspension formulation instead of the tablet formulation.

linezolid suspension and Sivextro tablet
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - for linezolid suspension, medical necessity for use of the suspension formulation instead of the tablet formulation; **and**
  - one of the following:
    - vancomycin-resistant enterococcus (VRE) infection or suspected VRE infection and one of the following:
      - for Sivextro and one of the following:
        - inadequate response, adverse reaction, or contraindication to linezolid; **or**
        - culture is resistant to linezolid (if cultures can be obtained); **or**
      - for linezolid suspension; **or**
    - culture is positive for methicillin-resistant *Staphylococcus aureus* (MRSA) and inadequate response or adverse reaction to one or contraindication to all of the following: clindamycin, doxycycline, linezolid, minocycline, sulfamethoxazole/trimethoprim, vancomycin IV; **or**
    - member has a history of past MRSA infection and inadequate response or adverse reaction to two or contraindication to all of the following: clindamycin, doxycycline, linezolid, minocycline, sulfamethoxazole/trimethoprim, vancomycin IV.

Lymepak
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ eight years of age and weighs ≥ 45 kg; **and**
  - appropriate dosing; **and**
  - inadequate response, adverse reaction, or contraindication to all doxycycline formulations available without prior authorization; **and**
  - medical necessity for the requested formulation instead of doxycycline 100 mg formulations available without prior authorization.

mebendazole
- Documentation of all of the following is required for a diagnosis of pinworm:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: albendazole, pyrantel pamoate.
- Documentation of all of the following is required for a diagnosis of whipworm, hookworm, or roundworm:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response, adverse reaction, or contraindication to albendazole.

metronidazole 125 mg tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction or contraindication to Likmez; **or**
    - medical necessity for the requested formulation instead of metronidazole tablets available without prior authorization.

minocycline extended-release 45 mg, 90 mg, 135 mg tablet, and minocycline tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - for minocycline immediate-release tablet, both of the following:
    - inadequate response to minocycline immediate-release capsule; **and**
    - medical necessity for the requested formulation instead of minocycline capsules; **and**
  - for minocycline extended-release tablet formulations and Ximino, inadequate response, adverse reaction, or contraindication to both of the following available without PA: minocycline immediate-release capsules, minocycline extended-release 55 mg, 65 mg, 80 mg, 105 mg or 115 mg tablet.

nitazoxanide tablet

- Documentation of all of the following is required for a diagnosis of giardiasis:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: metronidazole, tinidazole.
- Documentation of all of the following is required for a diagnosis of cryptosporidiosis:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member is ≥ 12 years of age.
- Documentation of all of the following is required for a diagnosis of Helicobacter pylori:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following:
    - clarithromycin-based triple therapy containing metronidazole: proton pump inhibitor, clarithromycin, and metronidazole; **and**
    - bismuth quadruple therapy: proton pump inhibitor, bismuth subsalicylate, metronidazole, and tertracycline.

nitrofurantoin 25 mg/5 mL suspension and nitrofurantoin 50 mg/5 mL suspension

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical necessity for use of the suspension formulation instead of the capsule formulation.

ofloxacin

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one of the following: ciprofloxacin, levofloxacin, moxifloxacin.

pyrimethamine

- Documentation of all of the following is required for toxoplasmosis treatment:
  - appropriate diagnosis; **and**
  - appropriate dosing and frequency; **and**
  - requested agent will be used as combination therapy.

- Documentation of all of the following is required for primary prophylaxis of toxoplasmosis:
  - indication is for primary prophylaxis of toxoplasmosis; **and**
  - appropriate dose and frequency; **and**
  - inadequate response, adverse reaction, or contraindication to trimethoprim-sulfamethoxazole; **and**
  - one of the following:
    - CD-4 count is < 200 cells/mm^3; **or**
    - clinical rationale for prophylaxis; **and**
  - requested agent will be used as combination therapy.
- Documentation of all of the following is required for secondary prophylaxis of toxoplasmosis:
  - indication is for secondary prophylaxis of toxoplasmosis; **and**
  - appropriate dose and frequency; **and**
  - one of the following:
    - CD-4 count is < 200 cells/mm^3; **or**
    - clinical rationale for prophylaxis; **and**
  - requested agent will be used as combination therapy.

Sirturo
- Documentation of all of the following is required for a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB):
  - appropriate diagnosis; **and**
  - requested agent will be used in combination with at least two other antitubercular agents.
- Documentation of all of the following is required for a diagnosis of non-tuberculous mycobacteria (NTM):
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one antimicrobial regimen not requiring PA, or contraindication to all regimens that do not require PA; **and**
  - requested agent will be used in combination with at least one other antitubercular agent; **and**
  - appropriate dosing.

Solosec
- Documentation of all of the following is required for a diagnosis of bacterial vaginosis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: oral or vaginal metronidazole, oral or vaginal clindamycin, oral tinidazole.
- Documentation of all of the following is required for a diagnosis of trichomoniasis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: oral metronidazole, oral tinidazole.

Sovuna
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation.

Tobi Podhaler
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**

- inadequate response, adverse reaction, or contraindication to tobramycin inhalation solution (Tobi).

tobramycin inhalation solution (Bethkis, Kitabis Pak)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to tobramycin inhalation solution (Tobi).

Xifaxan 550 mg

- Documentation of all of the following is required for a diagnosis of hepatic encephalopathy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to lactulose; **and**
  - requested quantity is ≤ two tablets/day.
- Docuentation of all of the following is required for a diagnosis of irritable bowel syndrome with diarrhea:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: bile acid sequestrant, bismuth subsalicylate, bulk-forming agent, diphenoxylate/atropine, loperamide, tricyclic antidepressant (TCA).
- Documentation of all of the following is required for a diagnosis of small intestinal bacterial overgrowth (SIBO):
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: amoxicillin-clavulanate, ciprofloxacin, doxycycline, metronidazole, neomycin, norfloxacin, tetracycline, trimethoprim/sulfamethoxazole; **and**
  - appropriate dosing (550 mg three times daily for 14 days).

SmartPA: Claims for Xifaxan 550 mg (≤ two tablets/day) will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for a diagnosis of hepatic encephalopathy, member's age is ≥ 18 years of age, and a history of paid MassHealth pharmacy claims for lactulose.†

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plan.

MassHealth Evaluation Criteria
Table 36 - Drug and Alcohol Cessation Agents

Drug Category: Central Nervous System Agents

Medication Class/Individual Agents: Alcohol/Drug Cessation Agents

I. Prior-Authorization Requirements

Drug and Alcohol Cessation Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acamprosate			A90
buprenorphine / naloxone film	Suboxone PD	PA - > 90 days (> 24 mg/day and ≤ 32 mg/day)	BP
buprenorphine / naloxone film	Suboxone PD	PA - > 32 mg/day	BP
buprenorphine / naloxone film ≤ 24 mg/day	Suboxone PD		BP
buprenorphine / naloxone sublingual tablet		PA - > 90 days (> 24 mg/day and ≤ 32 mg/day)	
buprenorphine / naloxone sublingual tablet		PA - > 32 mg/day	
buprenorphine / naloxone sublingual tablet ≤ 24 mg/day			
buprenorphine / naloxone sublingual tablet-Zubsolv	Zubsolv	PA	
buprenorphine extended-release injection	Brixadi PD		
buprenorphine extended-release injection	Sublocade PD		
buprenorphine sublingual tablet		PA	
disulfiram			A90
lofexidine	Lucemyra	PA	
nalmefene	Opvee	PA	
naloxone 3 mg nasal spray	Rivive		
naloxone 4 mg nasal spray	Narcan		
naloxone 4 mg nasal spray			
naloxone 5 mg / 0.5 mL syringe	Zimhi		
naloxone 8 mg	Kloxxado PD		

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Prescribing:

- Following the passage of the Consolidated Appropriations Act of 2023, and effective immediately, all practitioners who have a current DEA registration that includes Schedule III authority may now prescribe buprenorphine for Opioid Use Disorder in their practice if permitted by applicable state law. This also removes other federal requirements associated with the Drug Addiction and Treatment Act of 2000 (DATA 2000) that instituted discipline restrictions, patient limits, and certification related to provision of counseling.

FDA Approved Uses:

- Buprenorphine and buprenorphine/naloxone are Schedule III controlled substances approved for treatment of opioid dependence. These agents are not FDA-approved for pain management.
- Naltrexone injection is FDA-approved for the treatment of opioid and alcohol dependence in members who are abstinent at treatment initiation.

Contraindications:

- acamprosate: those who have had a hypersensitivity reaction to acamprosate in the past and severe renal impairment (creatinine clearance ≤ 30 mL/min)

Drug and Alcohol Cessation Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
nasal spray			
naloxone syringe kit	Lifems Naloxone	PA	
naloxone vial, 0.4 mg/mL syringe, 2 mg/2 mL syringe			
naltrexone injection	Vivitrol PD		
naltrexone tablet		PA - < 6 years	A90

Clinical Notes

- buprenorphine: hypersensitivity to buprenorphine
- buprenorphine/naloxone: hypersensitivity to buprenorphine and/or to naloxone
- disulfiram: recent use of metronidazole, paraldehyde, alcohol, or alcohol-containing products, myocardial disease or coronary occlusion, psychoses and hypersensitivity to disulfiram or other thiuram derivatives
- naltrexone: current use of or dependence on opioids, acute withdrawal, those who have failed a naloxone challenge test or have a positive urine screen for opioids, acute hepatitis, or liver failure and sensitivity to naltrexone or any component of the product

Warnings/Precautions:

- acamprosate: does not eliminate or diminish withdrawal symptoms
- buprenorphine: acute alcoholism, adrenal cortical insufficiency, delirium tremens, CNS depression, respiratory depression, head injury, dependence, large doses of narcotics, hypotension
- buprenorphine/naloxone: respiratory depression, CNS depression, CNS depressants, acute abdominal conditions, acute alcoholism, adrenal cortical insufficiency, concomitant CYP3A4 inhibitors, delirium tremens, elderly or debilitated members, dependence, hepatitis, allergic reactions, head injury and increased intracranial pressure, prostatic hypertrophy or urethral stricture, and opioid withdrawal effects
- disulfiram: diabetes mellitus, disulfiram-alcohol reaction, hepatic dysfunction; hypothyroidism, epilepsy, cerebral damage, renal impairment, rubber contact dermatitis and environmental or occupational exposure to ethylene dibromide or its vapors
- naltrexone: hepatotoxicity, hepatic impairment, history of suicide attempts, with or without depression, symptoms of withdrawal

Please see the following link to find out more information regarding buprenorphine/naloxone tablets and buprenorphine/naloxone film:

https://www.mass.gov/lists/masshealth-pharmacy-publications-and-notices-for-prescribers-and-other-providers-0

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	Clinical Notes
	In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions (see below).

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Management of opioid withdrawal symptoms
- Opioid dependence

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

buprenorphine tablet ≤ 24 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**

- clinical rationale for prescribing buprenorphine instead of buprenorphine/naloxone documented as one of the following:
  - medical records documenting naloxone allergy; **or**
  - current pregnancy (request must include anticipated date of delivery); **or**
  - member is breastfeeding; **or**
  - prescriber documents desire to avoid buprenorphine/naloxone due to moderate-to-severe hepatic impairment (i.e., Child-Pugh B to C).

buprenorphine tablet > 24 mg/day to ≤ 32 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale for prescribing buprenorphine instead of buprenorphine/naloxone documented as one of the following:
    - medical records documenting naloxone allergy; **or**
    - current pregnancy (request must include anticipated date of delivery); **or**
    - member is breastfeeding; **or**
    - prescriber documents desire to avoid buprenorphine/naloxone due to moderate-to-severe hepatic impairment (i.e., Child-Pugh B to C); **and**
  - one of the following:
    - this is the lowest effective dose for the member; **or**
    - complete treatment plan.

buprenorphine tablet > 32 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale for prescribing buprenorphine instead of buprenorphine/naloxone documented as one of the following:
    - medical records documenting naloxone allergy; **or**
    - current pregnancy (request must include anticipated date of delivery); **or**
    - member is breastfeeding; **or**
    - prescriber documents desire to avoid buprenorphine/naloxone due to moderate-to-severe hepatic impairment (i.e., Child-Pugh B to C); **and**
  - medical necessity for dosing greater than 32 mg/day as noted by CYP3A4 genotyping confirming member is a rapid CYP3A4 metabolizer.

buprenorphine/naloxone film and buprenorphine/naloxone tablet > 24 mg/day to ≤ 32 mg/day for > 90 days

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - this is the lowest effective dose for the member; **or**
    - complete treatment plan.

buprenorphine/naloxone film and buprenorphine/naloxone tablet > 32 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for dosing greater than 32 mg/day as noted by CYP3A4 genotyping confirming member is a rapid CYP3A4 metabolizer.

Lifems Naloxone

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale to establish medical necessity of the convenience kit formulation, as it pertains to the caregiver; **and**
  - requested quantity is ≤ 2 kits/year.

lofexidine

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**

- member is ≥ 18 years of age; **and**
- inadequate response, adverse reaction, or contraindication to oral clonidine; **and**
- requested dose is ≤ 0.72 mg four times daily; **and**
- requested duration is ≤ 14 days.

Opvee

- Documentation of all of the following is required:
  - indication is opioid overdose prevention/reversal; **and**
  - medical necessity for the use of a long-acting formulation for overdose reversal; **and**
  - requested quantity is ≤ two inhalers/year.

Zubsolv ≤ 17.2 mg/4.3 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an adverse reaction to buprenorphine/naloxone film that is allergic in nature, or cannot be expected or managed during the course of buprenorphine therapy.

Zubsolv > 17.2 mg/4.3 mg/day to ≤ 22.8 mg/5.8 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an adverse reaction to buprenorphine/naloxone film that is allergic in nature, or cannot be expected or managed during the course of buprenorphine therapy; **and**
  - one of the following:
    - this is the lowest effective dose for the member; **or**
    - complete treatment plan.

Zubsolv > 22.8 mg/5.8 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an adverse reaction to buprenorphine/naloxone film that is allergic in nature, or cannot be expected or managed during the course of buprenorphine therapy; **and**
  - medical necessity for dosing greater than 22.8/5.8 mg/day as noted by CYP3A4 genotyping confirming member is a rapid CYP3A4 metabolizer.

Behavioral Health Medication Polypharmacy ***(pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, viloxazine, and xanomeline/trospium] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; and
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease,

attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.
- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
    - one of the following:
      - member has a seizure diagnosis only; **or**
      - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
      - cross-titration/taper of mood stabilizer therapy; **or**
      - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
      - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
      - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, and one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

naltrexone for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g. psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**

- family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
- other significant barrier for therapy discontinuation.

†**Note**: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.
Please see the following link to find out more information regarding buprenorphine/naloxone tablets and buprenorphine/naloxone film: https://www.mass.gov/lists/masshealth-pharmacy-publications-and-notices-for-prescribers-and-other-providers-0.

MassHealth Evaluation Criteria
Table 37 - Respiratory Syncytial Virus (RSV) Prophylaxis Agents

Drug Category: Respiratory Tract Agents

Medication Class/Individual Agents: Individual Agent: Immunologic Agents

I. Prior-Authorization Requirements

RSV Prophylaxis Agents				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
nirsevimab-alip	Beyfortus	PA - ≥ 8 months of age		**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** **RSV Prophylaxis Agents Evaluation Criteria:** • Evaluation criteria are based on recommendations from the Massachusetts Chapter of the American Academy of Pediatrics (AAP). • Nirsevimab-alip and palivizumab are intended for the prophylaxis of respiratory syncytial virus (RSV) and not for the treatment of patients currently infected with RSV • In most regions of the Northern Hemisphere, the first dose of palivizumab should be administered at the beginning of November and the last dose should be administered at the beginning of March, which will provide protection into April. Polymerase chain reaction (PCR) testing for RSV uses a 3% threshold to determine the weekly percentage of tests positive and allows for a reasonable estimation of RSV season where RSV testing is not performed or reported throughout the year. This method (3% threshold) defines season onset as the first of two consecutive weeks when the weekly percentage of tests positive for RSV was >3%.
palivizumab	Synagis	PA		

II. Therapeutic Uses

FDA-approved, for example:

- prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of severe RSV disease

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Beyfortus in members ≥ eight months of age

- Documentation of all of the following is required:
  - appropriate indication; **and**
  - member is ≥ eight months to < 20 months of age; **and**
  - appropriate dosing; **and**
  - one of the following:
    - member is severely immunocompromised; **or**
    - cystic fibrosis with manifestations of severe lung disease; **or**
    - member is American Indian or Alaska Native descent; **or**
    - chronic lung disease of prematurity who require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the six-month period before start of the RSV season or bronchopulmonary dysplagia; **or**
    - congenital diaphragmatic hernia and comorbid chronic lung disease; **or**
    - Down syndrome and comorbid congenital heart disease, chronic lung disease, airway clearance issues, or prematurity; **or**
    - congenital abnormality of the airway or neuromuscular disease; **or**
    - congenital heart disease; **or**
    - underwent cardiopulmonary bypass procedure.

Synagis for chronic lung disease (CLD) of prematurity or bronchopulmonary dysplasia (BPD)

- Documentation of all of the following is required:
  - appropriate indication; **and**

- inadequate response, adverse reaction, or contraindication to Beyfortus; **and**
- one of the following:
  - member is < 12 months of age at the start of the RSV season and has all of the following:
    - diagnosis of CLD or BPD; **and**
    - gestational age < 32 weeks 0 days; **and**
    - a requirement for supplemental oxygen for at least the first 28 days after birth; **or**
  - member is < 24 months of age at the start of the RSV season and has all of the following:
    - diagnosis of CLD or BPD; **and**
    - gestational age < 32 weeks 0 days; **and**
    - a requirement for supplemental oxygen for at least the first 28 days after birth; **and**
    - member continues to require medical support within the six months prior to the start of the RSV season with chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen.

Synagis for prematurity

- Documentation of all of the following is required:
  - appropriate indication; **and**
  - member is < 12 months of age at the start of the RSV season with a gestational age < 29 weeks 0 days; **and**
  - inadequate response, adverse reaction, or contraindication to Beyfortus.

Synagis for congenital heart disease (CHD)

- Documentation of all of the following is required:
  - appropriate indication; **and**
  - inadequate response, adverse reaction, or contraindication to Beyfortus; **and**
  - member is < 12 months of age at the start of the RSV season and has all of the following:
    - hemodynamically significant CHD; **and**
    - one of the following:
      - moderate-to-severe pulmonary hypertension; **or**
      - member requires medication (s) to control congestive heart failure and will require cardiac surgical procedures; **or**
      - member has evidence of cyanotic heart disease and prescriber is a pediatric cardiologist or has consulted with a pediatric cardiologist.

MassHealth Evaluation Criteria
Table 38 - Antiretroviral/HIV Therapy

Drug Category: Anti-infectives

Medication Class/Individual Agents: Antiretroviral/HIV Therapy

I. Prior-Authorization Requirements

Antiretroviral/HIV Therapy – Integrase Strand Transfer Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cabotegravir injection	Apretude PD		
cabotegravir tablet	Vocabria		
dolutegravir tablet	Tivicay	PA - > 1 unit/day	
dolutegravir tablet for oral suspension	Tivicay PD		
raltegravir	Isentress		BP

Antiretroviral/HIV Therapy – Protease Inhibitors (PI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
atazanavir	Reyataz		# , A90
darunavir	Prezista		# , A90
fosamprenavir	Lexiva	PA	A90
lopinavir / ritonavir	Kaletra		# , A90
nelfinavir	Viracept		
ritonavir packet	Norvir		
ritonavir tablet	Norvir PD		BP, A90
tipranavir	Aptivus		

Antiretroviral/HIV Therapy – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
abacavir / dolutegravir / lamivudine	Triumeq PD		
abacavir / lamivudine	Epzicom		# , A90
abacavir / lamivudine / zidovudine	Trizivir		# , A90
atazanavir / cobicistat	Evotaz		

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Cabotegravir injection:

- Cabotegravir injection is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired human immunodeficiency virus type 1 (HIV-1) infection. Individuals must have a negative HIV-1 test prior to PrEP initiation and must be tested with each subsequent injection due to reports of drug-resistant HIV-1 variants when used by individuals with undiagnosed HIV-1 infection.

Fostemsavir:

- Fostemsavir in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

Ibalizumab-uiyk:

- Ibalizumab-uiyk, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug

Antiretroviral/HIV Therapy – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bictegravir / emtricitabine / tenofovir alafenamide	Biktarvy PD		
cabotegravir / rilpivirine	Cabenuva PD		
darunavir / cobicistat	Prezcobix PD		
darunavir / cobicistat / emtricitabine / tenofovir alafenamide	Symtuza PD		
dolutegravir / lamivudine	Dovato PD		
dolutegravir / rilpivirine	Juluca PD		
doravirine / lamivudine / tenofovir disoproxil fumarate	Delstrigo PD		
efavirenz / emtricitabine / tenofovir	Atripla		# , A90
efavirenz 400 mg / lamivudine 300 mg / tenofovir disoproxil fumarate 300 mg	Symfi Lo	PA	A90
efavirenz 600 mg / lamivudine 300 mg / tenofovir disoproxil fumarate 300 mg	Symfi	PA	A90
elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide	Genvoya PD		
elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil fumarate	Stribild		
emtricitabine / rilpivirine / tenofovir alafenamide	Odefsey PD		
emtricitabine / rilpivirine / tenofovir disoproxil fumarate	Complera		BP
emtricitabine / tenofovir alafenamide	Descovy PD		

Clinical Notes

resistant HIV-1 infection failing their current antiretroviral regimen.

Maraviroc Black Box Warning:

- Hepatotoxicity has been reported with maraviroc use. Evidence of a systemic allergic reaction (e.g., pruritic rash, eosinophilia, or elevated IgE) prior to the development of hepatotoxicity may occur. Members with signs or symptoms of hepatitis or allergic reaction following use of maraviroc should be evaluated immediately.

Maraviroc Warnings:

- Caution should be used when administering maraviroc to members with preexisting liver dysfunction or who are co-infected with viral hepatitis B or C.
- More cardiovascular events including myocardial ischemia and/or infarction were observed in members who received maraviroc. Use with caution in members at increased risk of cardiovascular events.

Antiretroviral/HIV Therapy – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
emtricitabine / tenofovir disoproxil fumarate	Truvada		# , A90
lamivudine / tenofovir disoproxil fumarate	Cimduo	PA	
lamivudine / zidovudine	Combivir		# , A90

Antiretroviral/HIV Therapy – Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
doravirine	Pifeltro PD		
efavirenz			A90
etravirine	Intelence		BP, A90
nevirapine			A90
nevirapine extended-release		PA	A90
rilpivirine	Edurant		BP

Antiretroviral/HIV Therapy – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cobicistat	Tybost		
tesamorelin	Egrifta SV	PA	

Antiretroviral/HIV Therapy – Nucleoside Analog Reverse Transcriptase Inhibitors (NRTI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
abacavir	Ziagen		# , A90
didanosine			A90
emtricitabine	Emtriva		BP, A90
lamivudine 10 mg/mL solution	Epivir		# , A90
lamivudine 150 mg, 300 mg tablet	Epivir		# , A90
stavudine			A90
zidovudine	Retrovir		# , A90

Antiretroviral/HIV Therapy – Fusion Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
enfuvirtide	Fuzeon		

Antiretroviral/HIV Therapy – gp120 Attachment Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fostemsavir	Rukobia PD	PA	

Antiretroviral/HIV Therapy – CCR5 Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
maraviroc solution	Selzentry	PA	
maraviroc tablet	Selzentry	PA	A90

Antiretroviral/HIV Therapy – Capsid Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
lenacapavir	Sunlenca	PA	

Antiretroviral/HIV Therapy – CD4-Directed Post-Attachment Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ibalizumab-uiyk	Trogarzo	PA	

Antiretroviral/HIV Therapy – Nucleotide Analog Reverse Transcriptase Inhibitors (NtRTI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
tenofovir disoproxil fumarate powder	Viread	PA - ≥ 13 years	A90
tenofovir disoproxil fumarate tablet	Viread	PA - > 1 unit/day	# , A90

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- HIV-associated visceral adipose tissue accumulation (VAT) lipodystrophy (Egrifta)
- HIV infection (Cimduo, efavirenz/lamivudine/tenofovir disoproxil fumarate, fosamprenavir, maraviroc, nevirapine extended-release, Rukobia, Sunlenca, tenofovir disoproxil fumarate, Tivicay, Trogarzo)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Cimduo

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member is ≥ 18 years of age; **or**
    - member is < 18 years of age and weighs ≥ 35 kg; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents as defined by one of the following:
    - significant psychiatric diagnosis leading to documented difficulty with adherence; **or**
    - homeless members who may have difficulty storing larger amounts of medications; **or**
    - difficulty with adherence leading to complications; **or**
    - child/adolescent member or a member with developmental issues without adequate supports to properly manage their own HIV

regimen; **and**
- concurrent antiretroviral therapy with at least one other antiretroviral; **and**
- requested quantity is ≤ one unit/day.

efavirenz 400 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member is ≥ 18 years of age; **or**
    - member is < 18 years of age and weighs ≥ 35 kg; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents as defined by one of the following:
    - significant psychiatric diagnosis leading to documented difficulty with adherence; **or**
    - homeless members who may have difficulty storing larger amounts of medications; **or**
    - difficulty with adherence leading to complications; **or**
    - child/adolescent member or a member with developmental issues without adequate supports to properly manage their own HIV regimen; **and**
  - requested quantity is ≤ one unit/day.

efavirenz 600 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member is ≥ 18 years of age; **or**
    - member is < 18 years of age and weighs ≥ 40 kg; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents as defined by one of the following:
    - significant psychiatric diagnosis leading to documented difficulty with adherence; **or**
    - homeless members who may have difficulty storing larger amounts of medications; **or**
    - difficulty with adherence leading to complications; **or**
    - child/adolescent member or a member with developmental issues without adequate supports to properly manage their own HIV regimen; **and**
  - requested quantity is ≤ one unit/day.

Egrifta SV
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - antiretroviral therapy for ≥ 60 days within the last 90 days; **and**
  - other potential causes of VAT accumulation/central obesity have been ruled out; **and**
  - one of the following:
    - for male member, waist circumference is currently > 102 cm (dated within the 90 days prior to treatment initiation); **or**
    - for female member, waist circumference is currently > 88 cm (dated within the 90 days prior to treatment initiation); **and**
  - member has failed lifestyle modification with diet and exercise.
- For recertification, documentation of a decrease in waist circumference from baseline is required.

fosamprenavir

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to an antiretroviral regimen containing one of the following protease inhibitors: atazanavir, darunavir, ritonavir; **and**
  - concurrent antiretroviral therapy with at least one other antiretroviral; **and**
  - appropriate dosing.

maraviroc
- Documentation of the following is required:
  - appropriate diagnosis.

SmartPA: Claims for maraviroc will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for HIV disease. †

nevirapine extended-release
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to nevirapine immediate-release formulation.

Rukobia and Sunlenca for HIV-1 infection
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - ongoing detectable viremia; **and**
  - antiretroviral-experienced with documented historical or baseline resistance, intolerability, and/or contraindication to antiretroviral; **and**
  - failing current antiretroviral regimen due to resistance, intolerance or safety considerations; **and**
  - concurrent antiretroviral therapy with at least one other antiretroviral; **and**
  - appropriate dosing; **and**
  - for Rukobia, requested quantity is ≤ two units/day.

tenofovir disoproxil fumarate tablet > one unit/day
- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - HIV infection; **or**
    - Chronic Hepatitis B; **and**
  - medical necessity for exceeding the quantity limit.

Tivicay > one unit/day
- For members <18 years of age, documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - concurrent therapy with Aptivus (tipranavir)/ritonavir, carbamazepine, efavirenz, fosamprenavir/ritonavir, or rifampin.
- For members ≥18 years of age, documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - concurrent therapy with Aptivus (tipranavir)/ritonavir, carbamazepine, efavirenz, fosamprenavir/ritonavir, or rifampin; **or**
    - integrase strand transfer inhibitor (INSTI)-associated resistance substitutions or clinically suspected INSTI-resistance.

Trogarzo
- Documentation of all of the following is required:

- appropriate diagnosis; **and**
- member is ≥ 18 years of age; **and**
- ongoing detectable viremia; **and**
- resistance to at least one agent from each of the following three classes of antiretrovirals: NRTI, NNRTI, PI; **and**
- concurrent antiretroviral therapy with at least one other antiretroviral; **and**
- appropriate dosing; **and**
- inadequate response or adverse reaction to one or contraindication to both of the following: Rukobia, Sunlenca.

Viread powder ≥ 13 years of age

- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - HIV infection; **or**
    - Chronic Hepatitis B; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member utilizes tube feeding G-tube/J-tube.

SmartPA: Claims will usually process at the pharmacy without a PA for members ≥ 13 years of age request if the member has a history of paid MassHealth pharmacy claims of the requested medication for at least 90 days out of the last 120 days.†

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 39 - Influenza Prophylaxis and Treatment Agents

Drug Category: Anti-infectives

Medication Class/Individual Agents: Antiviral/Influenza

I. Prior-Authorization Requirements

Influenza Prophylaxis and Treatment Agents				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.**
baloxavir	Xofluza	PA		*Contraindications:* • Zanamivir: hypersensitivity to any component of the product including lactose (milk proteins) *Warnings:* • Zanamivir: airway disease (e.g., COPD, asthma) • Oseltamivir: hereditary fructose intolerance (with suspension), renal impairment, self-injury and delirium, and serious skin reactions
oseltamivir 30mg	Tamiflu	PA - > 20 units/ claim and PA > 40 units/ 365 days	#	
oseltamivir 45 mg and 75 mg	Tamiflu	PA - > 10 units/ claim and PA > 20 units/ 365 days	#	
oseltamivir suspension	Tamiflu	PA - > 180 mL/ claim and PA > 360 mL/ 365 days	#	
zanamivir	Relenza	PA - < 5 years and PA > 20 inhalations/ claim and PA > 40 inhalations/ 365 days		

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

II. Therapeutic Uses

FDA-approved, for example:

- Influenza Type A and B (oseltamivir ≥ two weeks of age; Relenza ≥ seven years of age; Xofluza ≥ five years of age)
- Prophylaxis of Influenza Type A and B (oseltamivir ≥ one year of age; Relenza ≥ five years of age; Xofluza ≥ five years of age)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available)

require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Prophylaxis

oseltamivir and Relenza

- Documentation of all of the following is required for prophylaxis requests above the quantity limit:
  - if the request is for Relenza, member is five years of age or older; **and**
  - one of the following:
    - member is a resident in an institutional setting; **or**
    - both of the following:
      - one of the following:
        - member with likely exposure to others with confirmed, probable, or suspected influenza infection and are at risk of developing influenza-related complications with at least one risk factor, including:
          - members ≥ 65 years of age; **or**
          - members ≤ five years of age; **or**
          - members < 19 years of age who are receiving long-term aspirin therapy; **or**
          - residents of nursing homes or chronic care facilities; **or**
          - pregnant members and members up to two weeks postpartum; **or**
          - members with chronic medical conditions including:
            - chronic pulmonary disease (e.g., asthma, chronic obstructive pulmonary disease, cystic fibrosis); **or**
            - cardiovascular disease (except isolated hypertension); **or**
            - renal dysfunction; **or**
            - hepatic dysfunction; **or**
            - chronic metabolic or endocrine disease (e.g., diabetes mellitus, mitochondrial disease); **or**
            - hemoglobinopathies (e.g., sickle cell disease); **or**
            - immunosuppression, including HIV infection, organ or hematopoietic cell transplantation, malignancy (if prescriber notes immunosuppression is a concern), and inflammatory disorders treated with immunosuppressants; **or**
            - neurologic conditions that compromise handling of respiratory secretions (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, neuromuscular disorders); **or**
        - members from certain racial and ethnic minority groups are at increased risk for hospitalization with flu, including non-Hispanic Black members, Hispanic or Latino members, and American Indian or Alaska Native members; **or**
        - members who are morbidly obese (body mass index ≥ 40); **or**
      - members who work in institutions caring for individuals at high risk of serious complications of influenza infection during

an institutional outbreak; **and**

- one of the following:
  - requested dose and duration is consistent with current CDC recommendations; **or**
  - medical necessity for going above standard dosing or duration recommendations.

SmartPA: Claims for oseltamivir above quantity limits and Relenza above quantity limits (in members ≥ five years) will usually process at the pharmacy without a PA if MassHealth pharmacy claims data indicate the member is currently in an institutional setting.†

Treatment

oseltamivir and Relenza

- Documentation of all of the following is required for treatment requests above the quantity limit:
  - if the request is for Relenza, member is seven years of age or older; **and**
  - one of the following:
    - member is a resident in an institutional setting; **or**
    - all of the following:
      - member with confirmed, probable, or suspected influenza; **and**
      - member is at high risk for developing serious influenza-related complications with at least one risk factor (see above); **and**
      - one of the following:
        - requested dose and duration is consistent with current CDC recommendations; **or**
        - medical necessity for going above standard dosing or duration recommendations.

SmartPA: Claims for oseltamivir above quantity limits and Relenza above quantity limits (in members ≥ five years) will usually process at the pharmacy without a PA if MassHealth pharmacy claims data indicate the member is currently in an institutional setting.†

Xofluza

- Documentation of all of the following is required for prophylaxis or treatment requests:
  - member is ≥ five years of age; **and**
  - one of the following:
    - member with confirmed, probable, or suspected influenza; **or**
    - member with exposure to an individual with confirmed influenza infection; **and**
  - medical necessity for the use of single-dose preparation instead of treatment course with oseltamivir capsules; **and**
  - appropriate dosing; **and**
  - one of the following:
    - for the 20 mg tablet, requested quantity is ≤ two tablets per treatment; **or**
    - for the 40 mg and 80 mg tablets, requested quantity is ≤ one tablet per treatment.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 40 - Respiratory Agents - Oral

Drug Category: Respiratory Tract Agents

Medication Class/Individual Agents: Respiratory Agents - Oral

I. Prior-Authorization Requirements

Oral Respiratory Agents – Leukotriene Modifiers			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
montelukast granules	Singulair	PA	M90
montelukast tablet, chewable tablet	Singulair		# , M90
zafirlukast	Accolate	PA	M90
zileuton	Zyflo	PA	
zileuton extended-release		PA	

Oral Respiratory Agents – Selective Phosphodiesterase 4 [PDE4] Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
roflumilast tablet	Daliresp	PA	M90

Oral Respiratory Agents – Pulmonary Fibrosis Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
nintedanib	Ofev	PA	
pirfenidone	Esbriet	PA	A90

Oral Respiratory Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
theophylline			M90

Oral Respiratory Agents – Short-Acting Beta Agonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
albuterol syrup, tablet			A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Contraindications:

- All agents: hypersensitivity to any component
- roflumilast tablet:
  - moderate-to-severe liver impairment
- zileuton:
  - active liver disease
  - persistent liver enzyme elevations three or more times the upper limit of normal

Warnings:

- montelukast
  - Should not be used to treat an acute asthma attack: member should have short-acting beta-agonist
  - Should not be abruptly substituted for steroids
  - Neuropsychiatric events (e.g., agitation, aggressive behavior, depression, suicidal ideation, etc.) have been reported with use of this agent
  - Eosinophilic conditions (e.g., vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy) may present in asthmatic members taking montelukast
  - Chewable tablets contain phenylalanine
- nintedanib

	Clinical Notes
	• Do not use in moderate or severe liver impairment • Increased risk of bleeding • Increased risk of gastrointestinal perforation • pirfenidone • Liver enzyme elevations three times the upper limit of normal • Photosensitivity reaction or rash • roflumilast tablet • Should not be used to treat an acute asthma attack • May be associated with unexplained weight loss • Use with potential cytochrome P450 enzyme inducers may decrease roflumilast concentrations • Psychiatric events including suicidality have been reported with this agent. Use with caution in those with history of depression and/or suicidal thoughts • zafirlukast • Liver disease • Not for reversal of bronchospasm in acute asthma • zileuton • Alcohol intake of substantial quantities • Liver disease • Not for reversal of bronchospasm in acute asthma • Neuropsychiatric events (e.g., sleep disorders and behavior changes) have been reported with use of this agent

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- asthma (montelukast, zafirlukast, zileuton extended-release, Zyflo)
- allergic rhinitis (montelukast)
- chronic obstructive pulmonary disease (roflumilast tablet)
- exercise-induced bronchospasm (montelukast)
- chronic fibrosing interstitial lung diseases with a progressive phenotype (Ofev)
- idiopathic pulmonary fibrosis (Ofev, pirfenidone)
- systemic sclerosis-associated interstitial lung disease (Ofev)

Non-FDA-approved, for example:

- eosinophilic esophagitis (montelukast)

- urticaria (montelukast)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

montelukast granules

- Documentation of the following is required for the diagnosis of allergic rhinitis:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to one oral second-generation antihistamine (i.e., loratadine, cetirizine, fexofenadine); **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to one intranasal antihistamine or intranasal corticosteroid; **and**
  - medical necessity for the granule formulation as noted by one of the following:
    - member is < two years of age; **or**
    - inadequate response or adverse reaction to montelukast chewable tablets; **and**
  - requested quantity is ≤ one unit/day.
- Documentation of the following is required for the diagnosis of asthma:
  - appropriate diagnosis; **and**
  - medical necessity for the granule formulation as noted by one of the following:
    - member is < two years of age; **or**
    - inadequate response or adverse reaction to montelukast chewable tablets; **and**
  - requested quantity is ≤ one unit/day.
- Documentation of the following is required for the diagnosis of eosinophilic esophagitis:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 60 days of therapy) or adverse reaction to one or contraindication to all proton pump inhibitors; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to both of the following: budesonide, fluticasone propionate.

- Documentation of the following is required for the diagnosis of Exercise-Induced Bronchospasm (EIB):
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: one short-acting beta agonist inhaler (albuterol or levalbuterol), low dose inhaled corticosteroid-formoterol; **and**
  - medical necessity for the granule formulation as noted by one of the following:
    - member is < two years of age; **or**
    - inadequate response or adverse reaction to montelukast chewable tablets; **and**
  - requested quantity is ≤ one unit/day.
- Documentation of the following is required for the diagnosis of urticaria:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all second-generation antihistamines; **and**
  - medical necessity for the granule formulation as noted by one of the following:
    - member is < two years of age; **or**
    - inadequate response or adverse reaction to montelukast chewable tablets.

Ofev and pirfenidone for idiopathic pulmonary fibrosis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - for pirfenidone 267 mg, requested quantity is ≤ nine units/day; **or**
    - for pirfenidone 534 mg, requested quantity is ≤ three units/day; **or**
    - for pirfenidone 801 mg, requested quantity is ≤ three units/day; **or**
    - for Ofev, requested quantity is ≤ two units/day.

Ofev for chronic fibrosing interstitial lung diseases with a progressive phenotype
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ two units/day.

Ofev for systemic sclerosis-associated interstitial lung disease
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: cyclophosphamide, mycophenolate; **and**
  - requested quantity is ≤ two units/day.

roflumilast tablet
- Documentation of the following is required:
  - diagnosis of Chronic Obstructive Pulmonary Disease (COPD); **and**
  - appropriate dosing; **and**
  - one of the following:
    - inadequate response (within the last four months) or adverse reaction to one or contraindication to all of the following: Bevespi, Duaklir, Stiolto, umeclidinium/vilanterol; **or**
    - inadequate response (within the last four months) or adverse reaction to one or contraindication to both of the following: Breztri, Trelegy; **and**
  - requested quantity is ≤ one unit/day.

SmartPA: Claims for roflumilast 500 mg tablet (≤ one unit/day) will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for a diagnosis of chronic obstructive pulmonary disease and the member has a

history of paid MassHealth pharmacy claims within the last 120 days for Bevespi, Breztri, Duaklir, Stiolto, Trelegy, or umeclidinium/vilanterol.†

zafirlukast

- Documentation of the following is required:
  - diagnosis of asthma; **and**
  - requested quantity is ≤ two units/day.

SmartPA: Claims for zafirlukast (≤ two units/day) will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for a diagnosis of asthma, or paid MassHealth pharmacy claims for a short/long acting inhaled beta agonist for ≥ 90 days of therapy in the last 120 days, or paid MassHealth pharmacy claims for an inhaled corticosteroid in the last 90 days.†

zileuton extended-release

- Documentation of the following is required:
  - diagnosis of asthma; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to one or contraindication to both of the following: montelukast, zafirlukast; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to Zyflo; **and**
  - requested dose is ≤ 1,200 mg twice daily.

Zyflo

- Documentation of the following is required:
  - diagnosis of asthma; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to one or contraindication to both of the following: montelukast, zafirlukast; **and**
  - requested dose is ≤ 600 mg four times daily.

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 41 - Antibiotics - Topical

Drug Category: Dermatological

Medication Class/Individual Agents: Antibiotics

I. Prior-Authorization Requirements

Topical Antibacterials			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bacitracin			*, A90
bacitracin / polymyxin B topical ointment	double antibiotic ointment		*, A90
chlorhexidine gluconate			*, A90
gentamicin topical cream, ointment			A90
hydrogen peroxide			*, A90
iodine			*, A90
isopropyl alcohol			*, A90
mafenide	Sulfamylon		# , A90
mupirocin cream		PA	A90
mupirocin ointment	Centany		A90
mupirocin ointment			A90
neomycin / bacitracin / polymyxin B topical ointment	triple antibiotic ointment		*, A90
ozenoxacin	Xepi	PA	
povidone			*, A90
silver sulfadiazine			A90
silver sulfadiazine-Silvadene	Silvadene		# , A90

Vaginal Antibiotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
clindamycin vaginal cream-Cleocin	Cleocin		# , A90
clindamycin vaginal cream-Clindesse	Clindesse	PA	
clindamycin vaginal gel	Xaciato	PA	
clindamycin vaginal	Cleocin Vaginal Ovule		

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Warnings and Precautions:

- Contact with eyes should be avoided.
- Contact with mucosal surfaces should be avoided with mupirocin 2% ointment.
- If severe local irritation occurs, product should be discontinued.
- Prolonged use may result in overgrowth of nonsusceptible microorganisms, including fungi.
- Mupirocin 2% ointment contains polyethylene glycol. This product should be avoided if large quantities of polyethylene glycol could potentially be absorbed, especially in those with moderate-to-severe renal impairment or open wounds with damaged skin (other formulations do not contain polyethylene glycol).

Vaginal Antibiotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
suppository			
metronidazole 0.75% vaginal gel			A90
metronidazole 0.75% vaginal gel-Vandazole	Vandazole	PA	
metronidazole 1.3% vaginal gel	Nuvessa	PA	

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Bacterial vaginosis - Clindesse, Nuvessa, Vandazole, Xaciato
- Treatment of impetigo - mupirocin cream, Xepi
- Infected traumatic lesions - mupirocin cream

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Clindesse, Nuvessa, Vandazole, Xaciato

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: oral metronidazole tablets, metronidazole 0.75% vaginal gel available without PA; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: clindamycin vaginal cream, Cleocin Vaginal Ovule; **and**
  - appropriate dosing.

mupirocin cream for impetigo or infected traumatic lesions

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to mupirocin ointment; **and**
  - requested quantity is ≤ one package/30 days.

Xepi

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two months of age; **and**
  - medical records documenting an inadequate response or adverse reaction to one or contraindication to both of the following: mupirocin cream, mupirocin ointment; **and**
  - requested quantity is ≤ one package/30 days.

MassHealth Evaluation Criteria
Table 42 - Immune Suppressants - Topical

Drug Category: Topical Agents

Medication Class/Individual Agents: Immune Suppressants

I. Prior-Authorization Requirements

Dermatological Immune Suppressants				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
crisaborole	Eucrisa PD	PA		**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** *Topical Immunosuppressants:* • Crisaborole is a topical phosphodiesterase 4 inhibitor that is FDA-approved for the treatment of mild to moderate atopic dermatitis in members three months of age and older. • Ruxolitinib cream is a topical Janus kinase inhibitor that is FDA-approved for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised members 12 years of age and older.
pimecrolimus	Elidel	PA	A90	
roflumilast cream, foam	Zoryve PD	PA		
ruxolitinib cream	Opzelura PD	PA		
tacrolimus topical			A90	
tapinarof	Vtama	PA		

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Atopic dermatitis (eczema)
- Plaque psoriasis
- Seborrheic dermatitis

- Vitiligo

Non-FDA-approved, for example:

- Alopecia areata
- Seborrheic dermatitis

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Eucrisa

- Documentation of all of the following is required:
  - diagnosis of atopic dermatitis; **and**
  - member is ≥ three months of age; **and**
  - one of the following:
    - both of the following:
      - member has atopic dermatitis on the face or areas at high risk for skin atrophy (e.g., intertriginous areas, genitals); **and**
      - inadequate response, adverse reaction, or contraindication to a topical calcineurin inhibitor; **or**
    - inadequate response or adverse reaction to one or contraindication to both of the following: topical corticosteroids, topical calcineurin inhibitors; **and**
  - one of the following:
    - requested quantity is ≤ 60 grams/30 days; **or**
    - medical necessity for exceeding the quantity limit.

SmartPA: Claims for ≤ 60 grams/30 days of Eucrisa will usually process at the pharmacy without a PA request if the member is ≥ three months of age, has a history of MassHealth medical claims for atopic dermatitis, and has a history of a paid MassHealth pharmacy claim for one topical corticosteroid or one topical calcineurin inhibitor.†

Opzelura

- Documentation of all of the following is required for a diagnosis of atopic dermatitis:

- appropriate diagnosis; **and**
- one of the following:
  - both of the following:
    - member is ≥ two years and < 12 years of age; **and**
    - prescriber is a dermatologist or consult notes from a dermatologist are provided; **or**
  - member is ≥ 12 years of age; **and**
- inadequate response, adverse reaction, or contraindication to a topical calcineurin inhibitor; **and**
- one of the following:
  - requested quantity is ≤ 60 grams/30 days; **or**
  - medical necessity for exceeding the quantity limit.

- Documentation of all of the following is required for a diagnosis of vitiligo:
  - appropriate diagnosis; **and**
  - prescriber is a dermatologist or consult notes from a dermatologist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - total body surface area (BSA) to be treated is ≤ 10%; **and**
  - inadequate response, adverse reaction, or contraindication to a topical calcineurin inhibitor; **and**
  - one of the following:
    - requested quantity is ≤ 60 grams/30 days; **or**
    - medical necessity for exceeding the quantity limit.

- Documentation of all of the following is required for a diagnosis of alopecia areata:
  - appropriate diagnosis; **and**
  - prescriber is a dermatologist or consult notes from a dermatologist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Olumiant, Xeljanz, Xeljanz XR; **and**
  - one of the following:
    - requested quantity is ≤ 60 grams/30 days; **or**
    - medical necessity for exceeding the quantity limit; **and**
  - one of the following:
    - both of the following:
      - inadequate response or adverse reaction to one topical corticosteroid, or contraindication to all topical corticosteroids; **and**
      - inadequate response or adverse reaction to one intralesional corticosteroid, or contraindication to all intralesional corticosteroids; **or**
    - member has a large area of hair loss (e.g. ≥ 25 percent scalp hair loss).

pimecrolimus

- Documentation of all of the following is required:
  - diagnosis of atopic dermatitis; **and**
  - member is ≥ two years of age; **and**
  - one of the following:
    - member has atopic dermatitis on the face or areas at high risk for skin atrophy (e.g., intertriginous areas, genitals); **or**
    - inadequate response, adverse reaction, or contraindication to a topical corticosteroid; **and**
  - one of the following:
    - for members <16 years of age, inadequate response, adverse reaction, or contraindication to topical tacrolimus 0.03%; **or**
    - for members ≥16 years of age, inadequate response, adverse reaction, or contraindication to topical tacrolimus; **and**
  - one of the following:
    - requested quantity is ≤ 100 grams/30 days; **or**

- medical necessity for exceeding the quantity limit.

SmartPA: Claims for ≤ 100 grams/30 days of pimecrolimus will usually process at the pharmacy without a PA request if the member is ≥ two years of age, has a history of a paid MassHealth pharmacy claim for one topical corticosteroid, and a history of paid claim for topical tacrolimus for members ≥ 16 years of age or tacrolimus 0.03% for members < 16 years of age in all claims history .†

Vtama

- Documentation of all of the following is required:
  - diagnosis of plaque psoriasis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - both of the following:
      - member has plaque psoriasis on the face or areas at high risk for skin atrophy (e.g., intertriginous areas, genitals); **and**
      - inadequate response, adverse reaction, or contraindication to both of the following: topical calcineurin inhibitors, vitamin D analogs; **or**
    - inadequate response or adverse reaction to two or contraindication to all of the following: topical corticosteroids, topical calcineurin inhibitors, vitamin D analogs; **and**
  - one of the following:
    - requested quantity is ≤ 60 grams/30 days; **or**
    - medical necessity for exceeding the quantity limit.

Zoryve 0.15% cream

- Documentation of all of the following is required:
  - diagnosis of atopic dermatitis; **and**
  - member is ≥ six years of age; **and**
  - inadequate response, adverse reaction, or contraindication to a topical calcineurin inhibitor; **and**
  - one of the following:
    - requested quantity is ≤ 60 grams/30 days; **or**
    - medical necessity for exceeding the quantity limit.

Zoryve 0.3% cream

- Documentation of all of the following is required:
  - diagnosis of plaque psoriasis; **and**
  - member is ≥ six years of age; **and**
  - one of the following:
    - both of the following:
      - member has plaque psoriasis on the face or areas at high risk for skin atrophy (e.g., intertriginous areas, genitals); **and**
      - inadequate response or adverse reaction to one or contraindication to both of the following: topical calcineurin inhibitors, vitamin D analogs; **or**
    - inadequate response or adverse reaction to one or contraindication to all of the following: topical calcineurin inhibitors, topical corticosteroids, vitamin D analogs; **and**
  - one of the following:
    - requested quantity is ≤ 60 grams/30 days; **or**
    - medical necessity for exceeding the quantity limit.

Zoryve foam

- Documentation of all of the following is required for the diagnosis of seborrheic dermatitis:
  - appropriate diagnosis; **and**
  - member is ≥ nine years of age; **and**

- one of the following:
  - both of the following:
    - member has seborrheic dermatitis on the face or areas at high risk for skin atrophy (e.g., intertriginous areas, genitals); **and**
    - inadequate response or adverse reaction to one or contraindication to both of the following: topical antifungals, topical calcineurin inhibitors; **or**
  - inadequate response or adverse reaction to one or contraindication to all of the following: topical antifungals, topical corticosteroids, topical calcineurin inhibitors; **and**
- one of the following:
  - requested quantity is ≤ 60 grams/30 days; **or**
  - medical necessity for exceeding the quantity limit.

- Documentation of all of the following is required for the diagnosis of plaque psoriasis:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - one of the following:
    - both of the following:
      - member has plaque psoriasis on the face or areas at high risk for skin atrophy (e.g., intertriginous areas, genitals); **and**
      - inadequate response or adverse reaction to one or contraindication to both of the following: topical calcineurin inhibitors, vitamin D analogs; **or**
    - inadequate response or adverse reaction to one or contraindication to all of the following: topical calcineurin inhibitors, topical corticosteroids, vitamin D analogs; **and**
  - one of the following:
    - requested quantity is ≤ 60 grams/30 days; **or**
    - medical necessity for exceeding the quantity limit.

†**Note**: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 43 - Pulmonary Hypertension Agents

Drug Category: Cardiovascular Agents

Medication Class/Individual Agents: Peripheral Vasodilators and Pulmonary Hypertension Agents

I. Prior-Authorization Requirements

Pulmonary Hypertension Agents – Phosphodiesterase Type 5 Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
sildenafil 20 mg tablet	Revatio	PA	A90
sildenafil oral suspension-Liqrev	Liqrev	PA	
sildenafil oral suspension-Revatio	Revatio	PA	A90
tadalafil suspension	Tadliq	PA	
tadalafil tablet-Adcirca	Adcirca	PA	A90

Pulmonary Hypertension Agents – Soluble Guanylate Cyclase Stimulators			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
riociguat	Adempas	PA	

Pulmonary Hypertension Agents – Prostanoids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
epoprostenol-Flolan	Flolan		
epoprostenol-Veletri	Veletri	PA	
iloprost	Ventavis	PA	
treprostinil inhalation powder	Tyvaso DPI	PA	
treprostinil inhalation solution	Tyvaso	PA	
treprostinil injection	Remodulin	PA	BP

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report (2019)[1]

- For treatment naïve patients with WHO FC II and III, initial combination therapy with ambrisentan and tadalafil is suggested to improve 6-minute walk distance (6MWD). For patients unwilling or unable to tolerate combination therapy, monotherapy with an endothelin receptor antagonist (ERA), phosphodiesterase-5 (PDE-5) inhibitor, or riociguat is recommended.
- For treatment naïve patients in WHO FC IV, initiation of a parenteral prostanoid agent is recommended. For patients who are unwilling or unable to manage parenteral therapy, a combination of an inhaled prostanoid with an oral PDE-5 inhibitor and an ERA is recommended.
- For WHO FC III or IV patients who have an inadequate response to established PAH-specific monotherapy, the addition of a second class of PAH therapy is recommended to improve exercise capacity.

World Health Organization Functional Classification (WHO-FC) of Patients With PH[2]

Pulmonary Hypertension Agents – Prostanoids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
treprostinil tablet	Orenitram	PA	

Pulmonary Hypertension Agents – Endothelin Receptor Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ambrisentan	Letairis	PA	A90
bosentan	Tracleer	PA	BP, A90
macitentan	Opsumit	PA	

Pulmonary Hypertension Agents – Combination Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
macitentan / tadalafil	Opsynvi	PA	

Pulmonary Hypertension Agents – Prostacyclin Receptor Agonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
selexipag	Uptravi	PA	

Pulmonary Hypertension Agents – Activin Signaling Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
sotatercept-csrk	Winrevair	PA	

Clinical Notes

- Class I: Patients with no symptoms, and for whom ordinary physical activity does not cause fatigue, palpitation, dyspnea, or anginal pain.
- Class II: Patients who are comfortable at rest but who have symptoms with less-than-ordinary physical activity resulting in slight limitations of physical activity.
- Class III: Patients who are comfortable at rest but have symptoms with less-than-ordinary effort resulting in marked limitations of physical activity.
- Class IV: Patients who have symptoms at rest. These patients manifest signs of heart failure.

Key symptoms of PAH include fatigue, dizziness and fainting (near syncope).

[1] *Klinger JR, Elliott CG, Levine DJ, Bossone E, Duvall L, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report.* ***Chest. 2019 Mar;155(3):565-586****. doi: 10.1016/j.chest.2018.11.030. Epub 2019 Jan 17. Erratum in:* ***Chest. 2021 Jan;159(1):457****. PMID: 30660783.*

[2] *Barst RJ, McGoon M, Torbicki A, et al. Diagnosis and differential assessment of pulmonary arterial hypertension.* ***J Am Coll Cardiol 2004; 43:40S-47S.***

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Treatment of chronic thromboembolic pulmonary hypertension (CTEPH)
- Treatment of WHO Group 1 pulmonary arterial hypertension (PAH)
- Pulmonary hypertension associated with interstitial lung disease (PH, ILD)

Non-FDA-approved, for example:

- Raynaud phenomenon

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Adempas (riociguat)

- Documentation of the following is required for a diagnosis of CTEPH:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - persistent or recurrent CTEPH after surgical treatment, or CTEPH is inoperable; **and**
  - requested quantity is ≤ three tablets/day; **and**
  - one of the following:
    - no recent paid pharmacy claims for tadalafil or sildenafil; **or**
    - agent will not be coadministered with a PDE-5 inhibitor.
- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: sildenafil, tadalafil; **and**
  - requested quantity is ≤ three tablets/day; **and**
  - one of the following:
    - no recent paid pharmacy claims for tadalafil or sildenafil; **or**
    - agent will not be coadministered with a PDE-5 inhibitor.

SmartPA: Claims for Adempas will usually process at the pharmacy without a PA request if there is a history of paid claims of the requested agent, or if the member is ≥ 18 years of age, has a history of MassHealth medical claims for PAH, the prescriber is a pulmonologist or cardiologist, there is a history of paid MassHealth pharmacy claims for sildenafil 20 mg tablets or tadalafil 20 mg tablets, there is no history of paid MassHealth pharmacy claims for sildenafil 20 mg tablet and tadalafil 20 mg tablet within the last 30

days, and there is no history of paid MassHealth pharmacy claims for sildenafil 20 mg tablet and tadalafil 20 mg tablet for ≥ 15 days of therapy within the last 30 days, and the requested quantity is ≤ three tablets/day.†

ambrisentan, bosentan, and Opsumit (macitentan)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - one of the following:
    - for ambrisentan and Opsumit, requested quantity is ≤ one tablet/day; **or**
    - for bosentan tablet, requested quantity is ≤ two tablets/day; **or**
    - for bosentan for suspension, all of the following:
      - member is < 13 years of age; **and**
      - prescriber must provide member's current weight; **and**
      - requested quantity is ≤ four tablets/day.

SmartPA: Claims for ambrisentan, bosentan tablet, and Opsumit will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent, or if the member has a history of MassHealth medical claims for PAH, the prescriber is a pulmonologist or cardiologist, and the requested quantity is ≤ one tablet/day (ambrisentan and Opsumit) or ≤ two tablets/day (bosentan tablet).†

SmartPA: Claims for bosentan for suspension will usually process at the pharmacy without a PA request if the member is < 13 years of age, has a history of MassHealth medical claims for PAH, the prescriber is a pulmonologist or cardiologist, and the requested quantity is ≤ four tablets/day.†

epoprostenol (generic Veletri)

- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - inadequate response, adverse reaction, or contraindication to Flolan.

SmartPA: Claims for epoprostenol (generic Veletri) will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent.†

Liqrev, and sildenafil oral suspension (generic Revatio)

- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - one of the following:
    - no recent paid pharmacy claims for Adempas; **or**
    - requested agent will not be administered with Adempas; **and**
  - one of the following:
    - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets); **or**
    - member utilizes tube feeding; **or**
    - member is <13 years of age; **or**
    - medical necessity for the requested formulation instead of sildenafil tablets; **and**
  - for Liqrev, medical necessity for use instead of sildenafil oral suspension (generic Revatio).
  - For recertification for a diagnosis of PAH, documentation of continuation to meet the criteria for use of the suspension instead of the tablet formulation as noted by one of the following:
    - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed; **or**
    - member utilizes tube feeding; **or**

- member is <13 years of age; **or**
- medical necessity for the requested formulation instead of tablets.

- Documentation of the following is required for a diagnosis of Raynaud phenomenon:
  - appropriate diagnosis; **and**
  - one of the following:
    - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets); **or**
    - member utilizes tube feeding; **or**
    - member is <13 years of age; **or**
    - medical necessity for the requested formulation instead of sildenafil tablets; **and**
  - for Liqrev, medical necessity for use instead of sildenafil oral suspension (generic Revatio); **and**
  - one of the following:
    - inadequate response or adverse reaction to one, or contraindication to all of the following: amlodipine, nifedipine, topical nitroglycerin; **or**
    - PDE5 inhibitor is being used for the healing of digital ulcers.

Opsynvi
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents; **and**
  - requested quantity is ≤ one tablet/day; **and**
  - one of the following:
    - no recent paid pharmacy claims for Adempas; **or**
    - agent will not be coadministered with Adempas.

Orenitram (treprostinil), treprostinil injection, and Ventavis (iloprost)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - inadequate response, adverse reaction, or contraindication to epoprostenol (generic Veletri) or Flolan; **and**
  - for Ventavis, requested quantity is ≤ nine ampules/day.

SmartPA: Claims for Orenitram, treprostinil injection, and Ventavis will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent, or if the member has a history of MassHealth medical claims for PAH, member has a history of paid MassHealth pharmacy claims for epoprostenol (generic Veletri) or Flolan, the prescriber is a pulmonologist or cardiologist, and, if the request is for Ventavis, the requested quantity is ≤ nine ampules/day.†

sildenafil 20 mg tablet
- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - one of the following:
    - no recent paid pharmacy claims for Adempas; **or**
    - requested agent will not be administered with Adempas.

- Documentation of the following is required for a diagnosis of Raynaud phenomenon:
  - appropriate diagnosis; **and**

- one of the following:
  - inadequate response or adverse reaction to one, or contraindication to all of the following: amlodipine, nifedipine, topical nitroglycerin; **or**
  - PDE5 inhibitor is being used for the healing of digital ulcers.

SmartPA: Claims for sildenafil 20 mg tablets will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for PAH, there is no history of paid claims for Adempas within the last 30 days, and there is no history of paid MassHealth pharmacy claims for Adempas for ≥ 15 days of therapy within the last 30 days.†

tadalafil

- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - one of the following:
    - no recent paid pharmacy claims for Adempas; **or**
    - agent will not be co-administered with Adempas; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to sildenafil 20 mg tablets; **or**
    - member is treatment naïve and the requested agent will be used in combination with ambrisentan.

- Documentation of the following is required for a diagnosis of Raynaud phenomenon:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to one, or contraindication to all of the following: amlodipine, nifedipine, topical nitroglycerin; **or**
    - PDE5 inhibitor is being used for the healing of digital ulcers; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to sildenafil (generic Revatio); **or**
    - medical necessity for use of the requested agent instead of sildenafil (generic Revatio).

SmartPA: Claims for tadalafil 20 mg tablet will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for PAH, the prescriber is a pulmonologist or cardiologist, there is a history of paid MassHealth pharmacy claims for sildenafil 20 mg tablet, there is no history of paid MassHealth pharmacy claims for Adempas within the last 30 days, and there is no history of paid MassHealth pharmacy claims for Adempas for ≥ 15 days of therapy within the last 30 days.†

Tadliq

- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - one of the following:
    - no recent paid pharmacy claims for Adempas; **or**
    - agent will not be co-administered with Adempas; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to sildenafil 20 mg tablets; **or**
    - member is treatment naïve and the requested agent will be used in combination with ambrisentan; **and**
  - one of the following:
    - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets); **or**
    - member utilizes tube feeding; **or**
    - member is <13 years of age; **or**

- medical necessity for the requested formulation instead of tadalafil tablets.
- For recertification for a diagnosis of PAH, documentation of continuation to meet the criteria for use of the suspension instead of the tablet formulation as noted by one of the following:
  - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed; **or**
  - member utilizes tube feeding; **or**
  - member is <13 years of age; **or**
  - medical necessity for the requested formulation instead of tablets.

Tyvaso (treprostinil inhalation solution), Tyvaso DPI (treprostinil inhalation powder)

- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - inadequate response, adverse reaction, or contraindication to epoprostenol (generic Veletri) or Flolan; **and**
  - for Tyvaso DPI, medical records documenting an inadequate response, adverse reaction, or contraindication to Tyvaso inhalation solution.
- Documentation of the following is required for a diagnosis of PH-ILD:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or prescriber provides consultation notes from a pulmonologist or cardiologist regarding the diagnosis; **and**
  - for Tyvaso DPI, medical records documenting an inadequate response, adverse reaction, or contraindication to Tyvaso inhalation solution.

SmartPA: Claims for Tyvaso will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent, or if the member has a history of MassHealth medical claims for PAH, member has a history of paid MassHealth pharmacy claims for epoprostenol (generic Veletri) or Flolan, and the prescriber is a pulmonologist or cardiologist. †

Uptravi (selexipag)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - requested quantity is ≤ two tablets/day; **and**
  - for Uptravi vial, the member is stabilized on Uptravi tablets and is temporarily unable to take oral medications.

SmartPA: Claims for Uptravi tablets will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent.†

Winrevair

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - member is on stable background therapy for PAH; **and**
  - member's current weight.
- For recertification, prescriber must provide medical records documenting positive response to therapy (including, but not limited to improvement in walk distance, dyspnea, functional class, exercise capacity, or hemodynamic parameters such as NT-proBNP or pulmonary vascular resistance).

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 44 - Hepatitis Antiviral Agents

Drug Category: Anti-infectives

Medication Class/Individual Agents: Hepatitis antivirals

I. Prior-Authorization Requirements

Hepatitis Antiviral Agents – Miscellaneous Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
adefovir	Hepsera	PA - > 1 unit/day	# , A90
entecavir solution	Baraclude	PA - > 20 mL/day	
entecavir tablet	Baraclude	PA - > 1 unit/day	# , A90
lamivudine 100 mg tablet		PA - > 1 unit/day	A90
peginterferon alfa-2a	Pegasys	PA	
ribavirin 200 mg capsule		PA	A90
ribavirin tablet			A90
tenofovir alafenamide	Vemlidy PD		
tenofovir disoproxil fumarate powder	Viread	PA - ≥ 13 years	A90
tenofovir disoproxil fumarate tablet	Viread	PA - > 1 unit/day	# , A90

Hepatitis Antiviral Agents – Combination Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
elbasvir / grazoprevir	Zepatier	PA	
glecaprevir / pibrentasvir	Mavyret PD	PA	
ledipasvir / sofosbuvir PD	Harvoni	PA	
sofosbuvir / velpatasvir PD	Epclusa	PA	
sofosbuvir / velpatasvir / voxilaprevir	Vosevi	PA	

Hepatitis Antiviral Agents – Single Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
sofosbuvir	Sovaldi	PA	

Clinical Notes

PLEASE SEE SECTION III BELOW FOR PREFERRED HEPATITIS C PRODUCT REFERENCE TABLE

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Please note: For evaluation criteria where medical records and results of diagnostic tests assessing hepatic fibrosis and liver disease stage are required, staging information must clearly demonstrate early stage (e.g., Metavir Score F0-F2) or advanced stage (e.g., Metavir Score F3-F4) disease. If results are inconclusive, further diagnostic testing may be required.

Hepatitis B Virus (HBV) Nucleoside Analog Reverse Transcriptase Inhibitor:

- Tenofovir alafenamide is a prodrug of tenofovir FDA-approved for the treatment of chronic HBV infection in adults with compensated liver disease. No dosage adjustment is required in members with mild, moderate, or severe renal impairment.

Hepatitis C Virus (HCV) Combination Products:

- Elbasvir/grazoprevir is a once-daily combination of

	Clinical Notes
	elbasvir, an HCV NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor. Elbasvir/grazoprevir with or without ribavirin is indicated for the treatment of members with chronic HCV genotypes 1 or 4 infection including those with compensated cirrhosis. The FDA-approved treatment duration is 12 or 16 weeks depending on HCV genotype, prior treatment history, and for members HCV with genotype 1a infection, the presence of certain NS5A polymorphisms at baseline. • Glecaprevir/pibrentasvir is a once-daily combination of glecaprevir, an HCV NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor. It is indicated for the treatment of chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection in members three years and older, including members with renal impairment. It is also approved for adults with HCV genotype 1 who have been previously treated with an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. The recommended treatment duration is eight, 12, or 16 weeks depending on genotype, prior treatment history, and cirrhosis status. • Ledipasvir/sofosbuvir is a once-daily combination of ledipasvir, an HCV NS5A inhibitor, and sofosbuvir, an HCV NS5B polymerase inhibitor, that is FDA-approved for the treatment of chronic HCV genotype 1, 4, 5, or 6 infection. The FDA-approved treatment duration is eight, 12 or 24 weeks depending on prior treatment history, cirrhosis status, and baseline viral load. Eight weeks of treatment can be considered for treatment-naïve adults with HCV genotype 1 without cirrhosis and baseline HCV viral load <6 million IU/mL. • Ombitasvir/paritaprevir/ritonavir/dasabuvir includes fixed-dose ombitasvir, an HCV NS5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor and ritonavir, a CYP3A inhibitor co-packaged with dasabuvir, an HCV non-nucleoside NS5B palm polymerase inhibitor. Ombitasvir/paritaprevir/ritonavir/dasabuvir with or without ribavirin is indicated for the treatment of members with chronic HCV genotype 1 infection including those with compensated cirrhosis. The FDA-approved treatment duration is 12 or 24 weeks depending on prior treatment history and cirrhosis status. • Sofosbuvir/velpatasvir is a once-daily combination of sofosbuvir, an HCV NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, that is FDA

	Clinical Notes
	approved for the treatment of chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection. The FDA-approved treatment duration is 12 weeks regardless of the presence or absence of cirrhosis. The addition of ribavirin is recommended in members with decompensated cirrhosis. • Sofosbuvir/velpatasvir/voxilaprevir is a once-daily combination of sofosbuvir, an HCV NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor. It is indicated for the treatment of chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection in adults who have been previously treated with an HCV regimen containing an NS5A inhibitor. It is also indicated for the treatment of chronic HCV genotype 1a or 3 infection in adults who have been previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. The FDA-approved treatment duration is 12 weeks. The following regimens are not recommended by treatment guidelines for routine use in the treatment of hepatitis C.[1] Requests for these regimens will be reviewed on a case-by-case basis taking into consideration medical necessity for use over a standard of care regimen (e.g., regimen containing a combination product recommended for routine use). • Peginterferon alfa as monotherapy or in combination with other HCV antivirals • Sovaldi (sofosbuvir) plus peginterferon alfa and ribavirin • Sovaldi (sofosbuvir) plus ribavirin [1] AASLD-IDSA. HCV guidance: Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed December 16, 2019.

#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Hepatitis B (chronic) – adefovir, entecavir, lamivudine, Pegasys, tenofovir disoproxil fumarate
- Hepatitis C – ledipasvir/sofosbuvir, Mavyret, ribavirin, sofosbuvir/velpatasvir, Vosevi, Zepatier

Note: The above list may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Preferred Hepatitis C Product Reference Table:

HCV GT	Treatment History	Cirrhosis Status	Preferred Regimen(s) (listed in alphabetical order)[1]
GT1	Naïve	Non-cirrhotic	• ledipasvir/sofosbuvir x eight weeks (if viral load < six million IU/mL) • Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT1 (cont.)	Naïve	Cirrhotic (CTP A)	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT1 (cont.)	Experienced (PEG/RBV)	Non-cirrhotic	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT1 (cont.)	Experienced (PEG/RBV)	Cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks

GT1 (cont.)	Experienced (PI+PEG/RBV)	Non-cirrhotic or cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks
GT1 (cont.)	Experienced (SOF+PEG/RBV or SOF+RBV)	Non-cirrhotic	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks (GT 1b)[2]
GT1 (cont.)	Experienced (SOF+PEG/RBV or SOF+RBV)	Cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks (GT 1b)[2]
GT1 (cont.)	Experienced (SOF+SMV)	Non-cirrhotic or cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks (GT 1b)[2]
GT1 (cont.)	Experienced (NS5A inhibitor)	Non-cirrhotic or cirrhotic (CTP A)	• Mavyret x 16 weeks (no prior PI) • Vosevi x 12 weeks
GT2	Naïve or experienced (PEG/RBV)	Non-cirrhotic	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT2 (cont.)	Naïve	Cirrhotic (CTP A)	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT2 (cont.)	Experienced (PEG/RBV)	Cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks
GT2 (cont.)	Experienced (SOF+RBV)	Non-cirrhotic	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks[2]
GT2 (cont.)	Experienced (SOF+RBV)	Cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks[2]
GT2 (cont.)	Experienced (NS5A inhibitor)	Non-cirrhotic or cirrhotic (CTP A)	• Vosevi x 12 weeks
GT3	Naïve	Non-cirrhotic	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT3 (cont.)	Naïve	Cirrhotic (CTP A)	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks (plus RBV[2] if Y93H substitution is present)
GT3 (cont.)	Experienced (PEG/RBV)	Non-cirrhotic	• Mavyret x 16 weeks • sofosbuvir/velpatasvir x 12 weeks (plus RBV[2] if Y93H substitution is present)

GT3 (cont.)	Experienced (PEG/RBV)	Cirrhotic (CTP A)	• Mavyret x 16 weeks • sofosbuvir/velpatasvir +RBV x 12 weeks[2]
GT3 (cont.)	Experienced (SOF+PEG/RBV or SOF+RBV)	Non-cirrhotic or cirrhotic (CTP A)	• Mavyret x 16 weeks
GT3 (cont.)	Experienced (NS5A inhibitor)	Non-cirrhotic or cirrhotic (CTP A)	• Vosevi x 12 weeks (plus RBV[2] if cirrhosis is present)
GT4, 5, or 6	Naïve or experienced (PEG/RBV)	Non-cirrhotic	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT4, 5, or 6 (cont.)	Naïve or experienced (PEG/RBV)	Cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks
GT4, 5, or 6 (cont.)	Experienced (SOF+PEG/RBV or SOF+RBV)	Non-cirrhotic	• Mavyret x eight weeks • Vosevi x 12 weeks[2]
GT4, 5, or 6 (cont.)	Experienced (SOF+PEG/RBV or SOF+RBV)	Cirrhotic (CTP A)	• Mavyret x 12 weeks • Vosevi x 12 weeks[2]
GT4, 5, or 6 (cont.)	Experienced (NS5A inhibitor)	Non-cirrhotic or cirrhotic (CTP A)	• Vosevi x 12 weeks

CTP=Child Turcotte Pugh, DAA=direct-acting antiviral, eGFR=estimated glomerular filtration rate, GT=genotype, HCV=hepatitis C virus, PEG=peginterferon alfa, PI=protease inhibitor, RBV=ribavirin, SOF=sofosbuvir

Please note, pediatric dosing formulations of Brand name Epclusa and Harvoni are preferred. For all other strengths, generics are preferred.

[1]This Reference Table is intended for use as a reference only and does not guarantee prior authorization approval. PA requests for preferred regimens must meet PA criteria (see below for complete prior authorization criteria).

[2]Regimen is not FDA-approved in all clinical scenarios. Regimen is supported by the AASLD-IDSA treatment guidelines. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed December 16, 2019.

adefovir (> one unit/day), Baraclude solution (> 20 mL/day), entecavir tablets (> one unit/day), and lamivudine 100 mg tablets (> one unit/day)

- Documentation of the following is required:
  - diagnosis of chronic hepatitis B; **and**
  - medical necessity for exceeding the quantity limits.

ledipasvir/sofosbuvir

- Documentation of the following is required for treatment-naïve members without cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 4, 5, or 6; **and**
  - one of the following:
    - for genotype 1, member is ≥ three years of age; **or**
    - for genotype 4, 5, 6, member is ≥18 years of age and clinical rationale for use instead of sofosbuvir/velpatasvir or member is ≥ three and <18 years of age; **and**
  - appropriate dosing; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3); **and**

- one of the following:
  - for genotype 1, member is ≥ three and < 18 years of age and requested duration is 12 weeks; **or**
  - for genotype 1, member is ≥ 18 years of age and baseline viral load (within the last six months) < 6 million IU/mL and requested duration is eight weeks; **or**
  - both of the following:
    - for genotype 1, baseline viral load (within the last six months) ≥ 6 million IU/mL and requested duration is 12 weeks; **and**
    - clinical rationale for use instead of sofosbuvir/velpatasvir; **or**
  - for genotypes 4, 5, and 6, requested duration is 12 weeks.

- Documentation of the following is required for treatment-naïve members with compensated cirrhosis **or** treatment-experienced members (failed treatment with an interferon with or without ribavirin and/or protease inhibitor) without cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 4, 5, or 6; **and**
  - one of the following:
    - member is ≥ 18 years of age and clinical rationale for use instead of sofosbuvir/velpatasvir; **or**
    - member is ≥ three and < 18 years of age; **and**
  - appropriate dosing; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - requested duration is 12 weeks.

- Documentation of the following is required for treatment-experienced members (failed treatment with an interferon with or without ribavirin and/or protease inhibitor) with compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 4, 5, or 6; **and**
  - one of the following:
    - member is ≥ 18 years of age and clinical rationale for use instead of sofosbuvir/velpatasvir; **or**
    - member is ≥ three and < 18 years of age; **and**
  - appropriate dosing; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - one of the following:
    - for genotype 1, member is ≥ three and < 18 years of age and requested duration is 24 weeks; **or**
    - for genotype 1, member is ≥ 18 years of age and requested duration is 12 weeks and requested regimen includes ribavirin; **or**
    - for genotype 1, member is ≥ 18 years of age and requested duration is 24 weeks and prescriber provides clinical rationale for use of 24-week treatment with ledipasvir/sofosbuvir instead of 12-week treatment with ledipasvir/sofosbuvir and ribavirin; **or**
    - for genotype 4, 5, and 6, requested duration is 12 weeks.

- Documentation of the following is required for treatment-naïve or treatment-experienced members with decompensated cirrhosis (CTP class B or C) :
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - appropriate dosing; **and**
  - clinical rationale for use instead of sofosbuvir/velpatasvir; **and**
  - decompensated cirrhosis; **and**

- member is not s/p liver or kidney transplant; **and**
- medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
- one of the following:
  - member is treatment-naïve or treatment-experienced (prior failure of peginterferon and ribavirin with or without an HCV protease inhibitor only) and one of the following:
    - requested regimen includes ribavirin and requested duration is 12 weeks; **or**
    - requested duration is 24 weeks and contraindication or prior intolerance to ribavirin; **or**
  - member is treatment-experienced (prior failure of sofosbuvir- or NS5A inhibitor-containing regimen) and both of the following:
    - requested regimen includes ribavirin; **and**
    - requested duration is 24 weeks.

Mavyret

- Documentation of the following is required for treatment-naïve members with or without compensated cirrhosis or the following off-label indications: Treatment-naïve members post-liver transplant, post-kidney transplant, or HCV-Negative Organ Recipients from HCV-Positive Donors with or without compensated cirrhosis (CTP class A):
  - member is ≥ three years of age; **and**
  - for tablets, requested quantity is ≤ three units/day; **and**
  - for packets of pellets, requested quantity is ≤ five units/day.

- Documentation of the following is required for treatment-experienced members (failed treatment with interferon, peginterferon, ribavirin only; sofosbuvir plus peginterferon and ribavirin only; or sofosbuvir plus ribavirin only) with or without compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - appropriate dosing; **and**
  - for genotype 3, requested duration is 16 weeks; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - for genotype 1, 2, 4, 5, or 6, one of the following:
    - absence of cirrhosis and requested duration is eight weeks; **or**
    - compensated cirrhosis and requested duration is 12 weeks.

- Documentation of the following is required for treatment-experienced members (failed treatment with sofosbuvir plus simeprevir or a HCV protease inhibitor plus peginterferon alfa and ribavirin only) with or without compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1; **and**
  - member is ≥ three years of age; **and**
  - requested dose is three 100 mg/40 mg tablets once daily; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - requested duration is 12 weeks.

- Documentation of the following is required for treatment-experienced members (failed treatment with an HCV NS5A inhibitor without an HCV protease inhibitor) with or without compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1; **and**
  - member is ≥ three years of age; **and**
  - requested dose is three 100 mg/40 mg tablets once daily; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - requested duration is 16 weeks.

- Documentation of the following is required for requests noting prior failure with Mavyret or Vosevi:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - member has previously failed Mavyret or Vosevi; **and**
  - requested regimen includes glecaprevir/pibrentasvir three 100 mg/40 mg tablets once daily, sofosbuvir 400 mg once daily, and ribavirin; **and**
  - requested duration is 16 weeks; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - member does not have decompensated cirrhosis.

- Documentation of the following is required for treatment-experienced members (no prior NS5A failure) post-liver transplant with or without compensated cirrhosis (CTP class A):
  - diagnosis of hepatitis C and s/p liver transplant; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - appropriate dosing; **and**
  - for members with compensated cirrhosis, requested regimen includes ribavirin; **and**
  - one of the following:
    - for genotype 1, 2, 4, 5, or 6 and requested duration is 12 weeks; **or**
    - for genotype 3 (prior failure of peginterferon/ribavirin with or without sofosbuvir) and requested duration is 16 weeks; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis).

- Documentation of the following is required for treatment-experienced members (no prior NS5A failure) post-kidney transplant with or without compensated cirrhosis (CTP class A):
  - diagnosis of hepatitis C and s/p kidney transplant; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - appropriate dosing; **and**

- requested duration is 12 weeks; **and**
- medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
- stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis).

SmartPA: Claims for Mavyret tablet at a quantity of ≤ three units/day or Mavyret pellet packet at a quantity of ≤ five units/day will usually pay at the pharmacy without a PA request for members age ≥ three years of age if there are no paid MassHealth pharmacy claims for hepatitis C drug in all claims history, and there are no paid MassHealth pharmacy claims for drugs suggestive of decompensated cirrhosis in all claims history.

Pegasys for chronic hepatitis B

- Documentation of the following is required:
  - diagnosis of chronic hepatitis B.

ribavirin 200 mg capsule

- Documentation of the following is required:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype; **and**
  - medical necessity for requested capsule formulation instead of the 200 mg tablets.

sofosbuvir/velpatasvir

- Documentation of the following is required for treatment-naïve members with or without compensated cirrhosis or the following off -label indications: Treatment-naïve members post-liver transplant, post-kidney transplant, or HCV-Negative Organ Recipients from HCV-Positive Donors with or without compensated cirrhosis (CTP class A):
  - member is ≥ three years of age; **and**
  - requested quantity is ≤ one unit/day.

- Documentation of the following is required for treatment-experienced members (failed treatment with peginterferon alfa and ribavirin, with or without protease inhibitor) with or without compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - appropriate dosing; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - requested duration is 12 weeks; **and**
  - for members ≥ 18 years of age with genotype 3, one of the following:
    - absence of cirrhosis and one of the following:
      - testing results document absence of NS5A resistance-associated substitution Y93H; **or**
      - testing results document presence of NS5A resistance-associated substitution Y93H and requested regimen includes ribavirin; **or**
    - compensated cirrhosis and requested regimen includes ribavirin.

- Documentation of the following is required for treatment-naïve or treatment-experienced members with decompensated cirrhosis (CTP class B or C) :

- diagnosis of hepatitis C; **and**
- hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
- decompensated cirrhosis (Child Pugh Class B or C); **and**
- member is not s/p liver or kidney transplant; **and**
- member is ≥ three years of age; **and**
- appropriate dosing; **and**
- medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
- one of the following:
  - member is treatment-naïve or treatment-experienced (prior failure of peginterferon and ribavirin with or without an HCV protease inhibitor only) and one of the following:
    - requested regimen includes ribavirin and requested duration is 12 weeks; **or**
    - requested duration is 24 weeks and contraindication or prior intolerance to ribavirin; **or**
  - member is treatment-experienced (prior failure of sofosbuvir- or NS5A inhibitor-containing regimen) and both of the following:
    - requested regimen includes ribavirin; **and**
    - requested duration is 24 weeks.

- Documentation of the following is required for treatment-experienced members post-liver transplant with or without cirrhosis (CTP class A, B or C) :
  - diagnosis of hepatitis C and s/p liver transplant; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - appropriate dosing; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - one of the following:
    - absence of cirrhosis or compensated cirrhosis and requested duration is 12 weeks; **or**
    - decompensated cirrhosis and both of the following:
      - requested regimen includes ribavirin; **and**
      - requested duration is 12 weeks (treatment-naïve) or 24 weeks (treatment-experienced).

- Documentation of the following is required for treatment-naïve members or treatment-experienced† members post-kidney transplant with or without compensated cirrhosis (CTP class A):
  - diagnosis of hepatitis C and s/p liver transplant; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - appropriate dosing; **and**
  - requested duration is 12 weeks; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4).

SmartPA: Claims for generic sofosbuvir/velpatasvir, Epclusa 200 mg/50 mg tablet, Epclusa pellet packet, at a quantity of ≤ one unit/day will usually pay at the pharmacy without PA for members age ≥ three years of age if there are no paid MassHealth pharmacy claims for hepatitis C drug in all claims history, and there are no paid MassHealth pharmacy claims for drugs suggestive of decompensated cirrhosis in all claims history.

Sovaldi

- Documentation of the following is required for treatment-naïve members or treatment-experienced members with or without

compensated cirrhosis (CTP A):

- diagnosis of hepatitis C; **and**
- hepatitis C virus genotype 2 or 3; **and**
- member is ≥ three years of age; **and**
- clinical rationale for use instead of sofosbuvir/velpatasvir and Mavyret; **and**
- appropriate dosing; **and**
- medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
- stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
- one of the following:
  - for genotype 2, requested duration is 12 weeks; or
  - for genotype 3, requested duration is 24 weeks; **and**
- requested regimen includes ribavirin.

Vosevi

- Documentation of the following is required for treatment-experienced members (failed treatment with an HCV NS5A inhibitor) with or without compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is 400 mg/100 mg/100 mg once daily; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - requested duration is 12 weeks; **and**
  - for genotype 3 and compensated cirrhosis, requested regimen includes ribavirin.

- Documentation of the following is required for treatment-experienced members (failed treatment with sofosbuvir without an HCV NS5A inhibitor) with or without compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1a or 3; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is 400 mg/100 mg/100 mg once daily; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - requested duration is 12 weeks.

- Documentation of the following is required for requests noting prior failure with Mavyret or Vosevi:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ 18 years of age; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation

of cirrhosis); **and**
- member does not have decompensated cirrhosis; **and**
- one of the following:
  - both of the following:
    - member has previously failed Mavyret and requested regimen is 400 mg/100 mg/100 mg once daily for 12 week; **and**
    - for members with compensated cirrhosis, requested regimen includes ribavirin; **or**
  - both of the following:
    - member has previously failed Vosevi or Mavyret plus Sovaldi and requested regimen is 400 mg/100 mg/100 mg once daily plus ribavirin for 24 weeks; **and**
    - clinical rationale for use instead of Mavyret plus Sovaldi plus ribavirin.

- Documentation of the following is required for treatment-experienced (failed treatment with sofosbuvir or an HCV NS5A inhibitor) members post-liver transplant with or without compensated cirrhosis:
  - diagnosis of hepatitis C s/p liver transplant; **and**
  - one of the following:
    - genotype 1, 2, 3, 4, 5, or 6 and prior treatment failure with an HCV NS5A inhibitor; **or**
    - both of the following:
      - genotype 1 or 3 and prior treatment failure with sofosbuvir without an HCV NS5A inhibitor; **and**
      - clinical rationale for use instead of Mavyret; **or**
    - genotype 4, 5, or 6 and prior treatment failure with sofosbuvir without an HCV NS5A inhibitor; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is 400 mg/100 mg/100 mg once daily; **and**
  - for members with compensated cirrhosis, requested regimen includes ribavirin; **and**
  - requested duration is 12 weeks; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis).

- Documentation of the following is required for treatment-experienced (failed treatment with sofosbuvir or an HCV NS5A inhibitor) members post-kidney transplant with or without compensated cirrhosis:
  - diagnosis of hepatitis C s/p kidney transplant; **and**
  - genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is 400 mg/100 mg/100 mg once daily; **and**
  - for members with compensated cirrhosis, requested regimen includes ribavirin; **and**
  - requested duration is 12 weeks; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis).

Zepatier
- Documentation of the following is required for HCV genotype 1 in treatment-naïve members or treatment-experienced members (failed treatment with peginterferon alfa and ribavirin only):
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1; **and**
  - contraindication to all combination products FDA-approved for the treatment of hepatitis C virus genotype 1 infection; **and**

- member is ≥ 18 years of age; **and**
- requested dose is 50 mg/100 mg once daily; **and**
- medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
- stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
- member does not have decompensated cirrhosis; **and**
- one of the following:
  - for genotype 1a, testing results document absence of NS5A resistance-associated substitutions at amino acid positions 28, 30, 31, and 93, and requested duration is 12 weeks; **or**
  - for genotype 1a, testing results document presence of NS5A resistance-associated substitutions at amino acid positions 28, 30, 31, or 93, and requested regimen includes ribavirin and requested duration is 16 weeks; **or**
  - for genotype 1b, requested duration is 12 weeks.

- Documentation of the following is required for HCV genotype 1 in treatment-experienced members (failed treatment with a HCV protease inhibitor plus peginterferon alfa and ribavirin only):
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1; **and**
  - contraindication to all combination products FDA-approved for the treatment of hepatitis C virus genotype 1 infection; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is 50 mg/100 mg once daily; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - member does not have decompensated cirrhosis; **and**
  - requested regimen includes ribavirin; **and**
  - one of the following:
    - for genotype 1a, testing results document absence of NS5A resistance-associated substitutions at amino acid positions 28, 30, 31, and 93, and requested duration is 12 weeks; **or**
    - for genotype 1a, testing results document presence of NS5A resistance-associated substitutions at amino acid positions 28, 30, 31, or 93, and requested duration is 16 weeks; **or**
    - for genotype 1b, requested duration is 12 weeks.

- Documentation of the following is required for HCV genotype 4 in treatment-naïve or treatment-experienced members (failed treatment with peginterferon alfa and ribavirin only):
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 4; **and**
  - contraindication to all combination products FDA-approved for the treatment of hepatitis C virus genotype 4 infection; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is 50 mg/100 mg once daily; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - member does not have decompensated cirrhosis; **and**
  - one of the following:
    - member is treatment-naïve, and requested duration is 12 weeks; **or**

- member has a history of relapse to prior peginterferon alfa and ribavirin treatment, and requested duration is 12 weeks; **or**
- member has a history of on-treatment virologic failure (failure to suppress or breakthrough) while on peginterferon alfa and ribavirin treatment, requested regimen includes ribavirin, and requested duration is 16 weeks.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria

Table 45 - Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease Agents

Drug Category: Blood Disorder Agents

Medication Class/Individual Agents: Hematopoietic Agents

I. Prior-Authorization Requirements

Sickle Cell Disease Agents - P-Selectin Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
crizanlizumab-tmca	Adakveo	PA	MB

Beta Thalassemia Agents - Gene Therapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betibeglogene autotemcel	Zynteglo	PA	CO
exagamglogene autotemcel	Casgevy PD	PA	CO

Sickle Cell Disease Agents - Gene Therapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
exagamglogene autotemcel	Casgevy PD	PA	CO
lovotibeglogene autotemcel	Lyfgenia	PA	CO

Sickle Cell Disease Agents - Antimetabolites			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
hydroxyurea capsule	Droxia		
hydroxyurea solution	Xromi	PA	
hydroxyurea tablet	Siklos	PA	

Sickle Cell Disease Agents - Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
l-glutamine	Endari	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Please note: One-time cell and gene therapies are part of the ACPP and MCO unified pharmacy policy. PA requests for one-time cell and gene therapies for members with ACPP and MCO plans are reviewed by the MassHealth Drug Utilization Review (DUR) Program.

Beta thalassemia and myelodysplastic syndromes (MDS)

- Betibeglogene autotemcel is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of adult and pediatric patients with beta thalassemia who require regular red blood cell (RBC) transfusions. This agent is a one-time intravenous (IV) infusion designed to deliver a functional copy of human β-globin gene (βA-T87Q-globin) into a patient's own hematopoietic stem cells (HSC). Given the risk of serious adverse reactions, this agent is administered only by qualified treatment centers.
  - MassHealth Drug Utilization Review will be reaching out to prescribers after administration to verify clinical effectiveness and at ongoing intervals for long-term monitoring of sustained response. For additional information regarding betibeglogene autotemcel,

Beta Thalassemia Agents - Erythroid Maturation Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
luspatercept-aamt	Reblozyl	PA	MB

Telomerase Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
imetelstat	Rytelo	PA	MB

Clinical Notes

please see the Acute Hospital Carve-Out Drugs List found at **www.mass.gov/druglist**.

- Imetelstat is an oligonucleotide telomerase inhibitor that blocks the interaction between telomerase and telomeres, leading to the increased destruction of malignant cells with high telomerase activity. This inhibition can improve hematopoiesis in the bone marrow. Imetelstat is currently indicated for adults with low- to intermediate-1 risk MDS with transfusion-dependent anemia requiring ≥ four RBC units over eight weeks who have not responded to, or have lost response to, or are ineligible for, erythropoiesis stimulating agents (ESA).
- Luspatercept-aamt is a subcutaneously (SC) administered erythroid maturation agent.
  - This agent is FDA-approved for:
    - the treatment of anemia in adults with beta thalassemia who require regular RBC transfusions
    - the treatment of anemia without previous ESA use in adults with very low- to intermediate-risk MDS who may require regular RBC transfusions
    - the treatment of anemia failing an ESA and requiring ≥ two RBC units over eight weeks in adults with very low- to intermediate-risk MDS with ring sideroblasts (RS) or with MD/myeloproliferative neoplasm with RS and thrombocytosis (MDS/MPN-RS-T)
  - This agent should be administered by a medical professional.
  - Luspatercept-aamt should be discontinued if one does not experience a decrease in transfusion burden after nine weeks of treatment at the maximum dose level or if unacceptable toxicity occurs at any time.

Sickle Cell Disease (SCD)

- Crizanlizumab-tmca is the first humanized anti-P-selectin monoclonal antibody FDA-approved to reduce the frequency of vaso-occlusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease.
  - This agent should be administered by a medical professional.
- Exagamglogene autotemcel is an autologous, ex vivo CRISPR/Cas9 gene-editing therapy indicated for the treatment of patients 12 years of age and older with SCD with recurrent VOCs and for the treatment of transfusion-

	Clinical Notes
	dependent beta thalassemia (TDT). This agent is a one-time IV infusion that works to edit the erythroid-specific enhancer region of *BCL11A* in the $CD34^{+}$ hematopoietic stem and progenitor cells (HSPCs) to reduce erythroid-specific expression of *BCL11A* and thereby increase levels of fetal hemoglobin (HbF). Given the risk of serious adverse reactions, this agent is administered only by qualified treatment centers. • MassHealth Drug Utilization Review will be reaching out to prescribers after administration to verify clinical effectiveness and at ongoing intervals for long-term monitoring of sustained response. For additional information regarding exagamglogene autotemcel, please see the Acute Hospital Carve-Out Drugs List found at **www.mass.gov/druglist**. • Hydroxyurea (HU) is available in several formulations, including tablets, capsules, and as an oral solution. It is indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in patients with sickle cell anemia with recurrent moderate to severe painful crises. • Guidelines from the British Society for Haematology and the National Heart, Lung, and Blood Institute (NHLBI) recommend the use of HU for adults with SCD who have experienced three or more moderate to severe pain crises in a 12-month period, pain or chronic anemia interfering with daily activities or with severe or recurrent episodes of acute chest syndrome (ACS). In addition, they give a strong recommendation for use in children nine-to-42 months of age and a moderate recommendation for children and adolescents > 42 months of age regardless of disease severity. • NHLBI recommends aiming for target ANC ≥ 2,000/uL. Maintain PLT count ≥ 80,000/uL. If neutropenia or thrombocytopenia occurs, hold HU and monitor complete blood count with WBC differential weekly. When blood counts have recovered, reinstitute HU at 5 mg/kg/day and if warranted, increase by 5 mg/kg/day increments every eight weeks until mild myelosuppression (ANC 2,000 to 4,000/uL to a maximum dose of 35 mg/kg/day). • NHLBI notes that a clinical response to HU may take three-to-six months. A six-month trial on the maximum tolerated dose is required prior to

	Clinical Notes
	considering discontinuation due to treatment failure.[1] • L-glutamine is an oral agent indicated to reduce acute complications in children ≥ five years of age and adults with SCD. • Lovotibeglogene autotemcel is a one-time gene therapy treatment designed to add functional copies of a modified form of the β-globin gene (βA-T87Q-globin gene) into a patient's own HSCs, utilizing the BB305 lentiviral vector. Once patients have the βA-T87Q-globin gene, their RBCs can produce anti-sickling hemoglobin (HbAT87Q) that decreases the proportion of HbS, with the goal of reducing sickled RBCs, hemolysis, and other complications. This gene therapy is approved for the treatment of patients 12 years of age and older with SCD and a history of vaso-occlusive events. Given the risk of serious adverse reactions, this agent is administered only by qualified treatment centers. • MassHealth Drug Utilization Review will be reaching out to prescribers after administration to verify clinical effectiveness and at ongoing intervals for long-term monitoring of sustained response. For additional information regarding lovotibeglogene autotemcel, please see the Acute Hospital Carve-Out Drugs List found at www.mass.gov/druglist. 1.Yawn BP, Buchanan GR, Afenyi-Annan AN, Ballas SK, Hassell KL, James AH, et al. Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members. JAMA. 2014 Sep 10;312(10):1033-48.

CO Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements. All requests for one-time cell and gene therapies (as listed on the Acute Hospital Carve-Out Drug List), including for members enrolled in an Accountable Care Partnership Plan (ACPP) or Managed Care Organization (MCO), will be reviewed by the MassHealth Drug Utilization Review (DUR) Program.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Beta thalassemia (Casgevy, Reblozyl, Zynteglo)
- Myelodysplastic syndromes associated anemia (Reblozyl, Rytelo)
- Sickle cell disease (Adakveo, Casgevy, l-glutamine, Lyfgenia, Siklos, Xromi)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Adakveo

- Documentation of all of the following is required:
  - diagnosis of sickle cell disease; **and**
  - member is ≥ 16 years of age; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member has experienced ≥ two sickle cell crises in the previous 12 months; **and**
  - member's current weight; **and**
  - one of the following:
    - inadequate response to hydroxyurea at the maximally tolerated dose for at least three months; **or**
    - adverse reaction or contraindication to hydroxyurea.

Casgevy

- Documentation of all of the following is required for a diagnosis of sickle cell disease:
  - appropriate diagnosis; **and**
  - copy of genetic test confirming diagnosis of SCD; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - history of ≥ two sickle cell crises per year in the last two years; **and**
  - one of the following:

    - inadequate response to hydroxyurea therapy at the maximally tolerated dose for at least three months*; **or**
    - adverse reaction or contraindication to hydroxyurea; **and**
  - appropriate dosing and treatment dates; **and**
  - infusion will take place in a qualified treatment facility; **and**
  - member will receive pre-infusion conditioning with busulfan; **and**
  - member is clinically stable and eligible for HSCT; **and**
  - member does not have active HIV, HBV, or HCV infection; **and**
  - member has not received any prior SCD gene therapy.
- Documentation of all of the following is required for a diagnosis of transfusion-dependent beta thalassemia (TDT or beta thalassemia major):
  - appropriate diagnosis; **and**
  - copy of genetic test confirming diagnosis; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - appropriate dosing and treatment dates; **and**
  - member has required ≥ 100 mL/kg/year of pRBC or ≥ ten units per year in the previous two years; **and**
  - infusion will take place in a qualified treatment facility; **and**
  - member will receive pre-infusion conditioning with busulfan; **and**
  - member is clinically stable and eligible for HSCT; **and**
  - member does not have active HIV, HBV, or HCV infection; **and**
  - member has not received any prior TDT gene therapy.

* Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to these agents.

l-glutamine
- Documentation of all of the following is required:
  - diagnosis of sickle cell disease; **and**
  - member is ≥ five years of age; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member has experienced ≥ two sickle cell crises in the previous 12 months; **and**
  - member's current weight; **and**
  - inadequate response, adverse reaction, or contraindication to hydroxyurea.

Lyfgenia
- Documentation of all of the following is required:
  - diagnosis of sickle cell disease; **and**
  - copy of genetic test confirming diagnosis of SCD; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - history of ≥ two sickle cell crises per year in the last two years; **and**
  - one of the following:
    - inadequate response to hydroxyurea therapy at the maximally tolerated dose for at least three months*; **or**
    - adverse reaction or contraindication to hydroxyurea; **and**
  - medical necessity for use of requested agent instead of Casgevy; **and**
  - member has a negative serology test for HIV; **and**
  - member does not have α-thalassemia trait (-α3.7/-α3.7); **and**
  - appropriate dosing and treatment dates; **and**

- infusion will take place in a qualified treatment facility; **and**
- member is clinically stable and eligible for HSCT; **and**
- member has not received any prior SCD gene therapy.

* Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to these agents.

Reblozyl for beta thalassemia
- Documentation of all of the following is required:
  - medical records and genetic testing supporting diagnosis of transfusion-dependent beta thalassemia; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member's current weight.
- For recertification, documentation of positive response to therapy (e.g., decrease in transfusion requirements) is required.

Reblozyl for myelodysplastic syndromes associated anemia
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member's current weight.
- For recertification, documentation of positive response to therapy (e.g., decrease in transfusion requirements) is required.

Rytelo
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - appropriate dosing; **and**
  - member has required ≥ four RBC transfusions in the last eight weeks; **and**
  - inadequate response or adverse reaction to one or contraindication to all erythropoiesis stimulating agents (e.g., epoetin, darbepoetin); **and**
  - if the member has MDS with ring sideroblasts (RS), inadequate response, adverse reaction, or contraindication to Reblozyl; **and**
  - if the member has MDS associated with a del 5q cytogenic abnormality, inadequate response, adverse reaction, or contraindication to lenalidomide.
- For recertification, documentation of positive response to therapy (e.g., decrease in transfusion requirements) is required.

Siklos, Xromi
- Documentation of all of the following is required:
  - diagnosis of sickle cell disease; **and**
  - one of the following:
    - for Siklos, member is ≥ two years of age; **or**
    - for Xromi, member is ≥ six months of age; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member's current weight; **and**
  - medical necessity for the use of requested formulation as noted by one of the following:
    - member is < 13 years of age; **or**
    - member utilizes tube feeding (G-tube/J-tube); **or**

- member has a swallowing disorder or condition affecting ability to swallow.

SmartPA: Claims for Xromi will usually process at the pharmacy without a PA request if the member is < 13 years of age and has a history of MassHealth medical claims for sickle cell disease.†

Zynteglo

- Documentation of all of the following is required:
  - diagnosis of transfusion-dependent beta thalassemia; **and**
  - copy of genetic test confirming diagnosis; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member is < 51 years of age; **and**
  - appropriate dosing and treatment dates; **and**
  - member has a negative serology test for HIV; **and**
  - member has required ≥ 100 mL/kg/year of pRBC or ≥ eight transfusions within the last 12 months; **and**
  - infusion will take place in a qualified treatment center; **and**
  - medical necessity for the requested agent instead of Casgevy; **and**
  - member is clinically stable and eligible for HSCT; **and**
  - member has not received any prior gene therapy for transfusion-dependent beta thalassemia.

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 46 - Urinary Dysfunction Agents

Drug Category: Renal and Urinary

Medication Class/Individual Agents: Urinary Dysfunction Agents

I. Prior-Authorization Requirements

Urinary Dysfunction Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bethanechol			A90
darifenacin		PA - > 1 unit/day	A90
desmopressin injection, nasal spray, tablet	DDAVP		# , A90
desmopressin sublingual tablet	Nocdurna	PA	
fesoterodine	Toviaz		# , A90
flavoxate			A90
mirabegron extended-release	Myrbetriq		BP, A90
oxybutynin extended-release tablet			A90
oxybutynin immediate-release 2.5 mg tablet		PA	A90
oxybutynin immediate-release 5 mg tablet, syrup			A90
oxybutynin solution			A90
oxybutynin transdermal system	Oxytrol		
solifenacin suspension	Vesicare LS	PA	
solifenacin tablet	Vesicare		# , A90
tolterodine extended-release	Detrol LA		# , A90
tolterodine immediate-release	Detrol		# , A90
trospium extended -release		PA	A90
trospium immediate-release			A90
vibegron	Gemtesa	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- First-line treatment options according to the 2019 American Urological Association guidelines for overactive bladder activity are behavioral therapy.
- Pharmacological treatments recommended for overactive bladder include antimuscarinic agents or B-3 adrenergic receptor agonists, either monotherapy or in combination of one agent from each class. Literature does not support use of one specific agent over another.
- First-line pharmacological therapy for neurogenic detrusor overactivity includes anticholinergic agents. Fesoterodine, mirabegron, and solifenacin are all approved therapies for NDO in pediatric members.
- Once daily dosing with extended-release agents tend to have less antimuscarinic side effects than the immediate-release products.

References:

1. Lightner DJ, Gomelsky A, Souter L et al: Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline amendment 2019. J Urol 2019; 202:

	Clinical Notes
	558. Available from: https://www.auanet.org/guidelines/guidelines/overactive-bladder-(oab)-guideline . 2. The Committee for Establishment of the Clinical Guidelines for Nocturia of the Neurogenic Bladder Society (2010), Clinical guidelines for nocturia. International Journal of Urology, 17: 397–409.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Neurogenic detrusor overactivity
- Nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void
- Overactive bladder with symptoms of urinary frequency, urgency, or incontinence

Non-FDA-approved, for example:

- Postoperative pain related to catheter placement
- Primary focal hyperhidrosis

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.

- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

darifenacin > one unit/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - clinical rationale why the dose cannot be consolidated; **or**
    - clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA.

Gemtesa, and trospium extended-release

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: darifenacin, fesoterodine, mirabegron extended-release, oxybutynin extended-release tablet, solifenacin, tolterodine extended-release, trospium immediate-release; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - for requested quantity > 1 unit/day, one of the following:
      - clinical rationale why the dose cannot be consolidated; **or**
      - clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA.

SmartPA: Claims for Gemtesa, and trospium extended-release for a quantity of ≤ one unit/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims within the last 365 days for two of the following: darifenacin, fesoterodine, mirabegron extended-release, oxybutynin extended-release tablet, solifenacin, tolterodine extended-release. †

Nocdurna

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response or adverse reaction to desmopressin acetate tablets; **or**
    - medical necessity for the sublingual tablet instead of the tablet formulation available without prior authorization; **and**
  - appropriate dosing; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - for requested quantity > one unit/day, one of the following:
      - clinical rationale why the dose cannot be consolidated; **or**
      - clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA.

SmartPA: Claims for Nocdurna for a quantity of ≤ one unit/day will usually process at the pharmacy without a PA request if the member is ≥ 18 years of age and has a history of paid MassHealth pharmacy claims within the last 365 days for desmopressin tablets. †

oxybutynin 2.5 mg immediate-release tablet

- Documentation of all of the following is required for overactive bladder:
  - appropriate diagnosis; **and**

- member is ≥ six years of age; **and**
- medical necessity for use of the requested agent instead of formulations available without prior authorization; **and**
- appropriate dosing; **and**
- one of the following:
  - requested quantity is ≤ three units/day; **or**
  - for requested quantity > three units/day, one of the following:
    - clinical rationale why the dose cannot be consolidated; **or**
    - clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA.

- Documentation of all of the following is required for primary focal hyperhidrosis:
  - appropriate diagnosis; **and**
  - member is ≥ four years of age; **and**
  - appropriate dosing; **and**
  - medical necessity for use of the requested agent instead of formulations available without prior authorization; **and**
  - one of the following:
    - for requested quantity > two units/day, one of the following:
      - clinical rationale why the dose cannot be consolidated; **or**
      - clinical rationale why the member requires dosing at intervals exceeding two units/day; **or**
    - requested quantity is ≤ two units/day.

Oxytrol for Women
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - an intolerable adverse reaction to Oxytrol (oxybutynin transdermal system); **and**
  - one of the following:
    - requested quantity is ≤ eight patches/28 days; **or**
    - for requested quantity > eight patches/28 days, clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA; **and**
  - one of the following:
    - an intolerable adverse reaction to oral extended-release oxybutynin; **or**
    - medical necessity for the use of transdermal formulation as noted by one of the following:
      - member utilizes tube feeding (G-tube/J-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow.

Vesicare LS
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a urologist or consult notes from a urology office are provided; **and**
  - one of the following:
    - member is ≥ two years of age and < five years of age; **or**
    - inadequate response or adverse reaction to one or contraindication to both oxybutynin solution and oxybutynin syrup; **and**
  - appropriate dosing.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 47 - Antifungal Agents - Oral and Injectable

Drug Category: Anti-infectives

Medication Class/Individual Agents: Antifungal Agents - Oral and Injectable

I. Prior-Authorization Requirements

Oral and Injectable Antifungal Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amphotericin B			
amphotericin B lipid complex	Abelcet		
amphotericin B liposome	Ambisome		#
anidulafungin	Eraxis		
caspofungin	Cancidas		#
clotrimazole troche			A90
fluconazole	Diflucan		# , A90
flucytosine	Ancobon		BP, A90
griseofulvin suspension, tablet			A90
ibrexafungerp	Brexafemme	PA	
isavuconazonium	Cresemba	PA	
itraconazole 100 mg capsule	Sporanox		BP, A90
itraconazole 65 mg capsule	Tolsura	PA	
itraconazole solution	Sporanox		# , A90
ketoconazole tablet			A90
micafungin	Mycamine		#
miconazole buccal tablet	Oravig	PA	
nystatin oral suspension			A90
oteseconazole	Vivjoa	PA	
posaconazole injection	Noxafil	PA	BP
posaconazole powder for oral suspension	Noxafil	PA	
posaconazole suspension	Noxafil	PA	A90
posaconazole tablet	Noxafil		# , A90
rezafungin	Rezzayo	PA	
terbinafine tablet			A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Please see below criteria update based on the Centers for Disease Control and Prevention (CDC) recommendations regarding voriconazole suspension and tablet.

- Terbinafine is only FDA-approved for the treatment of onychomycosis of the toenail and fingernail due to dermatophytes.
- Certain azole antifungals have medication specific adverse events:
  - Fluconazole is associated with alopecia.
  - Itraconazole is associated with aldosterone-like effects and should be avoided in patients with a history of heart failure.
  - Voriconazole is associated with abnormal vision and rash.
- Voriconazole is an effective agent for *aspergillus, scedosporium,* and *fusarium* infections.
- Isavuconazonium and posaconazole are the only azole antifungals with activity against zygomycosis (mucormycosis) infections.
- Azole antifungals are potent inhibitors of various CYP450 enzymes:

Cytochrome P-450 Metabolism of Oral Antifungals

Oral and Injectable Antifungal Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
voriconazole injection, tablet	Vfend		#
voriconazole suspension	Vfend	PA	A90

Clinical Notes

Agent	2C19	2C9	3A4	1A2	2A6	2E1	2D6
fluconazole	X(S)	X(S)	X(M)				
itraconazole			X(S)				
voriconazole	X(W)	X(W)	X(M)				
posaconazole			X(S)				
ketoconazole			X(S)	X(M)	X(M)	X(M)	
clotrimazole			X(M)				
terbinafine			X(S)				X(S)
isavuconazole			X(M)				

S=Strong, M=Moderate, W=Weak

- Hepatic function abnormalities are associated with the azole class, including terbinafine, and as such, careful monitoring of liver function tests are recommended in all patients receiving these agents. Specific monitoring recommendations include:
  - isavuconazonium: at initiation and during course of treatment
  - itraconazole: for all patients being treated for longer than one month
  - posaconazole: at the start of and during the course of therapy
  - terbinafine: before initiation and should be repeated if

	Clinical Notes
	used for > six weeks • voriconazole: at initiation and during course of treatment

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Aspergillosis, blastomycosis, and histoplasmosis – Tolsura
- invasive Aspergillus infections – Cresemba, voriconazole suspension
- prevention of invasive Aspergillus and Candida infections – posaconazole injection, posaconazole oral suspension
- candidemia – Rezzayo, voriconazole suspension
- disseminated candidiasis – voriconazole suspension
- esophageal candidiasis – voriconazole suspension
- fungal infections caused by Fusarium and Scedosporium – voriconazole suspension
- invasive candidiasis – Rezzayo
- oropharyngeal candidiasis – Oravig, posaconazole oral suspension
- recurrent vulvovaginal candidiasis – Brexafemme, Vivjoa
- vulvovaginal candidiasis – Brexafemme
- zygomycosis (mucormycosis) – Cresemba

Non FDA-approved, for example:

- Aspergillus endophthalmitis and keratitis – voriconazole suspension
- esophageal candidiasis – posaconazole oral suspension
- fungal infections caused by Fusarium and Scedosporium – Cresemba
- oropharyngeal candidiasis – voriconazole suspension
- prevention of invasive Aspergillus and Candida infections – voriconazole suspension
- zygomycosis (mucormycosis) – posaconazole injection, posaconazole oral suspension

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.

- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Brexafemme

- Documentation of the following is required for the treatment of acute vulvovaginal candidiasis:
  - appropriate diagnosis; **and**
  - member is post-menarchal; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to oral fluconazole; **or**
    - Candida species is fluconazole-resistant.
- Documentation of the following is required for the treatment of recurrent vulvovaginal candidiasis:
  - appropriate diagnosis; **and**
  - results of a diagnostic test (e.g., KOH, nucleic acid probe-based test system, nucleic acid amplification, etc.) to confirm diagnosis; **and**
  - member has had ≥ 3 acute VVC episodes within the last 12 months; **and**
  - requested quantity is ≤ 24 tablets for one course of therapy; **and**
  - member is post-menarchal; **and**
  - one of the following:
    - inadequate response (defined as ≥ 24 weeks of therapy or recurrence of infection while on maintenance therapy), adverse reaction, or contraindication to oral fluconazole; **or**
    - candida species is fluconazole-resistant.

Cresemba

- Documentation of the following is required for the treatment of aspergillus infections:
  - appropriate diagnosis; **and**
  - one of the following:
    - for the capsule formulation, member is ≥ six years of age and weighs ≤ 16 kg; **or**
    - for the injection formulation, member is ≥ one year of age; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: posaconazole, voriconazole; **and**
  - for the injection formulation, medical necessity for the requested formulation as noted by one of the following:
    - member is < 13 years of age; **or**
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow.
- Documentation of the following is required for the treatment of zygomycosis (mucormycosis):
  - appropriate diagnosis; **and**
  - one of the following:
    - for the capsule formulation, member is ≥ six years of age and weighs ≤ 16 kg; **or**
    - for the injection formulation, member is ≥ one year of age; **and**

- for the injection formulation, medical necessity for the requested formulation as noted by one of the following:
  - member is < 13 years of age; **or**
  - member utilizes tube feeding (G-tube/J-tube); **or**
  - member has a swallowing disorder or condition affecting ability to swallow; **and**
- inadequate response, adverse reaction, or contraindication to posaconazole.

SmartPA: Claims for Cresemba capsule will usually process at the pharmacy without a PA request for members who are ≥ 18 years of age and with one of the following: a history of MassHealth medical claims for zygomycosis (mucormycosis) within the last 365 days with history of paid claims for posaconazole within the last 90 days, or a history of MassHealth medical claims for aspergillosis within the last 365 days with history of paid claims for posaconazole and voriconazole within the last 90 days.†

Oravig

- Documentation of the following is required for the diagnosis of oropharyngeal candidiasis:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: clotrimazole troches, fluconazole suspension or tablet, nystatin suspension or tablet.

posaconazole injection

- Documentation of the following is required for the prevention of invasive aspergillus and candida fungal infections:
  - member has a diagnosis of one of the following:
    - hematologic malignancy (e.g., acute myelogenous leukemia, myelodysplastic syndromes) with neutropenia; **or**
    - hematopoietic stem cell transplantation (HSCT); **or**
    - graft-versus-host disease (GVHD); **and**
  - member is ≥ two years of age; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member is < 13 years of age; **or**
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow.
- Documentation of the following is required for the treatment of invasive aspergillosis fungal infections:
  - appropriate diagnosis; **and**
  - member is ≥ 13 years of age; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow.
- Documentation of the following is required for the treament of zygomycosis (mucormycosis):
  - appropriate diagnosis; **and**
  - member is ≥ 13 years of age; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow.

posaconazole oral suspension

- Documentation of the following is required for the prevention of invasive aspergillus and candida fungal infections:
  - member has a diagnosis of one of the following:
    - hematologic malignancy (e.g., acute myelogenous leukemia, myelodysplastic syndromes) with neutropenia; **or**
    - hematopoietic stem cell transplantation (HSCT); **or**
    - graft-versus-host disease (GVHD); **and**
- Documentation of the following is required for the treatment of esophageal candidiasis:

- appropriate diagnosis; **and**
- member is ≥ 13 years of age; **and**
- inadequate response, adverse reaction, or contraindication to all of the following: oral fluconazole, itraconazole, voriconazole; **and**
- medical necessity for the requested formulation as noted by one of the following:
  - member utilizes tube feeding (G-tube/J-tube); **or**
  - member has a swallowing disorder or condition affecting ability to swallow.

- Documentation of the following is required for the treatment of oropharyngeal candidiasis:
  - appropriate diagnosis; **and**
  - member is ≥ 13 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: oral fluconazole, itraconazole; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow.
- Documentation of the following is required for the treatment of zygomycosis (mucormycosis):
  - appropriate diagnosis; **and**
  - member is ≥ 13 years of age; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow.

posaconazole powder for oral suspension

- Documentation of the following is required for the prevention of invasive aspergillus and candida fungal infections:
  - member has a diagnosis of one of the following:
    - hematologic malignancy (e.g., acute myelogenous leukemia, myelodysplastic syndromes) with neutropenia; **or**
    - hematopoietic stem cell transplantation (HSCT); **or**
    - graft-versus-host disease (GVHD); **and**
  - member is ≥ two and < 18 years of age; **and**
  - member is ≤ 40 kg; and
  - medical necessity for the requested formulation as noted by one of the following:
    - member is < 13 years of age; **or**
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow.

Rezzayo

- Documentation of all of the following is required:
  - member has a diagnosis of one of the following:
    - candidemia; **or**
    - invasive candidiasis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is an infectious disease specialist or consult notes from a specialist are provided; **and**
  - inadequate response, adverse reaction, contraindication, or Candida isolate is resistant to all of the following: anidulafungin, caspofungin, micafungin; **and**
  - requested quantity is ≤ six vials for one course of therapy.

Tolsura

- Documentation of the following is required for the treatment of aspergillosis, blastomycosis, and histoplasmosis:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation instead of the 100 mg capsule and oral suspension.

Vivjoa

- Documentation of the following is required for the treatment of recurrent vulvovaginal candidiasis:
  - appropriate diagnosis; **and**
  - results of a diagnostic test (e.g., KOH, nucleic acid probe-based test system, nucleic acid amplification, etc.) to confirm diagnosis; **and**
  - member has had ≥ three acute VVC episodes within past 12 months; **and**
  - requested quantity is ≤ 18 capsules for one course of therapy; **and**
  - one of the following:
    - member is ≥ 12 years of age and not of reproductive potential; **or**
    - member is post-menopausal; **and**
  - one of the following:
    - inadequate response (defined as ≥24 weeks of therapy or recurrence of infection while on maintenance therapy), adverse reaction, or contraindication to oral fluconazole; **or**
    - Candida species is fluconazole resistant.

voriconazole suspension

- Documentation of the following is required for the prevention of invasive aspergillus and candida fungal infections:
  - member has a diagnosis of one of the following:
    - hematologic malignancy (e.g., acute myelogenous leukemia, myelodysplastic syndromes) with neutropenia; **or**
    - hematopoietic stem cell transplantation (HSCT); **or**
    - graft-versus-host disease (GVHD).
- Documentation of the following is required for the treatment of aspergillus, scedosporium, and fusarium infections:
  - appropriate diagnosis.
- Documentation of the following is required for the treatment of aspergillus endophthalmitis and keratitis:
  - appropriate diagnosis.
- Documentation of the following is required for the treatment of candidemia and disseminated candidiasis infections:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to oral fluconazole.
- Documentation of the following is required for the treatment of esophageal candidiasis:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: oral fluconazole, itraconazole.
- Documentation of the following is required for the treatment of oropharyngeal candidiasis:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: oral fluconazole, itraconazole, posaconazole.

SmartPA: Claims for voriconazole suspension will usually process at the pharmacy without a PA request for members with a history of MassHealth medical claims for aspergillus within the last 365 days.†

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 48 - Antiparkinsonian Agents

Drug Category: CNS Agents

Medication Class/Individual Agents: Antiparkinsonian Agents

I. Prior-Authorization Requirements

Antiparkinsonian Agents – Dopamine Agonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
apomorphine film	Kynmobi	PA	
apomorphine injection	Apokyn		#
bromocriptine 2.5 mg, 5 mg	Parlodel		# , A90
pramipexole			A90
pramipexole extended-release	Mirapex ER	PA	A90
ropinirole			A90
ropinirole extended-release			A90
rotigotine transdermal system	Neupro	PA - > 1 unit/day	

Antiparkinsonian Agents – Monoamine Oxidase (MAO) Type-B Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
rasagiline	Azilect	PA - > 1 unit/day	A90
safinamide	Xadago	PA	
selegiline capsule, tablet			A90
selegiline orally disintegrating tablet	Zelapar	PA	

Antiparkinsonian Agents – Dopamine Analogues			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
carbidopa	Lodosyn		# , A90
carbidopa / levodopa enteral suspension	Duopa	PA	
carbidopa / levodopa extended-release	Crexont	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- There is no universal first choice in the treatment of Parkinson’s disease. Clinical and lifestyle characteristics of the member should be taken into account.
- Most patients will develop motor complications over time and will require levodopa therapy. Adjuvant medications may help to reduce motor complications and raise quality of life in late stage Parkinson’s disease.
- Anticholinergics are poorly tolerated in the elderly and should be avoided.

Antiparkinsonian Agents – Dopamine Analogues			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
capsule- Crexont			
carbidopa / levodopa extended-release capsule- Rytary	Rytary	PA	BP
carbidopa / levodopa extended-release tablet			A90
carbidopa / levodopa orally disintegrating tablet		PA	A90
carbidopa / levodopa tablet	Sinemet		# , A90
foscarbidopa / foslevodopa	Vyalev	PA	
levodopa	Inbrija	PA	

Antiparkinsonian Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amantadine extended-release capsule	Gocovri	PA	
amantadine extended-release tablet	Osmolex ER	PA	
amantadine immediate-release capsule, solution, tablet			A90
carbidopa / levodopa / entacapone			A90
istradefylline	Nourianz	PA	A90

Antiparkinsonian Agents – Catechol-O-Methyl Transferase (COMT) Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
entacapone			A90
opicapone	Ongentys	PA	
tolcapone	Tasmar	PA	A90

Antiparkinsonian Agents – Anticholinergic Medications			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
benztropine			A90
trihexyphenidyl			A90

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Drug-induced extrapyramidal symptoms (Gocovri, Osmolex ER)
- Parkinson's disease
- Parkinson's disease psychosis (Nuplazid)

Non-FDA-approved, for example:

- Restless leg syndrome (pramipexole extended-release)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

carbidopa/levodopa orally disintegrating tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the ODT formulation instead of conventional formulations; **and**
  - member is not utilizing other solid oral formulations.

Crexont and Rytary
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to the carbidopa/levodopa immediate-release tablet formulation; **and**
  - medical necessity for the requested agent instead of carbidopa/levodopa extended-release tablet; **and**
  - for Crexont, inadequate response or adverse reaction to Rytary.

Duopa and Vyalev
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is experiencing "off" symptoms with carbidopa/levodopa therapy despite maximizing dose; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to both of the following:
    - carbidopa/levodopa immediate-release or extended-release tablet formulation; **and**
    - carbidopa/levodopa extended-release capsule; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to carbidopa/levodopa in combination with all of the following: COMT inhibitor, dopamine agonist, monoamine oxidase-type B (MAO-B) inhibitor; **and**
  - for Duopa, member has a PEG tube.

Gocovri
- Documentation of the following is required for a diagnosis of Parkinson's disease:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: carbidopa/levodopa, dopamine agonist, MAO-B inhibitor, anticholinergic agent; **and**
  - for the 68.5 mg capsule, member has moderate or severe renal impairment; **and**
  - one of the following:
    - for 68.5 mg capsule, requested quantity is ≤ one unit/day; **or**
    - for 137 mg capsule, requested quantity is ≤ f two units/day; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release (capsules, tablets, oral solution); **and**
  - medical necessity for use of amantadine extended-release capsules instead of amantadine extended-release tablets.
- Documentation of the following is required for a diagnosis of Parkinson's disease with dyskinesia while on levodopa-based therapy:
  - appropriate diagnosis; **and**
  - member is experiencing dyskinesia while on levodopa-based therapy; **and**
  - member is concurrently taking carbidopa/levodopa; **and**
  - for the 68.5 mg capsule, member has moderate or severe renal impairment; **and**
  - one of the following:
    - for 68.5 mg capsule, requested quantity is ≤ one unit/day; **or**
    - for 137 mg capsule, requested quantity is ≤ two units/day; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release (capsules, tablets, oral solution); **and**
  - medical necessity for use of amantadine extended-release capsules instead of amantadine extended-release tablets.
- Documentation of the following is required for a diagnosis of Parkinson's disease with "off" episodes while on carbidopa/levodopa

therapy:
- appropriate diagnosis; **and**
- member is experiencing "off" symptoms with carbidopa/levodopa therapy despite maximizing dose; **and**
- medical records documenting an inadequate response, adverse reaction, or contraindication to carbidopa/levodopa in combination with all of the following: dopamine agonist, catechol-o-methyl transferase (COMT) inhibitor, MAO-B inhibitor; **and**
- for the 68.5 mg capsule, member has moderate or severe renal impairment; **and**
- one of the following:
  - for 68.5 mg capsule, requested quantity is ≤ one unit/day; **or**
  - for 137 mg capsule, requested quantity is ≤ two units/day; **and**
- medical necessity for use of amantadine extended-release instead of amantadine immediate-release (capsules, tablets, oral solution); **and**
- medical necessity for use of amantadine extended-release capsules instead of amantadine extended-release tablets.

- Documentation of the following is required for a diagnosis of drug-induced extrapyramidal symptoms:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all anticholinergic agents; **and**
  - for the 68.5 mg capsule, member has moderate or severe renal impairment; **and**
  - one of the following:
    - for 68.5 mg capsule, requested quantity is ≤ one unit/day; **or**
    - for 137 mg capsule, requested quantity is ≤ two units/day; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release (capsules, tablets, oral solution); **and**
  - medical necessity for use of amantadine extended-release capsules instead of amantadine extended-release tablets.

Inbrija and Kynmobi

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is experiencing "off" symptoms with carbidopa/levodopa therapy despite maximizing dose; **and**
  - medical records documenting an inadequate response or adverse reaction to carbidopa/levodopa immediate-release used as needed for "off" symptoms; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to carbidopa/levodopa in combination with all of the following: dopamine agonist, COMT inhibitor, MAO-B inhibitor; **and**
  - one of the following:
    - for Inbrija**,** requested dose is 84 mg (two 42 mg capsules) up to five times per day as needed for "off" symptoms; **or**
    - for Kynmobi, requested quantity is ≤ five units/day.

Neupro > one unit/day and rasagiline > one unit/day

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limit.

Nourianz

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is experiencing "off" symptoms with carbidopa/levodopa therapy despite maximizing dose; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to carbidopa/levodopa in combination with all of the following: dopamine agonist, COMT inhibitor, MAO B inhibitor; **and**
  - requested quantity is ≤ one unit/day.

Ongentys and tolcapone

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is concurrently taking carbidopa/levodopa; **and**
  - for Ongentys, an inadequate response, adverse reaction, or contraindication to entacapone.
  - for tolcapone, an inadequate response, adverse reaction, or contraindication to both of the following: entacapone, Ongentys.

SmartPA: Claims for Ongentys will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for Parkinson's disease, a history of paid MassHealth pharmacy claims for a carbidopa/levodopa product for at least 90 days within the last 120 days, and a history of paid MassHealth pharmacy claims for entacapone.†

SmartPA: Claims for tolcapone will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for Parkinson's disease, a history of paid MassHealth pharmacy claims for a carbidopa/levodopa product for at least 90 days within the last 120 days, and a history of paid MassHealth pharmacy claims for entacapone and Ongentys.†

Osmolex ER

- Documentation of the following is required for a diagnosis of Parkinson's disease:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: carbidopa/levodopa, dopamine agonist, MAO-B inhibitor, anticholinergic agent; **and**
  - one of the following:
    - for tablet, requested quantity is ≤ one unit/day; **or**
    - for tablet dose pack, requested quantity is ≤ two units/day; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release (capsules, tablets, oral solution).
- Documentation of the following is required for a diagnosis of Parkinson's disease with dyskinesia while on levodopa-based therapy:
  - appropriate diagnosis; **and**
  - member is experiencing dyskinesia while on levodopa-based therapy; **and**
  - member is concurrently taking carbidopa/levodopa; **and**
  - one of the following:
    - for tablet, requested quantity is ≤ one unit/day; **or**
    - for tablet dose pack, requested quantity is ≤ two units/day; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release.
- Documentation of the following is required for a diagnosis of Parkinson's disease with "off" episodes while on carbidopa/levodopa therapy:
  - appropriate diagnosis; **and**
  - member is experiencing "off" symptoms with carbidopa/levodopa therapy despite maximizing dose; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to carbidopa/levodopa in combination with all of the following: dopamine agonist, COMT inhibitor, and MAO B inhibitor; **and**
  - one of the following:
    - for tablet, requested quantity is ≤ one unit/day; **or**
    - for tablet dose pack, requested quantity is ≤ two units/day; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release.
- Documentation of the following is required for a diagnosis of drug-induced extrapyramidal symptoms:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all anticholinergic agents; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release (capsules, tablets, oral solution); **and**
  - one of the following:
    - for tablet, requested quantity is ≤ one unit/day; **or**

- for tablet dose pack, requested quantity is ≤ two units/day.

pramipexole extended-release

- Documentation of the following is required for the diagnosis of Parkinson's disease:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to both of the following: pramipexole immediate-release, ropinirole extended-release.

- Documentation of the following is required for the diagnosis of Restless leg syndrome:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to both of the following: pramipexole immediate-release, ropinirole extended-release.

Xadago

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is concurrently taking carbidopa/levodopa; **and**
  - member is experiencing "off" symptoms with carbidopa/levodopa therapy; **and**
  - medical records documenting an inadequate response or adverse reaction to selegiline and rasagiline; **and**
  - requested quantity is ≤ one unit/day.

Zelapar

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is concurrently taking carbidopa/levodopa; **and**
  - medical necessity for the ODT formulation instead of conventional formulations; **and**
  - member is not currently utilizing other solid oral formulations; **and**
  - requested quantity is ≤ two units/day.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 49 - Osteoporosis and Bone Metabolism Agents

Drug Category: Bone

Medication Class/Individual Agents: Osteoporosis and Bone Metabolism Agents

I. Prior-Authorization Requirements

Osteoporosis and Bone Metabolism Agents – Bisphosphonates			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alendronate / cholecalciferol	Fosamax Plus D	PA	
alendronate effervescent tablet	Binosto	PA	
alendronate solution		PA	M90
alendronate tablet	Fosamax		# , M90
ibandronate injection		PA	MB
ibandronate tablet			M90
pamidronate			MB
risedronate	Actonel	PA	M90
risedronate delayed-release	Atelvia	PA	BP, M90
zoledronic acid 4 mg			MB
zoledronic acid 5 mg	Reclast		MB

Osteoporosis and Bone Metabolism Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
abaloparatide	Tymlos	PA	
burosumab-twza	Crysvita	PA	
calcitonin salmon injection	Miacalcin	PA	
calcitonin salmon nasal spray			M90
denosumab-Prolia	Prolia	PA	
denosumab-Xgeva	Xgeva	PA	
estrogens, conjugated/bazed oxifene	Duavee	PA	
palopegteriparatide	Yorvipath	PA	
raloxifene	Evista		# , M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Pharmacologic treatment should be offered to members who have known osteoporosis and to those who have experienced fragility fractures.
- Pharmacologic treatment should be considered for members who are at risk for developing osteoporosis (patients with a T-score from –1.5 to –2.5, are receiving glucocorticoids, or are ≥ 62 years of age).
- The FDA recommends considering nonestrogen treatments prior to estrogen and/or hormone therapy for prevention of osteoporosis.
- While combination therapy may produce small increases in bone mineral density (BMD) compared to monotherapy, the impact of combination therapy on fracture rates is unknown. The potential side effects and additional costs should be weighed against potential gains.

Osteoporosis and Bone Metabolism Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
romosozumab-aqqg	Evenity	PA	
teriparatide 600 mcg/2.4 mL	Forteo	PA	BP
teriparatide 620 mcg/0.48 mL		PA	

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

M90 Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Paget's disease
- prevention of skeletal-related events secondary to bone metastases in cancer related to solid tumors and in multiple myeloma
- treatment of FGF23-related hypophosphatemia in tumor induced osteomalacia
- treatment of giant cell tumor of the bone
- treatment of hypercalcemia
- treatment of hypercalcemia of malignancy
- treatment of hypoparathyroidism
- treatment of moderate-to-severe vasomotor symptoms associated with menopause
- treatment of X-Linked hypophosphatemia
- treatment/prevention of glucocorticoid-induced osteoporosis
- treatment/prevention of postmenopausal osteoporosis and osteoporosis in biologic male/male sex assigned at birth
- treatment to increase bone mass in members at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer
- treatment to increase bone mass in members at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Paget's Disease (calcitonin salmon injection)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to alendronate; **or**
    - contraindication to oral bisphosphonates; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to pamidronate; **or**
    - inadequate response to an adequate trial or adverse reaction to zoledronic acid 5 mg; **or**
    - contraindication to IV bisphosphonates.

Paget's Disease (risedronate)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to an adequate trial or adverse reaction to alendronate.

Prevention of postmenopausal osteoporosis (Duavee)

- Documentation of all of the following is required:
  - indication of prevention of postmenopausal osteoporosis; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to one oral bisphosphonate; **or**
    - contraindication to all oral bisphosphonates; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: one menopausal hormonal agent available without PA, raloxifene, zoledronic acid 5 mg; **and**
  - requested quantity is ≤ one unit/day.

Prevention of skeletal-related events secondary to bone metastases in cancer related to solid tumors and in multiple myeloma, and

treatment of hypercalcemia of malignancy (Xgeva)

- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - prevention of skeletal-related events secondary to bone metastases in cancer related to solid tumors; **or**
    - prevention of skeletal-related events secondary to multiple myeloma; **or**
    - treatment of hypercalcemia of malignancy; **and**
  - prescriber is an oncologist, hematologist, or orthopedic specialist or consult notes from an oncologist, hematologist, or orthopedic specialist are provided; **and**
  - appropriate dosing.

Treatment/prevention of osteoporosis (calcitonin salmon injection, Evenity, Tymlos)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - bone mineral density indicating osteoporosis; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to an oral bisphosphonate; **or**
    - member is at very high risk for fracture indicated by at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - history of multiple fractures; **or**
      - history of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids); **or**
      - T-score less than −3.0; **or**
      - high risk for falls; **or**
      - history of injurious falls; **or**
      - very high fracture probability by FRAX (fracture risk assessment tool) or other validated fracture risk algorithm; **or**
    - contraindication to all oral bisphosphonates; **and**
  - one of the following:
    - diagnosis of severe osteoporosis defined as at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - T-score less than −3.0; **or**
      - T-score of -2.5 or below plus a fragility fracture; **or**
    - inadequate response or adverse reaction to one or contraindication to all of the following: ibandronate injection, Prolia, zoledronic acid 5 mg; **and**
  - inadequate response to an adequate trial, adverse reaction, or contraindication to teriparatide 600 mcg/2.4 mL; **and**
  - for calcitonin salmon injection, inadequate response, adverse reaction, or contraindication to calcitonin nasal spray.

Treatment/prevention of osteoporosis (teriparatide 600 mcg/2.4 mL, teriparatide 620 mcg/2.48 mL)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - bone mineral density indicating osteoporosis; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to an oral bisphosphonate; **or**
    - member is at very high risk for fracture indicated by at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - history of multiple fractures; **or**
      - history of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids); **or**

- T-score less than −3.0; **or**
- high risk for falls; **or**
- history of injurious falls; **or**
- very high fracture probability by FRAX (fracture risk assessment tool) or other validated fracture risk algorithm; **or**

- contraindication to all oral bisphosphonates; **and**

- one of the following:
  - diagnosis of severe osteoporosis defined as at least one of the following:
    - history of fracture within the past 12 months; **or**
    - history of fractures while on osteoporosis therapy; **or**
    - T-score less than −3.0; **or**
    - T-score of -2.5 or below plus a fragility fracture; **or**
  - inadequate response or adverse reaction to one or contraindication to all of the following: ibandronate injection, Prolia, zoledronic acid 5 mg; **and**
- for teriparatide 620 mcg/2.48 mL, medical necessity for the requested formulation instead of teriparatide 600 mcg/2.4 mL.

Treatment of FDF23-related hypophosphatemia in tumor induced osteomalacia (Crysvita)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - phosphaturic mesenchymal tumor cannot be resected or localized; **and**
  - appropriate dosing.
- For recertification, documentation of positive response to therapy (defined as either improved member serum phosphorus concentration and/or radiographic improvement) is required.

Treatment of giant cell tumor of the bone (Xgeva)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - tumor or metastases are unresectable; **or**
    - surgical resection is likely to result in severe morbidity; **or**
    - surgery is not an option at this time; **and**
  - appropriate dose and frequency for giant cell tumor of the bone.

Treatment of hypercalcemia (calcitonin salmon injection)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for calcitonin salmon injection.

Treatment of hypoparathyroidism (teriparatide 600 mcg/2.4 mL, teriparatide 620 mcg/2.48 mL)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 90 days of therapy), adverse reaction, or contraindication to calcium in conjunction with active vitamin D (e.g. calcitriol) supplementation; **and**
  - for teriparatide 620 mcg/2.48 mL, medical necessity for the requested formulation instead of teriparatide 600 mcg/2.4 mL.

Treatment of hypoparathyroidism (Yorvipath)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**

- inadequate response (defined as ≥ 90 days of therapy), adverse reaction, or contraindication to calcium in conjunction with active vitamin D (e.g. calcitriol) supplementation; **and**
- inadequate response, adverse reaction, or contraindication to teriparatide 600 mcg/2.4 mL; **and**
- prescriber is a specialist (i.e., endocrinologist, nephrologist, surgeon) or consult notes from a specialist are provided; **and**
- requested quantity is ≤ two units/28 days.

Treatment of moderate-to-severe vasomotor symptoms associated with menopause (Duavee)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction to one or contraindication to all menopausal hormonal agents available without PA; **and**
  - requested quantity is ≤ one unit/day.

Treatment of osteoporosis (Fosamax Plus D)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the combination product instead of the individual agents.

Treatment of X-Linked hypophosphatemia (Crysvita)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ six months of age; **and**
  - member's current weight; **and**
  - appropriate dosing.
- For recertification, documentation of positive response to therapy (defined as either improved member serum phosphorus concentration and/or radiographic improvement) is required.

Treatment/prevention of glucocorticoid-induced osteoporosis (teriparatide 600 mcg/2.4 mL, teriparatide 620 mcg/2.48 mL)

- Documentation of all of the following is required:
  - appropriate diagnosis or chronic glucocorticoid use for at least three months in duration; **and**
  - bone mineral density indicating osteoporosis; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to an oral bisphosphonate; **or**
    - member is at very high risk for fracture indicated by at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - history of multiple fractures; **or**
      - history of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids); **or**
      - T-score less than −3.0; **or**
      - high risk for falls; **or**
      - history of injurious falls; **or**
      - very high fracture probability by FRAX (fracture risk assessment tool) or other validated fracture risk algorithm; **or**
    - contraindication to all oral bisphosphonates; **and**
  - one of the following:
    - diagnosis of severe osteoporosis defined as at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - T-score less than −3.0; **or**
      - T-score of -2.5 or below plus a fragility fracture; **or**

- inadequate response or adverse reaction to one or contraindication to all of the following: ibandronate injection, Prolia, zoledronic acid 5 mg; **and**
- for teriparatide 620 mcg/2.48 mL, medical necessity for the requested formulation instead of teriparatide 600 mcg/2.4 mL.

Treatment/prevention of glucocorticoid-induced osteoporosis (risedronate, risedronate delayed-release)
- Documentation of all of the following is required:
  - appropriate diagnosis or chronic glucocorticoid use for at least three months in duration; **and**
  - inadequate response to an adequate trial or adverse reaction to an oral bisphosphonate.

Treatment/prevention of glucocorticoid-induced osteoporosis (Prolia)
- Documentation of all of the following is required:
  - appropriate diagnosis or chronic glucocorticoid use for at least three months in duration; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to one oral bisphosphonate; **or**
    - member is at very high risk for fracture indicated by at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - history of multiple fractures; **or**
      - history of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids); **or**
      - T-score less than −3.0; **or**
      - high risk for falls; **or**
      - history of injurious falls; **or**
      - very high fracture probability by FRAX (fracture risk assessment tool) or other validated fracture risk algorithm; **or**
    - contraindication to all oral bisphosphonates.

Treatment/prevention of osteoporosis (alendronate solution, Binosto)
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for requested formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age.

Treatment/prevention of osteoporosis (ibandronate injection, Prolia)
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to an oral bisphosphonate; **or**
    - member is at very high risk for fracture indicated by at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - history of multiple fractures; **or**
      - history of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids); **or**
      - T-score less than −3.0; **or**
      - high risk for falls; **or**
      - history of injurious falls; **or**
      - very high fracture probability by FRAX (fracture risk assessment tool) or other validated fracture risk algorithm; **or**
    - contraindication to all oral bisphosphonates.

Treatment/prevention of osteoporosis (risedronate, risedronate delayed-release)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to an adequate trial or adverse reaction to an oral bisphosphonate.

Treatment to increase bone mass in members at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer or treatment to increase bone mass in members at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer (Prolia)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to an adequate trial or adverse reaction to a bisphosphonate; **or**
  - contraindication to oral and injectable bisphosphonates.

MassHealth Evaluation Criteria

Table 50 - Narcolepsy and Miscellaneous Sleep Disorder Therapy Agents

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Narcolepsy and Sleep Disorder

I. Prior-Authorization Requirements

Narcolepsy and Miscellaneous Sleep Disorder Therapy Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
calcium oxybate / magnesium oxybate / potassium oxybate / sodium oxybate	Xywav	PA	
pitolisant	Wakix	PA	
sodium oxybate	Xyrem	PA	BP
solriamfetol	Sunosi	PA	
tasimelteon	Hetlioz	PA	BP, A90

Narcolepsy and Miscellaneous Sleep Disorder Therapy Agents – Modafinil Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
armodafinil	Nuvigil	PA - < 6 years and PA > 1 unit/day	#
modafinil 100 mg	Provigil	PA - < 6 years and PA > 1.5 units/day	#
modafinil 200 mg	Provigil	PA - < 6 years and PA > 2 units/day	#

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Clinical trials for solriamfetol did not evaluate its use in combination with other medications that could affect excessive sleepiness, including cerebral stimulants, modafinil agents, or sodium oxybate.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- cataplexy associated with narcolepsy - sodium oxybate, Wakix, Xywav

- excessive daytime sleepiness (EDS) associated with narcolepsy - sodium oxybate, Sunosi, Wakix, Xywav
- EDS associated with obstructive sleep apnea (OSA) - Sunosi
- idiopathic hypersomnia - sodium oxybate, Xywav
- non-24-hour sleep-wake disorder - tasimelteon
- Smith-Magenis syndrome (SMS) - tasimelteon

Non-FDA-approved, for example:

- EDS associated with OSA - sodium oxybate, Wakix, Xywav

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

armodafinil and modafinil exceeding quantity limits

- Documentation of all of the following is required:
  - appropriate dosing; **and**
  - medical necessity for exceeding the quantity limits.

concomitant use of modafinil and armodafinil (a history of at least one paid MassHealth pharmacy claim for the other agents within the last 30 days)

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for concomitant use of modafinil and armodafinil.

sodium oxybate and Xywav

- Documentation of all of the following is required for a diagnosis of cataplexy associated with narcolepsy:
  - appropriate diagnosis; **and**
  - medical records documenting the results of the sleep study used to confirm narcolepsy (PSG or MSLT); **and**
  - prescriber is a neurologist or sleep specialist, or consult notes from a neurologist or sleep specialist are provided; **and**

- inadequate response or adverse reaction to one, or contraindication to all of the following: atomoxetine, SSRI, tricyclic antidepressant, venlafaxine; **and**
- requested dose is ≤ nine grams (18 mL)/day; **and**
- for Xywav, clinical rationale for use instead of sodium oxybate.

- Documentation of all of the following is required for a diagnosis of EDS associated with narcolepsy (without cataplexy):
  - appropriate diagnosis; **and**
  - medical records documenting the results of the sleep study used to confirm narcolepsy (PSG or MSLT); **and**
  - prescriber is a neurologist or sleep specialist, or consult notes from a neurologist or sleep specialist are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to all cerebral stimulant agents; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: armodafinil, modafinil; **and**
  - requested dose is ≤ nine grams (18 mL)/day; **and**
  - for Xywav, clinical rationale for use instead of sodium oxybate.
- Documentation of all of the following is required for a diagnosis of idiopathic hypersomnia:
  - appropriate diagnosis; **and**
  - medical records documenting the results of the PSG ruling out other causes; **and**
  - medical records documenting the results of the MSLT; **and**
  - prescriber is a neurologist or sleep specialist, or consult notes from a neurologist or sleep specialist are provided; **and**
  - member does not have hypersomnia due to another medical, behavioral, or psychiatric disorder; **and**
  - member is not currently utilizing a drug that can cause EDS; **and**
  - inadequate response or adverse reaction to one or contraindication to all cerebral stimulant agents; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: armodafinil, modafinil; **and**
  - requested dose is ≤ nine grams (18 mL)/day; **and**
  - for Xywav, clinical rationale for use instead of sodium oxybate.
- Documentation of all of the following is required for a diagnosis of EDS associated with OSA:
  - appropriate diagnosis; **and**
  - medical records of the sleep study used to diagnose OSA (PSG); **and**
  - medical records documenting the member is utilizing CPAP/BiPAP, an oral appliance, or has undergone successful surgical treatment for OSA; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: armodafinil, modafinil; **and**
  - inadequate response, adverse reaction, or contraindication to Sunosi; **and**
  - requested dose is ≤ nine grams (18 mL)/day; **and**
  - for Xywav, clinical rationale for use instead of sodium oxybate.

Sunosi

- Documentation of all of the following is required for a diagnosis of EDS associated with narcolepsy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical records documenting the results of the sleep study used to confirm narcolepsy [polysomnogram (PSG) or Multiple Sleep Latency Test (MSLT)]; **and**
  - inadequate response or adverse reaction to one, or contraindication to all cerebral stimulant agents; **and**
  - inadequate response or adverse reaction to one, or contraindication to both of the following: armodafinil, modafinil; **and**
  - one of the following:
    - the requested medication will not be used in combination with stimulants or stimulant-like agents; **or**
    - clinical rationale for use of the requested agent in combination with other stimulants or stimulant-like agents; **and**
  - requested quantity is ≤ one unit/day.
- Documentation of all of the following is required for a diagnosis of EDS associated with obstructive sleep apnea (OSA):
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**

- medical records of the sleep study used to diagnose OSA (PSG); **and**
- one of the following:
  - medical records documenting the member is utilizing CPAP/BiPAP, an oral appliance, or has undergone successful surgical treatment for OSA; **or**
  - contraindication to CPAP/BiPAP or an oral appliance; **and**
- inadequate response or adverse reaction to one, or contraindication to both of the following: armodafinil, modafinil; **and**
- one of the following:
  - the requested medication will not be used in combination with stimulants or stimulant-like agents; **or**
  - clinical rationale for use of the requested agent in combination with other stimulants or stimulant-like agents; **and**
- requested quantity is ≤ one unit/day.

tasimelteon capsule

- Documentation of all of the following is required for non-24 hour sleep wake disorder:
  - appropriate diagnosis; **and**
  - member is totally blind; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a sleep specialist, or consult notes from a sleep specialist are provided; **and**
  - inadequate response (defined as at least 28 days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - requested quantity is ≤ one unit/day.
- Documentation of all of the following is required for SMS:
  - appropriate diagnosis; **and**
  - prescriber is a sleep specialist or consult notes from a sleep specialist are provided; **and**
  - member is ≥ three years of age; **and**
  - inadequate response (defined by at least 28 days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - requested quantity is ≤ one unit/day.

tasimelteon suspension

- Documentation of all of the following is required for SMS:
  - appropriate diagnosis; **and**
  - prescriber is a sleep specialist or consult notes from a sleep specialist are provided; **and**
  - member is ≥ three years of age; **and**
  - inadequate response (defined by at least 28 days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - medical necessity for use instead of capsule formulation; **and**
  - requested quantity is ≤ five mL/day.

Wakix

- Documentation of all of the following is required for a diagnosis of cataplexy associated with narcolepsy:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - medical records documenting the results of the sleep study used to confirm narcolepsy (PSG or MSLT); **and**
  - prescriber is a neurologist or sleep specialist, or consult notes from a neurologist or sleep specialist are provided; **and**
  - inadequate response or adverse reaction to one, or contraindication to all of the following: atomoxetine, SSRI, tricyclic antidepressant, venlafaxine; **and**
  - inadequate response or adverse reaction to one, or contraindication to all oxybate products; **and**
  - requested quantity is ≤ two units/day.
- Documentation of all of the following is required for a diagnosis of EDS associated with narcolepsy (without cataplexy):
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**

- medical records documenting the results of the sleep study used to confirm narcolepsy (PSG or MSLT); **and**
- prescriber is a neurologist or sleep specialist or consult notes from a neurologist or sleep specialist are provided; **and**
- inadequate response or adverse reaction to three, or contraindication to all of the following: armodafinil or modafinil, cerebral stimulant agent, sodium oxybate, Sunosi; **and**
- requested quantity is ≤ two units/day.

- Documentation of all of the following is required for a diagnosis of EDS associated with OSA:
  - appropriate diagnosis; **and**
  - medical records of the sleep study used to diagnose OSA (PSG); **and**
  - medical records documenting the member is utilizing CPAP/BiPAP, an oral appliance, or has undergone successful surgical treatment for OSA; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: armodafinil, modafinil; **and**
  - inadequate response, adverse reaction, or contraindication to Sunosi; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: sodium oxybate, Xywav; **and**
  - requested quantity is ≤ two units/day.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy ***(pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, viloxazine, and xanomeline/trospium] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:

- appropriate diagnoses; **and**
- treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
- prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
- if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation; **and**
- one of the following:
  - member has a seizure diagnosis only; **or**
  - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
  - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
  - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and**
  - one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

armodafinil and modafinil for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current alpha agonist(s) and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 51 - Antiglaucoma Agents - Ophthalmic

Drug Category: Ophthalmic

Medication Class/Individual Agents: Antiglaucoma Agents

I. Prior-Authorization Requirements

Antiglaucoma Agents: Ophthalmic – Alpha-Adrenergic Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
apraclonidine	Iopidine		# , M90
brimonidine 0.1%, 0.15% eye drops	Alphagan P		BP, M90
brimonidine 0.2% eye drops			M90

Antiglaucoma Agents: Ophthalmic – Carbonic Anhydrase Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
brinzolamide	Azopt		BP, M90
dorzolamide			M90

Antiglaucoma Agents: Ophthalmic – Beta-Adrenergic Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betaxolol 0.25%	Betoptic S		
betaxolol 0.5%			M90
carteolol			M90
levobunolol			M90
timolol 0.25% ophthalmic unit dose solution	Timoptic Ocudose	PA	M90
timolol 0.5% ophthalmic unit dose solution	Timoptic Ocudose	PA	BP, M90
timolol ophthalmic gel forming solution		PA	M90
timolol opthalmic solution			M90
timolol-Betimol	Betimol	PA	BP
timolol-Istalol	Istalol		BP, M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Patients diagnosed with ocular hypertension or suspected open-angle glaucoma should be offered medication based on the risk factors for developing primary open-angle glaucoma such as high intraocular pressure (IOP), type 2 diabetes mellitus, and older age.[1]
- Ophthalmic prostaglandin analogues are often considered first-line. If target IOP has not been achieved, switching to an alternative medication or adding additional medication (e.g., ophthalmic beta-blockers, alpha-2 adrenergic agonists, carbonic anhydrase inhibitors, parasympathomimetics) is recommended.[2]

[1] Gedde SJ, Lind JT, Wright MM, Chen PP, Muir KW, Vinod K, et al. Primary Open-Angle Glaucoma Suspect Preferred Practice Pattern Guidelines. Ophthalmology. 2020 Nov; 128(1):P151-192.

[2] Gedde SJ, Vinod K, Wright MM, Muir KW, Lind JT, Chen PP, et al. Primary Open-Angle Glaucoma Preferred Practice Pattern Guidelines. Ophthalmology. 2020 Nov;128(1):P71-P150.

Antiglaucoma Agents: Ophthalmic – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
brimonidine / timolol, ophthalmic	Combigan		BP, M90
brinzolamide / brimonidine	Simbrinza		
dorzolamide / timolol	Cosopt		# , M90
dorzolamide / timolol, preservative free	Cosopt PF	PA	BP, M90
netarsudil / latanoprost	Rocklatan	PA	

Antiglaucoma Agents: Ophthalmic – Prostaglandins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bimatoprost 0.01% ophthalmic solution	Lumigan		
bimatoprost 0.03% ophthalmic solution		PA	M90
bimatoprost implant	Durysta	PA	MB
latanoprost emulsion	Xelpros	PA	
latanoprost solution - Iyuzeh	Iyuzeh	PA	
latanoprost solution - Xalatan	Xalatan		# , M90
latanoprostene	Vyzulta	PA	
tafluprost	Zioptan	PA	BP, M90
travoprost 0.004% eye drop	Travatan Z		BP, M90
travoprost intracameral implant	Idose TR	PA	MB

Antiglaucoma Agents: Ophthalmic – Miotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acetylcholine chloride	Miochol-E		MB
carbachol 0.01%	Miostat		MB
echothiophate iodide	Phospholine Iodide		
pilocarpine 1%, 2%, 4% ophthalmic solution			M90

Antiglaucoma Agents: Ophthalmic – Rho Kinase Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
netarsudil	Rhopressa	PA	

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Ocular hypertension
- Open-angle glaucoma

Non-FDA-approved, for example:

- infantile hemangioma

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.

- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

bimatoprost 0.03% ophthalmic solution

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to Lumigan; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: latanoprost solution, travoprost 0.004% eye drop.

dorzolamide/timolol preservative free and Xelpros

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - sensitivity to benzalkonium chloride or any other preservative used in ophthalmic preparations.

Durysta

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - affected eye(s) have not previously been treated with Durysta; **and**
  - one of the following:
    - inadequate response or adverse reaction to Lumigan; **or**
    - medical necessity for the use of an implantable formulation as noted by one of the following:
      - limited dexterity; **or**
      - visual impairment; **or**
      - intellectual disability.

Idose TR

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to Travatan Z; **or**
    - medical necessity for the use of an implantable formulation as noted by one of the following: limited dexterity, visual impairment, intellectual disability; **and**
  - affected eye(s) have not previously been treated with Idose TR.

Iyuzeh and tafluprost

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to Xelpros; **and**
  - one of the following:
    - inadequate response, adverse reaction or contraindication to latanoprost solution available without PA; **or**
    - sensitivity to benzalkonium chloride or any other preservative used in ophthalmic preparations.

SmartPA: Claims for Iyuzeh or tafluprost will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for latanoprost solution available without PA and Xelpros.†

Rhopressa

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response to combination therapy with a prostaglandin analog and an ophthalmic beta-blocker; **or**
    - contraindication or adverse reaction to prostaglandin analogs and ophthalmic beta-blockers; **or**
    - both of the following:
      - contraindication to ophthalmic beta-blockers; **and**
      - inadequate response or adverse reaction to a prostaglandin analog in combination with one of the following: ophthalmic alpha-2 adrenergic agonist, parasympathomimetic, carbonic anhydrase inhibitor; **or**
    - both of the following:
      - contraindication to prostaglandin analogs; **and**
      - inadequate response or adverse reaction to an ophthalmic beta-blocker in combination with one of the following: ophthalmic alpha-2 adrenergic agonist, parasympathomimetic, carbonic anhydrase inhibitor.

Rocklatan
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response to combination therapy with a prostaglandin analog and an ophthalmic beta-blocker; **or**
    - both of the following:
      - contraindication to ophthalmic beta-blockers; **and**
      - inadequate response or adverse reaction to a prostaglandin analog in combination with one of the following: ophthalmic alpha-2 adrenergic agonist, parasympathomimetic, carbonic anhydrase inhibitor.

timolol (generic Betimol)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to an ophthalmic timolol product available without PA.

SmartPA: Claims for timolol (generic Betimol) will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for an ophthalmic timolol product that is available without PA.†

timolol ophthalmic gel forming solution
- Documentation of the following is required for diagnosis of ocular hypertension or open-angle glaucoma:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to an ophthalmic timolol-containing product available without PA.
- Documentation of the following is required for diagnosis of infantile hemangioma:
  - appropriate diagnosis.

SmartPA: Claims for timolol ophthalmic gel forming solution will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for an ophthalmic timolol-containing product.†

timolol ophthalmic unit dose solution
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to an ophthalmic timolol product available without PA; **or**
    - sensitivity to benzalkonium chloride.

SmartPA: Claims for timolol ophthalmic unit dose solution will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for an ophthalmic timolol product that is available without a PA.†

Vyzulta

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 17 years of age; **and**
  - one of the following:
    - inadequate response to combination therapy with latanoprost solution and an ophthalmic beta-blocker; **or**
    - both of the following:
      - inadequate response to latanoprost solution; **and**
      - contraindication or adverse reaction to an ophthalmic beta-blocker.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 52 - Multiple Sclerosis Agents

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Multiple Sclerosis Agents

I. Prior-Authorization Requirements

Multiple Sclerosis Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alemtuzumab 12 mg	Lemtrada	PA	MB
cladribine tablet	Mavenclad	PA	
dalfampridine	Ampyra	PA - > 2 units/day	# , A90
dimethyl fumarate	Tecfidera	PA - > 2 units/day	# , A90
diroximel fumarate	Vumerity	PA	
fingolimod capsule	Gilenya	PA - > 1 unit/day	# , A90
fingolimod orally disintegrating tablet	Tascenso ODT	PA	
glatiramer	Copaxone		BP
monomethyl fumarate	Bafiertam	PA	
natalizumab	Tysabri		
ocrelizumab	Ocrevus	PA	
ocrelizumab / hyaluronidase-ocsq	Ocrevus Zunovo	PA	
ofatumumab prefilled syringe	Kesimpta	PA	
ozanimod for multiple sclerosis	Zeposia	PA	
ponesimod	Ponvory	PA	
siponimod	Mayzent	PA	
teriflunomide	Aubagio	PA - > 1 unit/day	# , A90
ublituximab-xiiy	Briumvi	PA	

Multiple Sclerosis Agents – Interferons			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
interferon beta-1a-Avonex	Avonex		
interferon beta-1a-Rebif	Rebif		
interferon beta-1b	Betaseron		
peginterferon beta-1a	Plegridy	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Siponimod

- Genetic testing of CYP2C9 variants is required prior to initiation.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Active secondary-progressive MS (SPMS)
- Clinically isolated syndrome (CIS)
- Relapsing-remitting MS (RRMS)
- Primary-progressive MS (Ocrevus, Ocrevus Zunovo)
- To improve walking in patients with MS (dalfampridine)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Bafiertam

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for Bafiertam instead of dimethyl fumarate and Vumerity; **and**
  - requested quantity is ≤ four units/day.

Briumvi
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - requested dose is 450 mg every 24 weeks.

dalfampridine and dimethyl fumarate > two units/day
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limits.

fingolimod capsule and teriflunomide > one unit/day
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limits.

Kesimpta
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following:
    - Briumvi, Ocrevus, or Ocrevus Zunovo; **or**
    - dimethyl fumarate or Vumerity; **or**
    - fingolimod capsule; **or**
    - glatiramer acetate therapy; **or**
    - interferon therapy; **or**
    - teriflunomide; **or**
    - Tysabri; **and**
  - requested dose is 20 mg at weeks 0, 1, 2, 4 and then every month.

Lemtrada
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - requested dose is 12 mg daily for five days in first year of therapy or 12 mg daily for three days in second year of therapy; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following:
    - Briumvi, Ocrevus, or Ocrevus Zunovo; **or**
    - dimethyl fumarate or Vumerity; **or**
    - fingolimod capsule; **or**
    - glatiramer acetate therapy; **or**
    - interferon therapy; **or**
    - teriflunomide; **or**

- Tysabri.

Mavenclad

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following:
    - Briumvi, Ocrevus, or Ocrevus Zunovo; **or**
    - dimethyl fumarate or Vumerity; **or**
    - fingolimod capsule or Mayzent; **or**
    - glatiramer acetate therapy; **or**
    - interferon therapy; **or**
    - teriflunomide; **or**
    - Tysabri; **and**

Mayzent

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - requested dose is appropriate based on CYP2C9 genotype; **and**
  - genetic testing for CYP2C9 genotype showing the member does not have a CYP2C9 *3/*3 genotype; **and**
  - medical necessity for Mayzent instead of fingolimod capsule; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following:
    - Briumvi, Ocrevus, or Ocrevus Zunovo; **or**
    - dimethyl fumarate or Vumerity; **or**
    - glatiramer acetate therapy; **or**
    - interferon therapy; **or**
    - teriflunomide.

Ocrevus and Ocrevus Zunovo

- Documentation of all of the following is required for a diagnosis of primary progressive MS:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - one of the following:
    - for Ocrevus, requested dose is 600 mg every six months; **or**
    - for Ocrevus Zunovo, requested dose is 920 mg/23,000 units every six months.
- Documentation of all of the following is required for a diagnosis of CIS, RRMS, and active SPMS:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response, adverse reaction, or contraindication to Briumvi; **and**
  - one of the following:
    - for Ocrevus, requested dose is 600 mg every six months; **or**
    - for Ocrevus Zunovo, requested dose is 920 mg/23,000 units every six months.

Plegridy

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**

- medical necessity for Plegridy instead of Avonex or Rebif (interferon beta-1a); **and**
- requested quantity is ≤ two units/28 days; **and**
- inadequate response or adverse reaction to one or contraindication to all of the following:
  - Briumvi, Ocrevus, or Ocrevus Zunovo; **or**
  - dimethyl fumarate or Vumerity; **or**
  - fingolimod capsule; **or**
  - glatiramer acetate therapy; **or**
  - Lemtrada; **or**
  - teriflunomide; **or**
  - Tysabri.

Ponvory and Zeposia

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for the requested agent instead of fingolimod capsule; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following:
    - Briumvi, Ocrevus, or Ocrevus Zunovo; **or**
    - dimethyl fumarate or Vumerity; **or**
    - glatiramer acetate therapy; **or**
    - interferon therapy; **or**
    - teriflunomide; **and**
  - requested quantity is ≤ one unit/day.

Tascenso ODT

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member is ≥ 10 years of age; **and**
  - one of the following:
    - for the 0.25 mg ODT, member weight is ≤ 40 kg; **or**
    - for the 0.5 mg ODT, member weight is > 40 kg; **and**
  - medical necessity for Tascenso ODT instead of fingolimod capsule; **and**
  - requested quantity is ≤ one unit/day.

Vumerity

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for Vumerity instead of dimethyl fumarate; **and**
  - requested quantity is ≤ four units/day.

MassHealth Evaluation Criteria
Table 53 - Otic Agents

Drug Category: Otic Agents

Medication Class/Individual Agents: Otic Agents

I. Prior-Authorization Requirements

Otic Agents – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acetic acid / hydrocortisone			A90
ciprofloxacin / dexamethasone otic suspension		PA	A90
ciprofloxacin / fluocinolone	Otovel	PA	A90
ciprofloxacin / hydrocortisone	Cipro HC		
colistin / neomycin / thonzonium / hydrocortisone	Cortisporin-TC		A90
neomycin / polymyxin B / hydrocortisone otic			A90

Otic Agents – Single-Entity Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acetic acid			A90
ciprofloxacin 0.2% otic solution		PA	A90
fluocinolone oil, otic drops	Dermotic		# , A90
ofloxacin otic solution			A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

American Academy of Otolaryngology--Head and Neck Surgery Foundation. Clinical Practice Guideline: Acute Otitis Externa (AOE)[1]:

- Topical preparations are indicated for initial therapy of diffuse, uncomplicated AOE.
- If the infection extends outside of the ear canal or there are specific host factors (diabetes, immune deficiency, or inability to effectively deliver topical therapy despite aural toilet), systemic antimicrobial therapy should be administered.
- No significant differences in AOE clinical outcomes were found regarding the use of an antimicrobial versus an antiseptic, a quinolone antibiotic versus a nonquinolone antibiotic(s) or a steroid-antimicrobial agent versus an antimicrobial agent alone.
- If a patient has a known suspected perforation of the tympanic membrane, including a tympanostomy tube, a non-ototoxic topical preparation should be utilized (substances with ototoxic potential include aminoglycosides, alcohol, and ones with a low pH including most acidifying and antiseptic agents).

	Clinical Notes
	[1] *Rosenfeld RM, Schwartz SR, Cannon CR, et al. Clinical practice guideline: acute otitis externa [published correction appears in Otolaryngol Head Neck Surg. 2014 Mar;150(3):504] [published correction appears in Otolaryngol Head Neck Surg. 2014 Mar;150(3):504]. Otolaryngol Head Neck Surg. 2014;150(1 Suppl):S1-S24. doi:10.1177/0194599813517083.*

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Acute otitis media (ciprofloxacin/dexamethasone otic suspension)
- Acute otitis media with tympanostomy tubes (Otovel)
- External Otitis (ciprofloxacin 0.2% otic solution, ciprofloxacin/dexamethasone otic suspension)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

ciprofloxacin 0.2% otic solution

- Documentation of all of the following is required:

- appropriate diagnosis; **and**
- one of the following:
  - medical necessity for unit dosing; **or**
  - inadequate response or adverse reaction to two or contraindication to all of the following: Cipro HC, ciprofloxacin/dexamethasone, Cortisporin TC, neomycin/polymyxinB/hydrocortisone otic, ofloxacin otic solution

SmartPA: Claims for ciprofloxacin 0.2% otic solution will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two of the following within the last 30 days: Cipro HC, ciprofloxacin/dexamethasone, Cortisporin TC, neomycin/polymyxinB/hydrocortisone otic, ofloxacin otic solution.†

ciprofloxacin/dexamethasone otic suspension

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 6 months of age; **and**
  - one of the following:
    - member has tympanostomy tubes; **or**
    - inadequate response, adverse reaction, or contraindication to Cipro HC.

SmartPA: Claims for ciprofloxacin/dexamethasone otic suspension will usually process at the pharmacy without a PA request if the member is ≥ 6 months of age and has a history of paid MassHealth pharmacy claims for Cipro HC within the last 30 days or if the member has tympanostomy tubes.

Otovel

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ six months of age; **and**
  - inadequate response, adverse reaction, or contraindication to ciprofloxacin/dexamethasone otic suspension.

SmartPA: Claims for Otovel will usually process at the pharmacy without a PA request if the member is ≥ six months of age and has a history of paid MassHealth pharmacy claims for ciprofloxacin/dexamethasone otic suspension within the past 30 days.†

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 54 - Pediculicides and Scabicides

Drug Category: Dermatological

Medication Class/Individual Agents: Pediculicide/Scabicide

I. Prior-Authorization Requirements

Pediculicides and Scabicides			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
crotamiton	Eurax	PA	
malathion	Ovide	PA	
permethrin			*
permethrin cream	Elimite		#
piperonyl butoxide / pyrethrins			*
spinosad	Natroba	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Centers for Disease Control and Prevention: Treatment of Head Lice (2016)[1]

- Pyrethrins and permethrin are first-line treatments; however, a second course of therapy may be needed to kill newly hatched lice.
- Benzoyl alcohol is pediculicidal but not ovicidal. A second treatment is necessary after the first treatment to kill newly hatched lice.
- Ivermectin lotion is not ovicidal, but prevents newly hatched lice from surviving. It should not be used for retreatment without talking to a health care provider.
- Malathion is pediculicidal and partially ovicidal. Retreatment may be necessary if the first treatment is unsuccessful.
- Spinosad is pediculicidal and ovicidal. Therefore, retreatment is often not needed. Repeat treatment should only be given if live lice are seen seven days after the first treatment.

Centers for Disease Control and Prevention: Treatment of Scabies (2016)[2]

- Permethrin is the first-line treatment for scabies, killing scabies mites and eggs. It is FDA-approved for the treatment in patients at least two months of age. Two (or more) applications, each about a week apart, may be

	Clinical Notes
	necessary to eliminate all mites. • Crotamiton is FDA-approved for the treatment of scabies in adults, but not for treatment in children. Frequent treatment failure has been reported with this agent. • Oral ivermectin is a safe and effective treatment for scabies. The safety of ivermectin in children weighing less than 15 kg and in pregnant women has not been established. 1.Centers for Disease Control and Prevention. Treatment of Head Lice [guideline on the internet]. 2016. [cited 2017 Feb 10]. Available at: https://www.cdc.gov/parasites/lice/head/treatment.html 2. Centers for Disease Control and Prevention. Treatment of Head Scabies [guideline on the internet]. 2016. [cited 2017 Feb 10]. Available at: http://www.cdc.gov/parasites/scabies/health_professionals/meds.html.

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

* The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.

II. Therapeutic Uses

FDA-approved, for example:

- Head lice (ivermectin lotion OTC, malathion, spinosad)
- Scabies (crotamiton lotion, Eurax cream)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.

- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

crotamiton lotion and Eurax cream

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to permethrin 5% within the last 30 days; **or**
  - adverse reaction or contraindication to permethrin 5%; **and**
  - inadequate response to oral ivermectin within the last 30 days; **or**
  - adverse reaction or contraindication to oral ivermectin.

SmartPA: Claims for crotamiton cream and lotion will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for permethrin 5% and oral ivermectin within the last 30 days.†

ivermectin lotion OTC and spinosad

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ six months of age; **and**
  - inadequate response or adverse reaction to a permethrin product or a piperonyl butoxide/pyrethrins product within the last 30 days; **or**
  - adverse reaction at any time or contraindication to both permethrin and piperonyl butoxide/pyrethrins products.

SmartPA: Claims for spinosad will usually process at the pharmacy without a PA request if the member is ≥ six months of age and has a history of a paid MassHealth pharmacy claim for a permethrin product or a piperonyl butoxide/pyrethrins product within the last 30 days. Claims for ivermectin lotion and spinosad (in members ≥ six months of age) will usually process at the pharmacy without a PA request if MassHealth pharmacy claims data indicate the member is currently in an institutional setting.†

malathion

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - inadequate response or adverse reaction to a permethrin product or a piperonyl butoxide/pyrethrins product within the last 30 days; **or**
  - adverse reaction at any time or contraindication to both of the following: permethrin product, piperonyl butoxide/pyrethrins product.

SmartPA: Claims for malathion will usually process at the pharmacy without a PA request if the member is ≥ two years of age and has a history of a paid MassHealth pharmacy claim for a permethrin product or a piperonyl butoxide/pyrethrins product within the last 30 days.†

†Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 55 - Androgens

Drug Category: Androgen Therapy

Medication Class/Individual Agents: Androgens

I. Prior-Authorization Requirements

Androgens			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
methyltestosterone		PA	
testosterone 1% gel packet	Androgel	PA	
testosterone 1% gel tube	Testim	PA	BP
testosterone 1% gel tube, packet, pump	Vogelxo	PA	
testosterone 1.62% gel packet	Androgel	PA	
testosterone 1.62% gel pump		PA	
testosterone 2% gel pump		PA	
testosterone 2% solution		PA	
testosterone cypionate	Azmiro	PA	
testosterone cypionate	Depo-Testosterone	PA	
testosterone enanthate	Xyosted	PA	
testosterone enanthate		PA	
testosterone intramuscular pellet	Testopel	PA	
testosterone nasal gel	Natesto	PA	
testosterone undecanoate capsule	Jatenzo	PA	
testosterone undecanoate capsule	Tlando	PA	
testosterone undecanoate capsule		PA	
testosterone undecanoate injection	Aveed	PA	MB

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Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

The Endocrine Society: **Clinical Practice Guideline Testosterone Therapy in Men with Hypogonadism (2018)**[1]

- The Endocrine Society recommends the use of testosterone replacement therapy (TRT) in men with low testosterone levels due to hypogonadism, drug therapy and human immunodeficiency virus (HIV) infection who are experiencing related complications. However, they recommend against the use of testosterone in older members with age-related decline in testosterone levels and lack of related symptoms.[1]
- The International Society for the Study of the Aging Male as well as the European Association of Urology state the diagnosis of male hypogonadism should be based on signs and symptoms of androgen deficiency, together with consistently low serum testosterone levels.[2,3]
- Choice of therapy should be a joint decision between the member and physician and should be made after consideration of member preferences, the pharmacokinetic profiles of the respective agents, treatment burden and cost.
- Several organizations recommend discussing the cessation of TRT three to six months after initiation of treatment in individuals who experience normalization of

	Clinical Notes
	total testosterone levels but fail to achieve symptom improvement.[4,5] [1] Bhasin S, Brito JP, Cunningham GR, Hayes FJ, Hodis HN, Matsumoto AM, et al. Testosterone therapy in men with hypogonadism: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2018 May 1;103(5):1715-44. [2] Lunenfeld B, Mskhalaya G, Zitzmann M, Arver S, Kalinchenko S, Tishova Y, Morgentaler A. Recommendations on the diagnosis, treatment and monitoring of hypogonadism in men. Aging Male. 2015; 18(1): 5 to 15. Doi: 10.3109/13685538.2015.1004049. [3] Dohle GR, Arver S, Bettochi C, Jones TH, Kliesch S, Punab M. European Association of Urology: Guidelines on male hypogonadism. Male hypogonadism. 2015 Mar. Available from: http://uroweb.org/wp-content/uploads/18-Male-Hypogonadism_LR1.pdf. [4] Mulhall JP, Trost LW, Brannigan RE, Kurtz EG, Redmon JB, Chiles KA, et al. American Urological Association (AUA). Evaluation and management of testosterone deficiency (2018). Available from: https://www.auanet.org/guidelines/testosterone-deficiency-guideline. [5] Qaseem A, Horwitch CA, vijan S, Etxeandia-Ikobaltzeta I, Kansagara D. Testosterone treatment in adult men with age-related low testosterone: A clinical guideline from the American College of Physicians. Annals of Internal Medicine. 2020 Jan 21;172(2): 126-134.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Delayed puberty

- Hypogonadotropic hypogonadism
- Metastatic mammary cancer (biologic female/female sex assigned at birth)
- Primary hypogonadism

non-FDA-approved, for example:

- Delayed puberty
- Gender identity disorder
- Gender dysphoria
- Therapy after gender reassignment surgery

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member’s condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member’s current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Any testosterone product used for delayed puberty

- Documentation of all the following is required:
  - individual drug criteria must be met first where applicable; **and**
  - appropriate diagnosis; **and**
  - prescriber is a pediatric endocrinologist or consultation notes from a pediatric endocrinologist are provided; **and**
  - member is ≥ 14 years of age and < 17 years of age; **and**
  - one of the following:
    - Tanner staging of I or II for sexual maturation ratings; **or**
    - other physical signs of delayed puberty such as: arm span exceeding the member's height by > 5 cm, abnormal testicular growth (testicular volume < 4 mL), bone ages documented as less than the member's current age; **and**
  - lab results of two tests (dated ≤ 3 months apart and drawn within one year of the PA request) documenting low testosterone levels (defined as total serum testosterone <300 ng/dL).

Any testosterone product used for gender identity disorder, gender dysphoria, therapy after gender reassignment surgery

- Documentation of all the following is required:

- individual drug criteria must be met first where applicable, excluding testosterone levels prior to initiating therapy; **and**
- diagnosis of one of the following:
  - gender identity disorder; **or**
  - gender dysphoria; **or**
  - transgenderism; **or**
  - therapy after gender reassignment surgery.

SmartPA: Claims for Natesto, Testopel, testosterone cypionate, testosterone enanthate, testosterone 1% gel 5 gram packet, testosterone 1% gel packet and tube, testosterone 1.62% gel 2.5 gram packet and pump, and testosterone 2% gel pump and solution will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for gender identity disorder or personal history of sex reassignment.†
SmartPA: Claims for testosterone 1% gel 2.5 gram packet at a quantity of ≤1 unit/day and testosterone 1.62% gel 1.25 gram packet at a quantity of ≤1 unit/day will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for gender identity disorder or personal history of sex reassignment.†

Aveed
- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - lab results of two tests (dated ≤ three months apart and drawn within one year of the PA request) documenting low testosterone levels (defined as total serum testosterone <300 ng/dL); **and**
  - inadequate response (defined as ≥ 90 days of therapy) or adverse reaction to both of the following: testosterone cypionate intramuscular injection, testosterone enanthate intramuscular injection.

Azmiro
- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - lab results of two tests (dated ≤ 3 months apart and drawn within one year of the PA request) documenting low testosterone levels (defined as total serum testosterone <300 ng/dL); **and**
  - medical necessity for the requested agent instead of testosterone cypionate injection (Depo-Testosterone); **and**
  - inadequate response, adverse reaction, or contraindication to testosterone enanthate intramuscular injection.

Jatenzo, testosterone undecanoate capsule, and Tlando
- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - lab results of two tests (dated ≤ three months apart and drawn within one year of the PA request) documenting low testosterone levels (defined as total serum testosterone <300 ng/dL); **and**
  - inadequate response (defined as ≥ 90 days of therapy) or adverse reaction to two or a contraindication to all non-injectable formulations of testosterone; **and**
  - for Jatenzo, one of the following:
    - for 237 mg, requested quantity is ≤ two units/day; **or**
    - for 158 mg and 198 mg, requested quantity is ≤ four units/day; **or**
    - clinical rationale for exceeding the quantity limit.

methyltestosterone for biologic female/female sex assigned at birth
- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - for methyltestosterone capsules, medical necessity for use of capsules instead of tablets.

methyltestosterone for biologic male/male sex assigned at birth

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - lab results of two tests (dated ≤ three months apart and drawn within one year of the PA request) documenting low testosterone levels (defined as total serum testosterone <300 ng/dL); **and**
  - inadequate response (defined as ≥ 90 days of therapy), adverse reaction, or contraindication to Jatenzo or Tlando; **and**
  - inadequate response (defined as ≥ 90 days of therapy) or adverse reaction to two non-injectable formulations of testosterone, or a contraindication to all non-injectable formulations of testosterone; **and**
  - appropriate dosing; **and**
  - for methyltestosterone capsules, medical necessity for use of capsules instead of tablets.

Natesto, Testopel, testosterone cypionate, testosterone enanthate, testosterone 1% gel packet and tube, testosterone 1.62% gel packet and pump, and testosterone 2% gel pump and solution

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - lab results of two tests (dated ≤ three months apart and drawn within one year of the PA request) documenting low testosterone levels (defined as total serum testosterone <300 ng/dL); **and**
  - for testosterone 1% gel 2.5 gram packet (Androgel) and testosterone 1.62% gel 1.25 gram packet, one of the following:
    - requested quantity is ≤ one packet/day; **or**
    - clinical rationale for exceeding the quantity limit.

SmartPA: Claims for Natesto, Testopel, testosterone cypionate, testosterone enanthate, testosterone 1% gel 5 gram packet, testosterone 1 % gel packet and tube, testosterone 1.62% gel 2.5 gram packet and pump, and testosterone 2% gel pump and solution will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for primary hypogonadism or hypogonadotropic hypogonadism and a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

SmartPA: Claims for testosterone 1% gel 2.5 gram packet at a quantity of ≤1 unit/day and testosterone 1.62% gel 1.25 gram packet at a quantity of ≤1 unit/day will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for primary hypogonadism or hypogonadotropic hypogonadism and a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

testosterone enanthate for biologic female/female sex assigned at birth

- Documentation of the following is required:
  - diagnosis of metastatic mammary cancer.

Xyosted

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - lab results of two tests (dated ≤ three months apart and drawn within one year of the PA request) documenting low testosterone levels (defined as total serum testosterone <300 ng/dL); **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy), adverse reaction, or contraindication to both of the following: testosterone cypionate intramuscular injection, testosterone enanthate intramuscular injection; **or**
    - both of the following:
      - member has needle phobia; **and**
      - inadequate response (defined as ≥ 90 days of therapy), or adverse reaction to two or contraindication to all topical non-injectable formulations of testosterone.

Please note: The MassHealth agency does not pay for any drug when used for the treatment of sexual dysfunction as described in 130 CMR 406.413(B): Drug Exclusions (see link below).
https://www.mass.gov/regulations/130-CMR-406000-pharmacy-services

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 56 - Alzheimer's Agents

Drug Category: CNS Agents

Medication Class/Individual Agents: Alzheimer's Agents

I. Prior-Authorization Requirements

Alzheimer's Agents – Cholinesterase Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
donepezil 10 mg tablet	Aricept	PA - < 6 years and PA > 2 units/day	# , A90
donepezil 5 mg, 23 mg tablet	Aricept	PA - < 6 years and PA > 1 unit/day	# , A90
donepezil orally disintegrating tablet		PA - < 6 years and PA > 1 unit/day	A90
donepezil patch	Adlarity	PA	
galantamine extended-release capsule		PA - > 1 unit/day	A90
galantamine solution		PA	A90
galantamine tablet		PA - > 2 units/day	A90
rivastigmine capsule		PA - > 2 units/day	A90
rivastigmine patch	Exelon	PA - > 1 unit/day	BP, A90

Alzheimer's Agents – Anti-Amyloid Monoclonal Antibodies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
donanemab-azbt	Kisunla	PA	
lecanemab-irmb	Leqembi	PA	

Alzheimer's Agents – NMDA Receptor Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
memantine extended-release	Namenda XR	PA - < 6 years and PA > 1 unit/day	# , A90
memantine solution		PA	A90
memantine tablet		PA - < 6 years and PA > 2 units/day	A90
memantine titration pack	Namenda	PA - < 6 years and PA > 49 units/28 days	A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

American Psychiatric Association (APA):[1,2]

- There is modest evidence to support the efficacy of cholinesterase inhibitors in mild-to-severe AD and memantine in moderate-to-severe AD.
- Cholinesterase inhibitors should be considered for patients with dementia with Lewy bodies (DLB).
- Cholinesterase inhibitors can be considered for patients with mild-to-moderate dementia associated with Parkinson's disease (PDD), although the data is weak.
- Memantine has not been shown to improve cognition in patients with DLB or PDD.
- The benefit of memantine for mild-to-moderate AD is unclear. Memantine may provide modest benefits and has few adverse effects; it may be considered for members with moderate-to-severe AD.

1. Rabins PV, Blacker D, Rovner BW, Rummans T, Schneider LS, Tariot PN, et al. American Psychiatric Association practice guideline for the treatment of patients with Alzheimer's disease and other dementias. Second edition. Am J Psychiatry. 2007 Dec;164(12 Suppl):5-56.

2. Rabins PV, Rovner BW, Rummans T, Schneider LS, Tariot PN. Guideline Watch (October 2014): Practice

Alzheimer's Agents – Combination Products				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
memantine / donepezil extended-release	Namzaric	PA	BP, A90	*Guideline for the Treatment of Patients With Alzheimer's Disease and Other Dementias. Focus (Am Psychiatr Publ). 2017 Jan;15(1):110-128. doi: 10.1176/appi.focus.15106. Epub 2017 Jan 11.*

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Alzheimer's Disease (AD)
- Dementia associated with Parkinson's Disease
- Mild cognitive impairment (MCI) or mild dementia due to AD

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Adlarity

- Documentation of all of the following is required:

- appropriate diagnosis; **and**
- requested quantity is ≤ 4 units/28 days; **and**
- medical necessity for the requested formulation instead of donepezil tablets or ODT.

galantamine solution

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ 6 mL/day; **and**
  - one of the following:
    - inadequate response or adverse reaction to galantamine tablets or galantamine extended-release capsules; **or**
    - medical necessity for the solution formulation instead of solid oral formulation.

Kisunla

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a specialist in the treatment of dementia or AD; **and**
  - test results indicating clinically significant AD neuropathology based on one of the following
    - amyloid PET; **or**
    - cerebral spinal fluid (CSF) biomarkers; **and**
  - member has had a brain magnetic resonance imaging (MRI) within the last twelve months; **and**
  - appropriate dosing; **and**
  - inadequate response, adverse reaction, or contraindication to Leqembi; **and**
  - baseline cognitive function test (dated within the last three months) based on one of the following objective assessments;
    - MMSE score ≥ 20; **or**
    - MoCA score ≥ 15; **or**
    - SLUMS score ≥ 16.1.
- For recertification, documentation of all of the following is required:
  - appropriate dosing; **and**
  - attestation that all MRI monitoring has been completed in accordance with the FDA-approved label; **and**
  - current cognitive function test (dated within the last three months) based on one of the following objective assessments:
    - MMSE; **or**
    - MoCA; **or**
    - SLUMS.

Leqembi

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a specialist in the treatment of dementia or AD; **and**
  - test results indicating clinically significant AD neuropathology based on one of the following:
    - amyloid PET; **or**
    - cerebral spinal fluid (CSF) biomarkers; **and**
  - member has had a brain magnetic resonance imaging (MRI) within the last twelve months; **and**
  - appropriate dosing; **and**
  - baseline cognitive function test (dated within the last three months) based on one of the following objective assessments;
    - MMSE score ≥ 22; **or**
    - MoCA score ≥ 15; **or**
    - SLUMS score ≥ 16.1.
- For first recertification (after completion of six months of treatment), documentation of all of the following is required:

- appropriate dosing; **and**
- attestation that all MRI monitoring has been completed in accordance with the FDA-approved label; **and**
- current cognitive function test (dated within the last three months) based on one of the following objective assessments:
  - MMSE; **or**
  - MoCA; **or**
  - SLUMS.

- For subsequent recertification (after completion of 18 months of treatment), documentation of all of the following is required:
  - attestation that all MRI monitoring has been completed in accordance with the FDA approved label; **and**
  - current cognitive function test (dated within the last three months) based on one of the following objective assessments:
    - MMSE; **or**
    - MoCA; **or**
    - SLUMS; **and**
  - one of the following:
    - dosing frequency reduced to every four weeks; **or**
    - clinical rationale for continuing biweekly dosing.

memantine solution

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ 10 mL/day; **and**
  - one of the following:
    - inadequate response or adverse reaction to memantine tablets or memantine extended-release capsules; **or**
    - medical necessity for the solution formulation instead of solid oral formulation.

memantine/donepezil extended-release

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one unit/day; **and**
  - medical necessity for the use of the combination product instead of the commercially available separate agents.

All agents at quantities requested above FDA approved limits

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - titration of medication to dose exceeding FDA-recommendations.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy (*pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha2 agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, viloxazine, and xanomeline/trospium] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period***) for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the

following is required:

- one of the following:
  - member had a recent psychiatric hospitalization (within the last three months); **or**
  - member has a history of severe risk of harm to self or others; **or**
- all of the following:
  - appropriate diagnoses; **and**
  - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
    - one of the following:
      - member has a seizure diagnosis only; **or**
      - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
      - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
      - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and**
      - one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

donepezil and memantine for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.

- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist [e.g., psychiatrist, child adolescent psychiatrist (including psychiatric nurse practitioners), neurologist, pediatric neurologist, developmental and behavioral pediatrics] or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 57 - Oncology Agents

Drug Category: Oncology Agents

Medication Class/Individual Agents: Antineoplastics

I. Prior-Authorization Requirements

Oncology Agents – Antimicrotubulars

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
cabazitaxel	Jevtana	PA	MB	IV	**Jevtana** • Documentation of the following is required: • diagnosis of metastatic castration-resistant prostate cancer; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with prednisone; **and** • inadequate response or adverse reaction to one docetaxel-containing regimen.
ixabepilone	Ixempra		MB	IV	
paclitaxel injectable suspension	Abraxane		MB	IV	
paclitaxel injection				IV	

Oncology Agents – Interferon

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
interferon gamma-1b	Actimmune			SC	**Besremi** • Documentation of the following is required: • diagnosis of polycythemia vera; **and** • prescriber is a hematologist; **and** • appropriate dosing; **and** • one of the following: • polycythemia vera is low risk; **or** • polycythemia vera is high risk and inadequate response, adverse reaction, or contraindication to hydroxyurea.
ropeginterferon alfa-2b-njft	Besremi	PA		SC	

Oncology Agents – Mitotic Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
brentuximab	Adcetris	PA	MB	IV	**Adcetris for relapsed or refractory Hodgkin lymphoma in adult members** • Documentation of the following is required: • appropriate diagnosis; **and**
docetaxel	Docivyx		MB	IV	
docetaxel			MB	IV	
eribulin	Halaven	PA	MB	IV	
polatuzumab vedotin-piiq	Polivy	PA	MB	IV	

	Clinical Notes

	• member is ≥ 18 years of age; **and**
	• prescriber is an oncologist or hematologist; **and**
	• appropriate dosing; **and**
	• one of the following:
	  • member is at high risk of relapse as post-autologous hematopoietic stem cell transplantation (auto-HSCT); **or**
	  • inadequate response to auto-HSCT; **or**
	  • member is not a candidate for auto-HSCT and inadequate response or adverse reaction to two prior multi-agent chemotherapy regimens; **or**
	  • clinical rationale as to why the other available treatment regimens cannot be used.
	Adcetris for treatment-naïve Hodgkin lymphoma in adult members
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with doxorubicin, vinblastine, and dacarbazine.
	Adcetris for treatment-naïve Hodgkin lymphoma in pediatric members
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ two and < 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with all of the following: cyclophosphamide, doxorubicin, etoposide, prednisone, vincristine.
	Adcetris for primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing.
	Adcetris for previously untreated CD-30 expressing PTCL, including systemic anaplastic large cell lymphoma (sALCL) used in combination with chemotherapy
	• Documentation of the following is required:

	Clinical Notes
	• appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with cyclophosphamide, doxorubicin, and prednisone. **Adcetris for sALCL after failure of at least one prior multiagent chemotherapy regimen, used as monotherapy** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • inadequate response or adverse reaction to one prior chemotherapy regimen or agent; **or** • clinical rationale as to why the other available treatment regimens cannot be used. **eribulin for metastatic or recurrent breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to two prior chemotherapy regimens that included an anthracycline and a taxane; **and** • inadequate response, adverse reaction, or contraindication to vinorelbine (may have been part of prior chemotherapy regimens). **eribulin for unresectable or metastatic liposarcoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to an anthracycline-containing regimen. **Polivy** • Documentation of the following is required: • diagnosis of diffuse large B-cell lymphoma (DLBCL); **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist or consult notes from a specialist are provided; **and** • appropriate dosing; **and** • one of the following:

	Clinical Notes
	• DLBCL is previously untreated and International Prognostic Index score of ≥ two; **or** • inadequate response or adverse reaction to at least one or contraindication to all systemic therapies.

Oncology Agents – Anthracyclines

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
arsenic trioxide	Trisenox		#	IV	
daunorubicin			MB	IV	
doxorubicin	Adriamycin		MB	IV	
doxorubicin liposomal injection	Doxil		MB	IV	
epirubicin	Ellence		#	IV	
idarubicin	Idamycin PFS		MB	IV	
streptozocin	Zanosar		MB	IV	
teniposide				IV	
valrubicin	Valstar		MB	Intravesically	

Oncology Agents – Intravesical Bladder Cancer Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
nadofaragene firadenovec-vncg	Adstiladrin	PA	MB	Intravesically	**Adstiladrin and Anktiva** • Documentation of the following is required: • diagnosis of non-muscle-invasive bladder cancer (NMIBC); **and** • disease is high-risk with carcinoma in situ (CIS); **and** • prescriber is an oncologist or urologist; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to BCG; **and** • for Anktiva, inadequate response or adverse reaction to one or contraindication to both of the following: Adstiladrin (nadofaragene firadenovec-vncg), Keytruda (pembrolizumab).
nogapendekin alfa inbakicept-pmln	Anktiva	PA	MB	Intravesically	

Oncology Agents – mTOR Kinase Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg	Afinitor	PA	A90	PO	**everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg and everolimus tablets for oral suspension for treatment-resistant epilepsy associated with tuberous sclerosis complex (TSC)**
everolimus tablets for oral	Afinitor Disperz	PA	BP, A90	PO	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
suspension					• Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is a neurologist or consult notes from a neurologist are provided; **and** • inadequate response to combination therapy with at least two anticonvulsants or contraindication to all other anticonvulsants; **and** • requested agent will be used as adjunctive therapy with at least one anticonvulsant agent; **and** • requested quantity is ≤ one unit/day. **everolimus tablets for oral suspension for subependymal giant cell astrocytoma (SEGA) with TSC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested quantity is ≤ one unit/day. **everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg for advanced hormone receptor-positive, HER2-negative breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested regimen includes exemestane, fulvestrant, or tamoxifen; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: anastrozole, letrozole, tamoxifen, toremifene, exemestane; **and** • requested quantity is ≤ one unit/day. **everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg for advanced renal cell carcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • tumor is clear cell histology and requested agent will be used as monotherapy or in combination with Lenvima; **or** • tumor is non-clear cell histology and inadequate response or adverse reaction to one or contraindication to both of the following: Cabometyx, sunitinib; **and** • requested quantity is ≤ one unit/day.
sirolimus gel	Hyftor	PA		Topical	
sirolimus injection	Fyarro	PA		IV	
temsirolimus	Torisel		#	IV	

	Clinical Notes

	everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg for renal angiomyolipoma with TSC, advanced PNET, advanced neuroendocrine tumors (NET) of gastrointestinal or lung origin, and SEGA with TSC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is a specialist (e.g., oncologist or nephrologist) or consult notes from a specialist are provided; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ one unit/day.
	Fyarro
	• Documentation of the following is required:
	  • diagnosis of locally advanced or metastatic malignant perivascular epithelioid cell tumor (PEComa); **and**
	  • appropriate dosing.
	Hyftor
	• Documentation of the following is required:
	  • diagnosis of facial angiofibroma; **and**
	  • member is ≥ six years of age; **and**
	  • prescriber is a neurologist or dermatologist or consult notes from a neurologist or dermatologist are provided; **and**
	  • one of the following:
	  • for members < 12 years of age, requested quantity is ≤ 20 grams/30 days (2 tubes/30 days); **or**
	  • for members ≥ 12 years of age, requested quantity is ≤ 30 grams/30 days (3 tubes/30 days).

Oncology Agents – Miscellaneous

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

aldesleukin	Proleukin	PA		PO	Akeega
					• Documentation of the following is required:
					  • diagnosis of mCRPC; **and**
					  • member has deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) cancer; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with prednisone; **and**
					  • requested quantity is ≤ two units/day.

belzutifan	Welireg	PA		PO	
eflornithine	Iwilfin	PA		PO	
iobenguane I 131	Azedra		MB	IV	
leucovorin			A90	IV / PO	
levoleucovorin injection		PA		IV	
levoleucovorin powder for injection	Fusilev	PA		IV	
levoleucovorin powder for injection	Khapzory	PA		IV	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

mitotane	Lysodren			PO	**Fusilev, Khapzory, and levoleucovorin injection**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • member is ≥ six years of age; **and**
					  • medical records documenting member is not a candidate for leucovorin therapy due to hypersensitivity to a component of leucovorin; **and**
					  • for Khapzory, clinical rationale for use instead of Fusilev (levoleucovorin powder for injection).
					Imlygic
					• Documentation of the following is required:
					  • diagnosis of unresectable melanoma; **and**
					  • prescriber is an oncologist; **and**
					  • requested quantity is ≤ four mL/treatment; **and**
					  • unresectable cutaneous, subcutaneous, or nodal lesions; **and**
					  • melanoma is recurrent after initial surgery.
					Iwilfin
					• Documentation of the following is required:
					  • diagnosis of high-risk neuroblastoma; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • member has a partial response to prior multiagent, multimodality therapy which includes anti-GD2 immunotherapy (e.g., Unituxin); **and**
					  • requested quantity is ≤ eight units/day.
					Kimmtrak
					• Documentation of the following is required:
					  • diagnosis of unresectable or metastatic uveal melanoma; **and**
					  • member is positive for HLA-A*02:01 genotype
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • member is refractory to radiation therapy or radiation therapy is not appropriate.
					Proleukin
					• Documentation of the following is required:
					  • diagnosis of chronic graft versus host disease (GVHD); **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • disease is refractory to steroid treatment; **and**
					  • for members ≥ 18 years of age, inadequate response or adverse reaction to one or contraindication to both of

niraparib/abiraterone	Akeega	PA		PO	
omacetaxine mepesuccinate	Synribo	PA		SC	
selinexor	Xpovio	PA		PO	
sipuleucel-T	Provenge	PA	MB	IV	
talimogene laherparepvec	Imlygic	PA	MB	Intralesional	
tazemetostat	Tazverik	PA		PO	
tebentafusp-tebn	Kimmtrak	PA	MB	IV	
thyrotropin alfa	Thyrogen			IM	
vemurafenib	Zelboraf	PA		PO	
venetoclax	Venclexta	PA		PO	

	Clinical Notes

	the following: cyclosporine, tacrolimus.
	Please note, for requests for all other indications, drug may be subject to additional non-rebate restrictions. Please see MassHealth Pharmacy Operational document for additional information.
	Provenge
	• Documentation of the following is required:
	  • diagnosis of metastatic castration-resistant prostate cancer; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • ECOG score 0-1 (good performance status); **and**
	  • estimated life expectancy > six months; **and**
	  • no hepatic metastases; **and**
	  • no/minimal symptoms; **and**
	  • requested quantity is ≤ three doses (one completed cycle).
	Synribo
	• Documentation of the following is required:
	  • diagnosis of chronic myelogenous leukemia (CML); **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to two or contraindication to all of the following: Bosulif (bosutinib), dasatinib, Iclusig (ponatinib), imatinib, Tasigna (nilotinib capsule).
	Tazverik for FL
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ eight units/day; **and**
	  • member is ≥ 18 years of age; **and**
	  • one of the following:
	  • both of the following:
	  • member has FL with an EZH2 mutation (as detected by an FDA-approved test); **and**
	  • prior therapy for the treatment of FL with at least two systemic therapies; **or**
	  • both of the following:
	  • member has relapsed or refractory FL; **and**
	  • member has no satisfactory alternative treatment

	Clinical Notes

	options.
	Tazverik for metastatic or locally advanced epithelioid sarcoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ eight units/day; **and**
	  • member is ≥ 16 years of age.
	Venclexta for AML
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • member is not a candidate for intensive induction therapy; **or**
	  • member has poor-risk AML; **or**
	  • clinical rationale for use of requested agent instead of intensive induction chemotherapy; **and**
	  • requested agent will be used in combination with one of the following: azacitidine, decitabine, low-dose cytarabine.
	Venclexta for CLL or SLL
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • member has not received treatment for CLL or SLL and requested agent will be used in combination with Gazyva (obinutuzumab); **or**
	  • prior therapy with at least one systemic therapy.
	Venclexta for multiple myeloma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • member has t(11;14) mutation; **and**
	  • prior therapy with at least one prior chemotherapy regimen.
	Welireg for advanced renal cell carcinoma

	Clinical Notes

	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ three units/day; **and**
	  • inadequate response, adverse reaction, or contraindication to both of the following: a programmed death receptor-1 (PD-1) inhibitor or programmed death-ligand 1 (PD-L1) inhibitor, and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI).
	Welireg for von Hippel-Lindau (VHL) disease
	• Documentation of the following is required:
	  • diagnosis of VHL disease as confirmed by germline VHL alteration; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ three units/day; **and**
	  • member has renal cell carcinoma, central nervous system hemangioblastomas, or pancreatic neuroendocrine tumors; **and**
	  • member is not a candidate for or does not require immediate surgery.
	Xpovio
	• Documentation of the following is required for monotherapy:
	  • diagnosis of multiple myeloma; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • member has received at least four prior chemotherapy regimens or contraindication to the use of recommended chemotherapy regimens; **and**
	  • inadequate response or adverse reaction to two or contraindication to all of the following proteasome inhibitors: bortezomib, Kyprolis (carfilzomib), Ninlaro (ixazomib), Velcade (bortezomib); **and**
	  • inadequate response or adverse reaction to two or contraindication to all of the following immunomodulatory agents: lenalidomide, Pomalyst (pomalidomide), Thalomid (thalidomide); **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following anti-CD38 monoclonal antibodies: Darzalex (daratumumab), Darzalex Faspro (daratumumab-hyaluronidase-fihj),

	Clinical Notes
	Sarclisa (isatuximab-irfc); **and** • requested medication will be used in combination with dexamethasone. • Documentation of the following is required for combination therapy: • diagnosis of multiple myeloma; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one prior chemotherapy regimen for the requested indication; **and** • requested medication will be used in combination with Velcade (bortezomib) or bortezomib and dexamethasone. • Documentation of the following is required for diagnosis of diffuse large B-cell lymphoma (DLBCL): • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • member has received at least two prior chemotherapy regimens or contraindication to the use of recommended chemotherapy regimens. **Zelboraf for Erdheim-Chester Disease** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • requested quantity is ≤ eight units/day; **and** • positive BRAF V600 mutation. **Zelboraf for low-grade or high-grade gliomas** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • positive BRAF V600E mutation; **and** • appropriate dosing; **and** • requested agent will be used in combination with Cotellic (cobimetinib) ≤ 60 mg/day. **Zelboraf for unresectable or metastatic melanoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • requested quantity is ≤ eight units/day; **and** • positive BRAF V600E mutation.

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

alectinib	Alecensa	PA		PO	**Alecensa for metastatic non-small cell lung cancer (NSCLC)**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • cancer is anaplastic lymphoma kinase (ALK)-positive; **and**
					  • requested quantity is ≤ eight units/day.
					Alecensa for non-small cell lung cancer (NSCLC)
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • cancer is anaplastic lymphoma kinase (ALK)-positive (tumors ≥ 4 cm or node positive); **and**
					  • requested agent will be used as adjuvant treatment; **and**
					  • requested quantity is ≤ eight units/day.
					Alunbrig
					• Documentation of the following is required:
					  • diagnosis of metastatic NSCLC; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • cancer is ALK-positive; **and**
					  • one of the following:
					  • for 30 mg tablets, requested quantity is ≤ two units/day; **or**
					  • for 90 mg or 180 mg tablets, or the 90 mg-180 mg tablet pack, requested quantity is ≤ one unit/day.
					Augtyro for locally advanced or metastatic NSCLC
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • cancer is ROS1-positive; **and**
					  • one of the following:
					  • member has a resistance mutation G2032R; **or**
					  • inadequate response or adverse reaction to one or contraindication to both of the following: Rozlytrek (entrectinib), Xalkori (crizotinib); **and**
					  • one of the following:
					  • for the 40 mg capsule, requested quantity is ≤ eight units/day; **or**
					  • for the 160 mg capsule, requested quantity is ≤ two

asciminib	Scemblix	PA		PO	
avapritinib	Ayvakit	PA		PO	
axitinib	Inlyta	PA		PO	
bosutinib	Bosulif	PA		PO	
brigatinib	Alunbrig	PA		PO	
cabozantinib capsule	Cometriq	PA		PO	
cabozantinib tablet	Cabometyx	PA		PO	
ceritinib	Zykadia	PA		PO	
crizotinib	Xalkori	PA		PO	
dasatinib	Sprycel		BP, A90	PO	
erlotinib	Tarceva	PA	A90	PO	
gefitinib	Iressa	PA	A90	PO	
gilteritinib	Xospata	PA		PO	
imatinib	Gleevec		# , A90	PO	
lapatinib	Tykerb		BP, A90	PO	
lazertinib	Lazcluze	PA		PO	
lenvatinib	Lenvima	PA		PO	
midostaurin	Rydapt	PA		PO	
nilotinib capsule	Tasigna		BP	PO	
nilotinib tablet	Danziten	PA		PO	
pazopanib	Votrient	PA	BP, A90	PO	
pexidartinib	Turalio	PA		PO	
ponatinib	Iclusig	PA		PO	
quizartinib	Vanflyta	PA		PO	
repotrectinib	Augtyro	PA		PO	
revumenib	Revuforj	PA		PO	
sorafenib	Nexavar	PA	BP, A90	PO	
sunitinib	Sutent	PA	BP, A90	PO	
tivozanib	Fotivda	PA		PO	
tucatinib	Tukysa	PA		PO	
vandetanib	Caprelsa	PA		PO	

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	units/day.
	Augtyro for solid tumors with NTRK gene fusion
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • tumor is metastatic; **or**
	  • member is not a candidate for surgical resection; **and**
	  • one of the following:
	  • requested agent is first-line for the requested indication; **or**
	  • member has no satisfactory alternative treatment options; **or**
	  • disease has progressed following at least one first-line treatment for the requested indication (e.g., chemotherapy, radiation, surgical intervention); **and**
	  • one of the following:
	  • for the 40 mg capsule, requested quantity is ≤ eight units/day; **or**
	  • for the 160 mg capsule, requested quantity is ≤ two units/day.
	Ayvakit for unresectable or metastatic GIST
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member has disease harboring a PDGFRA exon 18 mutation (including PDGFRA D842V mutations); **and**
	  • requested quantity is ≤ one unit/day.
	Ayvakit for advanced systemic mastocytosis (AdvSM), systemic mastocytosis (SM) with associated hematological neoplasm, mast cell leukemia
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ one unit/day; **and**
	  • one of the following:
	  • D816V c-Kit mutation positive (as determined by an FDA-approved test); **or**
	  • both of the following:
	  • member has aggressive SM without the D816V c-

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	Kit mutation (as determined by an FDA-approved test) or with c-Kit mutation status unknown; **and** • inadequate response, adverse reaction, or contraindication to imatinib. **Ayvakit for indolent systemic mastocytosis (ISM)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is a specialist (e.g., hematologist, oncologist, allergist/immunologist) or consult notes from a specialist are provided; **and** • appropriate dosing; **and** • requested quantity is ≤ one unit/day; **and** • inadequate response, adverse reaction, or contraindication to both of the following: histamine$_1$ antihistamine, histamine$_2$ antihistamine; **and** • for symptoms involving the cardiovascular or pulmonary system, an inadequate response, adverse reaction or contraindication to Xolair; **and** • for symptoms involving the skin or gastrointestinal system, an inadequate response, adverse reaction or contraindication to a leukotriene inhibitor (montelukast, zafirlukast, zileuton). **Bosulif** • Documentation of the following is required: • diagnosis of CML; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • member has chronic phase Philadelphia chromosome-positive (Ph+) CML; **or** • inadequate response or adverse reaction to one prior therapy for CML or contraindication to all other therapies for CML. **Cabometyx for advanced renal cell carcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • both of the following: • member has clear cell histology; **and** • requested agent will be used in combination with Opdivo; **or** • all of the following:

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	• member has clear cell histology; **and** • member has received a previous treatment in the metastatic setting; **and** • requested agent will be used as monotherapy; **or** • member has non-clear cell histology; **and** • requested quantity is ≤ one unit/day. **Cabometyx for locally recurrent, advanced, and/or metastatic differentiated thyroid carcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one of the following, or contraindication to both of the following: Lenvima (lenvatinib), sorafenib; **and** • requested quantity is ≤ one unit/day; **and** • one of the following: • member is refractory to radioactive iodine; **or** • radioactive iodine treatment is not appropriate. **Cabometyx for unresectable HCC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: • atezolizumab + bevacizumab; **or** • Imfinzi (durvalumab); **or** • Lenvima (lenvatinib); **or** • sorafenib; **and** • requested quantity is ≤ one unit/day. **Caprelsa** • Documentation of the following is required: • diagnosis of symptomatic or progressive medullary thyroid cancer; **and** • one of the following: • for 100 mg tablets, requested quantity is ≤ two units/day; **or** • for 300 mg tablets, requested quantity is ≤ one unit/day; **or** • medical necessity for exceeding quantity limit of two units/day for 100 mg tablets or one unit/day for 300 mg tablets. **Cometriq**

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	• Documentation of the following is required:
	  • diagnosis of symptomatic or progressive medullary thyroid cancer; **and**
	  • one of the following:
	  • requested dose is ≤ 140 mg/day; **or**
	  • medical necessity for exceeding the 140 mg/day dose.
	Danziten
	• Documentation of the following is required:
	  • diagnosis of Ph+ CML; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • member is ≥ 18 years of age; **and**
	  • appropriate dosing; **and**
	  • medical necessity for use of the requested agent instead of Tasigna (nilotinib capsule); **and**
	  • one of the following:
	  • member has chronic phase Ph+ CML; **or**
	  • member has accelerated phase Ph+ CML and inadequate response or adverse reaction to one prior therapy for CML that included imatinib.
	erlotinib for advanced or metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations; **and**
	  • requested quantity is ≤ one unit/day.
	erlotinib for advanced or metastatic pancreatic cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member will be using the requested agent in combination with gemcitabine; **and**
	  • requested quantity is ≤ one unit/day.
	Fotivda
	• Documentation of the following is required:
	  • diagnosis of advanced renal cell carcinoma; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • tumor is clear cell histology; **and**
	  • inadequate response or adverse reaction to two or

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	contraindication to all systemic therapies; **and** • requested quantity is ≤ one unit/day. **gefitinib** • Documentation of the following is required: • diagnosis of metastatic NSCLC; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has EGFR mutations; **and** • requested quantity is ≤ one unit/day. **Iclusig for Ph+ ALL** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • inadequate response or adverse reaction to one or contraindication to all of the following: dasatinib, imatinib, Tasigna (nilotinib capsule); **or** • confirmed T315I mutation; **or** • requested agent will be given in combination with chemotherapy. **Iclusig for CML** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • inadequate response or adverse reaction to two or contraindication to all of the following: Bosulif (bosutinib), dasatinib, imatinib, Tasigna (nilotinib capsule); **or** • confirmed T315I mutation. **Inlyta** • Documentation of the following is required: • diagnosis of advanced renal cell carcinoma; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • both of the following: • tumor is clear cell histology; **and** • requested agent will be used in combination with Bavencio (avelumab) or Keytruda (pembrolizumab); **or** • both of the following:

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	• requested agent will be used as monotherapy; **and** • member has failed one prior line of systemic therapy. **Lazcluze** • Documentation of the following is required: • diagnosis of locally advanced or metastatic NSCLC with an EGFR exon 19 deletion or exon 21 L858R mutation; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with Rybrevant (amivantamab-vmjw); **and** • inadequate response, adverse reaction, or contraindication to Tagrisso (osimertinib) with or without chemotherapy; **and** • one of the following: • for 80 mg tablet, requested quantity is ≤ two units/day; **or** • for 240 mg tablet, requested quantity is ≤ one unit/day. **Lenvima for advanced renal cell carcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • all of the following: • tumor is clear cell histology; **and** • requested agent will be used in combination with everolimus; **and** • member has failed one first-line therapy for advanced renal cell carcinoma; **or** • both of the following: • tumor is clear cell histology; **and** • requested agent will be used in combination with Keytruda (pembrolizumab); **or** • tumor is non-clear cell histology and agent will be used in combination with Keytruda (pembrolizumab) or everolimus. **Lenvima for differentiated thyroid cancer (DTC)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing.

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	Lenvima for endometrial carcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one prior line of systemic therapy or contraindication to systemic therapy; **and**
	  • requested agent will be used in combination with Keytruda (pembrolizumab).
	Lenvima for unresectable hepatocellular carcinoma (HCC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing.
	pazopanib for advanced renal cell carcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ four units/day.
	pazopanib for soft tissue sarcoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to prior chemotherapy; **and**
	  • requested quantity is ≤ four units/day.
	pazopanib for GIST
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • inadequate response, adverse reaction, or contraindication to all of the following: imatinib, Qinlock (ripretinib), sunitinib, Stivarga (regorafenib); **and**
	  • requested quantity is ≤ four units/day.
	Revuforj for AML/ALL
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ one year of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • cancer has a lysine methyltransferase 2A (KMT2A)

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	gene translocation; **and**
	• member has relapsed or refractory disease; **and**
	• all of the following:
	  • for Revuforj 25 mg, requested quantity is ≤ eight units/day; **and**
	  • for Revuforj 110 mg, requested quantity is ≤ four units/day; **and**
	  • for Revuforj 160 mg, requested quantity is ≤ two units/day.
	Rydapt for FLT3-mutated acute myeloid leukemia (AML)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • for induction therapy, requested agent will be used in combination with cytarabine and daunorubicin; **or**
	  • for consolidation therapy, requested agent will be used in combination with cytarabine; **or**
	  • for maintenance therapy, requested agent will be used as monotherapy.
	Rydapt for aggressive systemic mastocytosis (SM), SM with associated hematological neoplasm, and mast cell leukemia
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • both of the following:
	  • member has aggressive SM without the D816V c-Kit mutation (as determined by an FDA-approved test) or with c-Kit mutation status unknown; **and**
	  • inadequate response, adverse reaction, or contraindication to imatinib; **or**
	  • D816V c-Kit mutation positive (as determined by an FDA-approved test).
	Scemblix
	• Documentation of the following is required:
	  • diagnosis of CML; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:

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	• confirmed T315I mutation; **or** • inadequate response or adverse reaction to two or contraindication to all of the following: Bosulif (bosutinib), dasatinib, Iclusig (ponatinib), imatinib, Tasigna (nilotinib capsule). **sorafenib for advanced renal cell carcinoma, DTC, or unresectable HCC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested quantity is ≤ four units/day. **sorafenib for FLT3-ITD mutated AML** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • member has relapsed/refractory disease; **and** • requested agent will be used in combination with a hypomethylating agent (5-azacytidine or decitabine); **and** • requested quantity is ≤ four units/day. **sunitinib for advanced renal cell carcinoma and advanced pancreatic neuroendocrine tumors (PNET)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested quantity is ≤ one unit/day. **sunitinib for GIST** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to imatinib; **and** • requested quantity is ≤ one unit/day. **sunitinib for renal cell carcinoma (adjuvant setting)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • tumor is clear cell histology; **and** • requested quantity is ≤ one unit/day.

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	Tukysa for advanced unresectable or metastatic HER2-positive breast cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with trastuzumab and capecitabine; **and**
	  • inadequate response or adverse reaction to one anti-HER2-based regimen; **and**
	  • requested quantity is ≤ four units/day.
	Tukysa for RAS wild-type (WT), HER2-positive unresectable or metastatic colorectal cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with trastuzumab; **and**
	  • inadequate response or adverse reaction to at least one or contraindication to all of the following regimens: CAPEOX, FOLFOX, FOLFIRI, FOLFOXIRI, FOLFIRINOX, irinotecan-based therapy, oxaliplatin-based therapy; **and**
	  • requested quantity is ≤ four units/day.
	Turalio
	• Documentation of the following is required:
	  • diagnosis of tenosynovial giant cell tumor; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or consult notes from an oncologist are provided; **and**
	  • appropriate dosing; **and**
	  • member is not a candidate for surgery.
	Vanflyta for FLT3-ITD mutated AML
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ two units/day; **and**
	  • one of the following:
	  • for relapsed or refractory disease, requested agent will be used as monotherapy; **or**
	  • for induction therapy, clinical rationale for use of

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	requested agent instead of Rydapt and requested agent will be used in combination with cytarabine and daunorubicin or idarubicin; **or** • for consolidation therapy, clinical rationale for use of requested agent instead of Rydapt and requested agent will be used in combination with cytarabine; **or** • for maintenance therapy, requested agent will be used as monotherapy. **Xalkori for systemic anaplastic large cell lymphoma (ALCL)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer is ALK-positive; **and** • one of the following: • member has relapsed or refractory disease to one prior agent or regimen; **or** • clinical rationale as to why the other available treatment regimens cannot be used; **and** • for Xalkori (crizotinib) oral pellets, medical necessity for the use of the oral pellet formulation instead of the capsule as noted by one of the following: • member is < 13 years of age; **or** • member has a swallowing disorder or condition affecting ability to swallow; **or** • requested dose cannot be obtained from capsule formulation. **Xalkori for unresectable, recurrent, or refractory inflammatory myofibroblastic tumors (IMT)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • member is ≥ one year of age; **and** • appropriate dosing; **and** • cancer is ALK-positive; **and** • for Xalkori (crizotinib) oral pellets, medical necessity for the use of the oral pellet formulation instead of the capsule as noted by one of the following: • member is < 13 years of age; **or** • member has a swallowing disorder or condition affecting ability to swallow; **or** • requested dose cannot be obtained from capsule

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	formulation.
	Xalkori for ALK-positive or ROS1 positive metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer is ALK-positive or ROS1 positive; **and**
	  • for Xalkori (crizotinib) oral pellets, medical necessity for the use of the oral pellet formulation instead of the capsule as noted by one of the following:
	  • member is < 13 years of age; **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • requested dose cannot be obtained from capsule formulation.
	Xalkori for MET positive amplification metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer is MET positive amplification; **and**
	  • for Xalkori (crizotinib) oral pellets, medical necessity for the use of the oral pellet formulation instead of the capsule as noted by one of the following:
	  • member is < 13 years of age; **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • requested dose cannot be obtained from capsule formulation.
	Xospata
	• Documentation of the following is required:
	  • diagnosis of relapsed or refractory FLT3-mutated AML; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ three units/day.
	Zykadia for ALK-positive metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer is ALK-positive; **and**

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	• requested quantity is ≤ three units/day.
	Zykadia for ROS1-rearrangement metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • cancer is ROS1-rearrangement; **and**
	  • requested quantity is ≤ three units/day.

Oncology Agents – Antimetabolites

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

allopurinol sodium	Aloprim		#	IV	**Axtle, Pemfexy, and Pemrydi RTU**
					• Documentation of the following is required:
					  • diagnosis of malignant pleural mesothelioma or NSCLC; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • inadequate response, adverse reaction, or contraindication to a pemetrexed product available without PA.
					Infugem
					• Documentation of the following is required:
					  • diagnosis of breast cancer, non-small cell lung cancer, ovarian cancer or pancreatic cancer; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • member is ≥ 18 years of age; **and**
					  • appropriate dosing; **and**
					  • inadequate response, adverse reaction, or contraindication to a gemcitabine product available without PA.
					mercaptopurine oral suspension
					• Documentation of the following is required:
					  • diagnosis of acute lymphoblastic leukemia (ALL); **and**
					  • one of the following:
					  • member is < 13 years of age; **or**
					  • medical necessity for the use of an oral suspension formulation (e.g. swallowing disorder).
					SmartPA: Claims for mercaptopurine oral suspension will usually process at the pharmacy without a PA request if the member has a MassHealth history of medical claims for ALL and the member is < 13 years of age. †

capecitabine	Xeloda		# , A90	PO	
cladribine injection			MB	IV	
clofarabine	Clolar		MB	IV	
cytarabine			MB	IV	
floxuridine			MB	Intra-arterial	
fludarabine				IV	
fluorouracil injection			MB	IV	
gemcitabine premixed infusion	Infugem	PA	MB	IV	
gemcitabine vial			MB	IV	
hydroxyurea capsule	Hydrea		# , A90	PO	
mercaptopurine oral suspension	Purixan	PA	A90	PO	
mercaptopurine tablet			A90	PO	
methotrexate injection				IM / IV / Intra-arterial	
methotrexate tablet			A90	PO	
nelarabine	Arranon	PA	MB	IV	
pemetrexed			MB	IV	
pemetrexed dipotassium	Axtle	PA	MB	IV	
pemetrexed disodium-Alimta	Alimta		MB	IV	
pemetrexed disodium-Pemrydi RTU	Pemrydi RTU	PA	MB	IV	
pemetrexed-Pemfexy	Pemfexy	PA	MB	IV	
pentostatin	Nipent		MB	IV	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

pralatrexate	Folotyn		MB	IV	**nelarabine**
					• Documentation of the following is required:
					  • diagnosis of T-cell acute lymphoblastic leukemia (T-ALL) or T-cell lymphoblastic lymphoma (T-LBL); **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing.

Oncology Agents – Alkylating Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

bendamustine	Belrapzo		MB	IV	**Gleostine for Brain Tumor**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • member has received surgical and/or radiotherapeutic procedures, as appropriate.
					Hepzato for uveal melanoma with unresectable hepatic metastases
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • member is ≥ 18 years of age
					  • prescriber is an oncologist or consult notes from oncologist are provided; **and**
					  • appropriate dosing; **and**
					  • member has liver metastases that affect < 50% of the liver; and
					  • one of the following:
					  • member does not have any extra hepatic disease; or
					  • extra hepatic disease is limited to the bone, lymph nodes, subcutaneous tissue, or lung and is amenable to resection or radiation; and
					  • requested duration is ≤ six doses.
					Leukeran for Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • member is ≥ 18 years of age; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • prior therapy with at least two systemic therapies.
					Leukeran for Follicular Lymphoma (FL) or Marginal Zone Lymphoma (MZL)

bendamustine	Bendeka		MB	IV	
bendamustine	Treanda		MB	IV	
bendamustine	Vivimusta		MB	IV	
busulfan injection	Busulfex		MB	IV	
busulfan tablet	Myleran			PO	
carboplatin			MB	IV	
carmustine	Bicnu		MB	IV/ Implantation	
chlorambucil	Leukeran	PA		PO	
cisplatin			MB	IV	
cyclophosphamide capsule, tablet			A90	PO	
cyclophosphamide injection			MB	IV	
dacarbazine			MB	IV	
estramustine	Emcyt			PO	
ifosfamide	Ifex		MB	IV	
lomustine	Gleostine	PA		PO	
lurbinectedin	Zepzelca	PA	MB	IV	
mechlorethamine gel	Valchlor			Topical	
melphalan hepatic delivery system	Hepzato	PA	MB	IV	
melphalan hydrochloride injection	Alkeran		MB	IV	
melphalan injection	Evomela		MB	IV	
melphalan tablet	Alkeran		# , A90	PO	
oxaliplatin			MB	IV	
procarbazine	Matulane			PO	
temozolomide	Temodar		# , A90	IV / PO	

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	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to rituximab monotherapy.
	Zepzelca
	• Documentation of the following is required:
	  • diagnosis of metastatic small cell lung cancer (SCLC); **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to platinum-based chemotherapy.

Oncology Agents – Anti-VEGF

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

bevacizumab	Avastin	PA	MB	IV	**Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for cervical cancer**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with one of the following:
					  • paclitaxel and carboplatin;**or**
					  • paclitaxel and cisplatin; **or**
					  • paclitaxel and topotecan.
					Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for recurrent glioblastoma
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing.
					Avastin for hepatocellular carcinoma
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with

bevacizumab-adcd	Vegzelma	PA	MB	IV	
bevacizumab-awwb	Mvasi	PA	MB	IV	
bevacizumab-bvzr	Zirabev	PA	MB	IV	
bevacizumab-maly	Alymsys	PA	MB	IV	
ramucirumab	Cyramza	PA	MB	IV	
ziv-aflibercept	Zaltrap	PA	MB	IV	

	Clinical Notes

	Tecentriq (atezolizumab).
	Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for metastatic colorectal cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with fluoropyrimidine-, capecitabine-, oxaliplatin-, or irinotecan-containing therapy.
	Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for metastatic renal cell carcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • if predominant clear cell histology, requested agent will be used in combination with interferon alfa.
	Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for non-squamous non-small cell lung cancer (NSCLC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with both of the following: carboplatin, paclitaxel.
	Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for non-squamous NSCLC with EGFR Mutation Positive
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • requested agent will be used in combination with erlotinib.
	Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for adenocarcinoma, large cell, NSCLC not otherwise specified (NOS) with PD-L1 Expression Positive
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • requested agent will be used in combination with all of the following: carboplatin, paclitaxel, atezolizumab.
	Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for initial

	Clinical Notes

	therapy of advanced or metastatic adenocarcinoma, large cell, NSCLC NOS (performance status [PS] 0-2)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • member has a contraindication to to PD-1 or PD-L1 inhibitors; **and**
	  • requested agent will be used in combination with one of the following:
	  • carboplatin and pemetrexed; **or**
	  • cisplatin and pemetrexed.
	Alymsys, Avastin, Mvasi, and Zirabev for maintenance therapy of advanced or metastatic adenocarcinoma, large cell, NSCLC NOS (PS 0-2)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • one of the following:
	  • requested agent will be used as monotherapy; **or**
	  • requested agent will be used in combination with one of the following: atezolizumab or pemetrexed.
	Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for ovarian, fallopian, or primary peritoneal cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing.
	Avastin for wet age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, or myopic choroidal neovascularization
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • requested dosing is 1.25 mg intravitreally every four or eight weeks or as needed.
	Cyramza for gastric or gastro-esophageal junction (GEJ) adenocarcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one or

	Clinical Notes

	contraindication to both of the following: a fluoropyrimidine-containing chemotherapy regimen, a platinum-containing chemotherapy regimen.
	Cyramza for HCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member has alpha fetoprotein (AFP) ≥ 400 ng/mL; **and**
	  • inadequate response, adverse reaction, or contraindication to sorafenib.
	Cyramza for metastatic colorectal cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with one of the following: FOLFIRI or irinotecan; **and**
	  • inadequate response or adverse reaction to one or contraindication to both of the following: 5-fluorouracil/leucovorin, a capecitabine-based regimen.
	Cyramza for NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • both of the following:
	  • requested agent will be used in combination with docetaxel; **and**
	  • inadequate response, adverse reaction, or contraindication to a platinum-containing chemotherapy regimen; **or**
	  • all of the following:
	  • requested agent will be used in combination with erlotinib; **and**
	  • cancer displays the EGFR exon 19 deletion or exon 21 L858R mutation; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: Gilotrif (afatinib), gefitinib, Tagrisso (osimertinib), Vizimpro (dacomitinib).
	Zaltrap
	• Documentation of the following is required:

	Clinical Notes
	• diagnosis of metastatic colorectal cancer; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with either irinotecan or FOLFIRI; **and** • inadequate response or adverse reaction to one of the following regimens or a contraindication to all of the following regimens: a fluoropyrimidine (capecitabine or fluorouracil), CAPEOX, FOLFOX, oxaliplatin-based therapy; **and** • inadequate response, adverse reaction, or contraindication to a bevacizumab product.

Oncology Agents – Aromatase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
anastrozole	Arimidex		# , A90	PO	
exemestane	Aromasin		# , A90	PO	
letrozole	Femara		# , A90	PO	

Oncology Agents – Monoclonal Antibodies

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
alemtuzumab 30 mg	Campath			IV	**Arzerra for relapsed or refractory CLL** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to two or contraindication to all systemic therapies; **and** • one of the following: • requested agent will be used in combination with fludarabine and cyclophosphamide; **or** • requested agent will be used for extended treatment of patients who are in complete or partial response after at least two systemic therapies; **or** • requested agent will be used to treat disease that is refractory to treatment with both of the following: alemtuzumab, fludarabine. **Arzerra for untreated CLL** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and**
blinatumomab	Blincyto	PA	MB	IV	
cetuximab	Erbitux		MB	IV	
daratumumab	Darzalex	PA	MB	IV	
daratumumab / hyaluronidase-fihj	Darzalex Faspro	PA	MB	SC	
elotuzumab	Empliciti	PA	MB	IV	
isatuximab-irfc	Sarclisa	PA	MB	IV	
loncastuximab tesirine-lpyl	Zynlonta	PA		IV	
margetuximab-cmkb	Margenza	PA	MB	IV	
mogamulizumab-kpkc	Poteligeo	PA	MB	IV	
naxitamab-gqgk	Danyelza	PA	MB	IV	
necitumumab	Portrazza	PA	MB	IV	
obinutuzumab	Gazyva	PA	MB	IV	
ofatumumab vial	Arzerra	PA	MB	IV	
panitumumab	Vectibix		MB	IV	
pertuzumab	Perjeta	PA	MB	IV	
rituximab	Rituxan	PA	MB	IV	
rituximab / hyaluronidase	Rituxan Hycela	PA	MB	SC	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
human					
rituximab-abbs	Truxima	PA	MB	IV	
rituximab-arrx	Riabni	PA	MB	IV	
rituximab-pvvr	Ruxience	PA	MB	IV	
tafasitamab-cxix	Monjuvi	PA		IV	
trastuzumab	Herceptin	PA	MB	IV	
trastuzumab / hyaluronidase-oysk	Herceptin Hylecta	PA	MB	SC	
trastuzumab-anns	Kanjinti	PA	MB	IV	
trastuzumab-dkst	Ogivri	PA	MB	IV	
trastuzumab-dttb	Ontruzant	PA	MB	IV	
trastuzumab-pkrb	Herzuma	PA	MB	IV	
trastuzumab-qyyp	Trazimera	PA	MB	IV	
trastuzumab-strf	Hercessi	PA	MB	IV	
zanidatamab-hrii	Ziihera	PA	MB	IV	

zenocutuzumab-zbco	Bizengri	PA	MB	IV	• prescriber is an oncologist or hematologist; **and**
					• appropriate dosing; **and**
					• inadequate response or adverse reaction to two or contraindication to all systemic therapies; **and**
					• contraindication to fludarabine; **and**
					• one of the following:
					  • requested agent will be used in combination with chlorambucil; **or**
					  • clinical rationale as to why the agent will not be used with chlorambucil.
					Bizengri
					• Documentation of the following is required:
					  • diagnosis of one of the following:
					  • advanced unresectable or metastatic NSCLC; **or**
					  • advanced unresectable or metastatic pancreatic adenocarcinoma; **and**
					  • member is ≥ 18 years of age; **and**
					  • prescriber is an oncologist; **and**
					  • member has NRG1 fusion-positive disease; **and**
					  • inadequate response or adverse reaction to one or contraindication to all systemic therapies for requested indication; **and**
					  • appropriate dosing.
					Blincyto
					• Documentation of the following is required:
					  • diagnosis of ALL; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • one of the following:
					  • member with complete remission following initial treatment; **or**
					  • both of the following:
					  • Philadelphia chromosome-positive; **and**
					  • inadequate response or adverse reaction to one tyrosine kinase inhibitor for the treatment of ALL; **or**
					  • all of the following:
					  • Philadelphia chromosome-negative; **and**
					  • B-cell precursor ALL; **and**
					  • prior therapy for the treatment of ALL with one systemic therapy.
					Danyelza
					• Documentation of the following is required:
					  • diagnosis of high-risk neuroblastoma of bone or bone

	Clinical Notes
	marrow; **and** • member is ≥ one year of age; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member had had partial response, minor response, or stable disease to prior treatment; **and** • requested agent will be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF) agent. **Darzalex and Darzalex Faspro for multiple myeloma** • Documenation of the following is required for monotherapy: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all of the following proteasome inhibitors: bortezomib, Kyprolis (carfilzomib), Ninlaro (ixazomib), Velcade (bortezomib); **and** • inadequate response or adverse reaction to one or contraindication to all of the following immunomodulatory agents: lenalidomide, Pomalyst (pomalidomide), Thalomid (thalidomide); **and** • one of the following: • inadequate response or adverse reaction to one proteasome inhibitor and one immunomodulatory agent noted above; **or** • history of a total of three trials with chemotherapy regimens for the requested indication. • Documentation of the following is required for combination therapy: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • both of the following: • member is newly diagnosed and eligible for transplant; **and** • requested agent will be used in combination with Velcade (bortezomib) or bortezomib and thalidomide and dexamethasone; **or** • both of the following; • inadequate response or adverse reaction to at least one prior line of systemic therapy; **and** • requested agent will be used in combination with

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	dexamethasone and at least one other agent for treatment of multiple myeloma (excluding anti-CD38 agents); **or** • all of the following: • member is newly diagnosed and ineligible for transplant; **and** • one of the following: • requested agent will be used in combination with lenalidomide and dexamethasone; **or** • requested agent will be used in combination with Velcade (bortezomib) or bortezomib and melphalan and prednisone; **or** • clinical rationale for the use of the requested combination instead of Velcade (bortezomib) or bortezomib and lenalidomide and dexamethasone. **Darzalex Faspro for light chain amyloidosis** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • concurrent therapy with Velcade (bortezomib) or bortezomib and cyclophosphamide and dexamethasone. **Empliciti** • Documentation of the following is required: • diagnosis of multiple myeloma; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • both of the following: • inadequate response or adverse reaction to at least one prior chemotherapy regimen for the requested indication; **and** • requested agent will be used in combination with lenalidomide and dexamethasone; **or** • all of the following: • inadequate response or adverse reaction to at least two prior chemotherapy regimens for the requested indication; **and** • inadequate response or adverse reaction to one or contraindication to all of the following proteasome inhibitors: bortezomib, Kyprolis (carfilzomib), Ninlaro (ixazomib), Velcade

	Clinical Notes
	(bortezomib); **and** • inadequate response, adverse reaction, or contraindication to lenalidomide; **and** • requested medication will be used in combination with Pomalyst (pomalidomide) and dexamethasone. **Gazyva for CLL or SLL** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • member has CLL or SLL without del(17p)/TP53 mutation; **or** • member has CLL or SLL with del(17p)/TP53 mutation AND is treatment naive. **Gazyva for FL** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • relapsed or refractory FL after treatment with a rituximab-containing regimen; **or** • concurrent therapy with first-line chemotherapy agent. **Herceptin, Herceptin Hylecta, Hercessi, Herzuma, Kanjinti, Ogivri, Ontruzant, and Trazimera for HER2-overexpressing breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing. **Herceptin, Hercessi, Herzuma, Kanjinti, Ogivri, Ontruzant, and Trazimera for RAS wild-type (WT), HER2-positive unresectable or metastatic colorectal cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or

	Clinical Notes
	contraindication to all of the following regimens: CAPEOX, FOLFOX, FOLFIRI, FOLFOXIRI, FOLFIRINOX, irinotecan-based therapy, oxaliplatin-based therapy; **and** • requested agent will be used in combination with Tukysa. **Herceptin, Hercessi, Herzuma, Kanjinti, Ogivri, Ontruzant, and Trazimera for HER2-overexpessing metastatic gastric or gastroesophageal adenocarcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with chemotherapy. **Margenza** • Documentation of the following is required: • diagnosis of metastatic HER-2 positive breast cancer; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with chemotherapy (capecitabine, eribulin, gemcitabine, or vinorelbine); **and** • inadequate response or adverse reaction to two anti-HER-2 based regimens. **Monjuvi for diffuse large B cell lymphoma (DLBCL)** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all systemic therapies. **Perjeta** • Documentation of the following is required: • diagnosis of HER-2 positive breast cancer; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • for recurrent or stage IV disease, requested agent will be used in combination with Herceptin (trastuzumab) and docetaxel or paclitaxel; **or** • for adjuvant or neoadjuvant chemotherapy,

	Clinical Notes

	requested agent will be used in combination with trastuzumab and chemotherapy.
	Portrazza
	• Documentation of the following is required:
	  • diagnosis of advanced or metastatic NSCLC; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer of squamous cell histology; **and**
	  • requested agent will be used in combination with gemcitabine and cisplatin; **and**
	  • medical necessity for use of the requested agent instead of all other clinically appropriate alternatives.
	Poteligeo for mycosis fungoides
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • Stage IA disease and member is refractory to skin-directed therapy; **or**
	  • Stage IB to III disease.
	Poteligeo for Sézary syndrome
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing.
	Riabni, Rituxan, Ruxience, and Truxima
	• Documentation of the following is required for autoimmune encephalitis:
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: intravenous glucocorticoids, intravenous immune globulin, plasma exchange; **and**
	  • inadequate response, adverse reaction, or contraindication to cyclophosphamide.
	• Documentation of the following is required for autoimmune epilepsy:
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: intravenous glucocorticoids, intravenous immune globulin, plasma exchange; **and**
	  • inadequate response or adverse reaction to one or

	Clinical Notes

	contraindication to all of the following: azathioprine, cyclophosphamide, mycophenolate.
	• Documentation of the following is required for autoimmune hemolytic anemia (AIHA) or IgG-related disease:
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to one or contraindication to all corticosteroids.
	• Documentation of the following is required for CLL:
	  • appropriate diagnosis; **and**
	  • appropriate dosing.
	• Documentation of the following is required for moderate-to-severe cryoglobulinemia syndrome:
	  • appropriate diagnosis; **and**
	  • requested agent will be used in combination with systemic glucocorticoids.
	• Documentation of the following is required for graft versus host disease (GVHD):
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to one or contraindication to all corticosteroids; **and**
	  • inadequate response or adverse reaction to two or contraindication to all of the following: abatacept, alemtuzumab, belumosudil, cyclosporine, etanercept, everolimus, hydroxychloroquine, ibrutinib, imatinib, methotrexate, mycophenolate mofetil, ruxolitinib, sirolimus, tacrolimus, temsirolimus.
	• Documentation of the following is required for granulomatosis with polyangitis (GPA) or microscopic polyangitis (MPA):
	  • For induction (initial) therapy, documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to cyclophosphamide; **and**
	  • one of the following:
	  • requested agent will be used in combination with a glucocorticoid; **or**
	  • adverse reaction or contraindication to glucocorticoids.
	• Documentation of the following is required for idiopathic membranous nephropathy (IMN):
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to one or

	Clinical Notes
	contraindication to both of the following: chlorambucil, cyclophosphamide; **and** • inadequate response or adverse reaction to one or contraindication to both of the following: cyclosporine, tacrolimus. • Documentation of the following is required for idiopathic thrombocytopenia purpura (ITP): • appropriate diagnosis; **and** • inadequate response or adverse reaction to one or contraindication to all corticosteroids. • Documentation of the following is required for lupus nephritis (LN): • appropriate diagnosis; **and** • inadequate response, adverse reaction, or contraindication to both of the following: cyclophosphamide, mycophenolate. • Documentation of the following is required for minimal change disease: • appropriate diagnosis; **and** • inadequate response, adverse reaction, or contraindication to both of the following: cyclophosphamide, cyclosporine. • Documentation of the following is required for multiple sclerosis: • appropriate diagnosis; **and** • prescriber is a neurologist or consult notes from a neurologist are provided. • Documentation of the following is required for generalized myasthenia gravis (MG): • appropriate diagnosis; **and** • inadequate response, adverse reaction, or contraindication to pyridostigmine; **and** • inadequate response or adverse reaction to one or contraindication to all corticosteroids; **and** • one of the following: • member has muscle-specific tyrosine kinase (MuSK)-positive MG; **or** • inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, cyclophosphamide, cyclosporine, eculizumab, efgartigimod, intravenous immune globulin, mycophenolate, ravulizumab, tacrolimus. • Documentation of the following is required for neuromyelitis optica spectrum disorder (NMOSD) maintenance therapy:

	Clinical Notes
	• appropriate diagnosis; **and** • inadequate response or adverse reaction to one or contraindication to both of the following: azathioprine, mycophenolate. • Documentation of the following is required for non-Hodgkin lymphoma (NHL): • appropriate diagnosis; **and** • appropriate dosing. • Documentation of the following is required for pemphigus foliaceus (PF): • appropriate diagnosis; **and** • one of the following: • requested agent will be used in combination with systemic glucocorticoids; **or** • inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids; **and** • appropriate dosing. • Documentation of the following is required for Polymyositis (PM) or Dermatomyositis (DM): • appropriate diagnosis; **and** • inadequate response or adverse reaction to one or contraindication to all corticosteroids; **and** • inadequate response or adverse reaction to two or contraindication to all of the following: azathioprine, cyclophosphamide, cyclosporine, methotrexate. • Documentation of the following is required for Post-Transplantation Lymphoproliferative Disease (PTLD) or Waldenström's macroglobulinemia: • appropriate diagnosis. • Documentation of the following is required for rheumatoid arthritis (RA): • appropriate diagnosis; **and** • appropriate dosing; **and** • inadequate response, adverse reaction to one or contraindication to all of the following: Cimzia, Enbrel, Humira, infliximab, Simponi Aria, Simponi; **and** • one of the following: • requested agent will be used in combination with methotrexate; **or** • adverse reaction or contraindication to methotrexate. • Documentation of the following is required for Systemic Lupus Erythematosus (SLE): • appropriate diagnosis; **and** • inadequate response or adverse reaction to two or

	Clinical Notes

	contraindication to all of the following: azathioprine, cyclophosphamide, cyclosporine, leflunomide, methotrexate, mycophenolate.
	• Documentation of the following is required for Thrombotic Thrombocytopenia Purpura (TTP):
	  • appropriate diagnosis; **and**
	  • one of the following:
	  • member underwent plasma exchange; **or**
	  • clinical rationale as to why plasma exchange was not performed; **and**
	  • inadequate response or adverse reaction to one or contraindication to all corticosteroids.
	Rituxan for pediatric members with mature B-cell NHL or mature B-cell acute leukemia (B-AL)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • appropriate dosing; **and**
	  • member is ≥ six months and < 18 years of age.
	Rituxan for Pemphigus Vulgaris (PV)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • requested agent will be used in combination with systemic glucocorticoids; **or**
	  • inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids.
	Rituxan Hycela for CLL, diffuse large B-cell lymphoma, or FL
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • appropriate dosing.
	Sarclisa
	• Documentation of the following is required:
	  • diagnosis of multiple myeloma; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • both of the following:
	  • inadequate response or adverse reaction to one chemotherapy regimen for the requested indication; **and**
	  • requested agent will be used in combination with Kyprolis (carfilzomib) and dexamethasone; **or**

	Clinical Notes

	• all of the following:
	  • inadequate response, adverse reaction, or contraindication to lenalidomide; **and**
	  • history of a total of at least two trials with appropriate regimens for the requested indication; **and**
	  • requested agent will be used in combination with Pomalyst (pomalidomide) and dexamethasone; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following proteasome inhibitors**:** bortezomib, Kyprolis (carfilzomib), Ninlaro (ixazomib), Velcade (bortezomib).
	Ziihera
	• Documentation of the following is required:
	  • diagnosis of unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC); **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist; **and**
	  • member's current weight; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one prior gemcitabine-containing regimen for BTC.
	Zynlonta
	• Documentation of the following is required:
	  • diagnosis of relapsed or refractory large B cell lymphoma; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • prior therapy with at least two or contraindication to all recommended chemotherapy regimens.

Oncology Agents – Asparaginase

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

asparaginase erwinia chrysanthemi	Erwinase	PA	MB	IV	**Asparlas**
					• Documentation of the following is required:
					  • diagnosis of ALL; **and**
					  • member is ≥ one month and < 22 years of age; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • inadequate response, adverse reaction, or

asparaginase erwinia chrysanthemi-rywn	Rylaze	PA	MB	IM	
calaspargase pegol-mknl	Asparlas	PA	MB	IV	
pegaspargase	Oncaspar		MB	IM or IV	

	Clinical Notes
	contraindication to Oncaspar (pegaspargase); **or** • clinical rationale for use instead of Oncaspar (pegaspargase). • For recertification requests that exceed a total treatment duration of 36 weeks, documentation of clinical evidence supporting such an extended duration is required. **Erwinase, Rylaze** • Documentation of the following is required: • diagnosis of ALL; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • hypersensitivity to *E. coli*-derived asparaginase. • For recertification requests that exceed a total treatment duration of 36 weeks, documentation of clinical evidence supporting such an extended duration is required.

Oncology Agents – Kinase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
abemaciclib	Verzenio	PA		PO	**Balversa** • Documentation of the following is required: • diagnosis of FGFR3-mutated locally advanced or metastatic urothelial carcinoma; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to at least one prior systemic therapy for requested indication, or contraindication to the use of all systemic therapy; **and** • inadequate response or adverse reaction to one prior PD-1 or PD-L1 inhibitor therapy, or contraindication to the use of all PD-1 or PD-L1 inhibitors. **Braftovi for mCRC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • requested quantity is ≤ four units/day; **and** • positive BRAF V600E mutation; **and** • requested agent will be used in combination with Erbitux (cetuximab) or Vectibix (panitumumab); **and** • inadequate response or adverse reaction to one or a contraindication to all of the following regimens: CAPEOX, FOLFOX, irinotecan-based therapy, oxaliplatin-based therapy.
afatinib	Gilotrif	PA		PO	
alpelisib-Piqray	Piqray	PA		PO	
belumosudil	Rezurock	PA		PO	
binimetinib	Mektovi	PA		PO	
capivasertib	Truqap	PA		PO	
capmatinib	Tabrecta	PA		PO	
cobimetinib	Cotellic	PA		PO	
dabrafenib	Tafinlar	PA		PO	
dacomitinib	Vizimpro	PA		PO	
duvelisib	Copiktra	PA		PO	
encorafenib	Braftovi	PA		PO	
erdafitinib	Balversa	PA		PO	
fedratinib	Inrebic	PA		PO	
fruquintinib	Fruzaqla	PA		PO	
futibatinib	Lytgobi	PA		PO	
idelalisib	Zydelig	PA		PO	
inavolisib	Itovebi	PA		PO	
lorlatinib	Lorbrena	PA		PO	
momelotinib	Ojjaara	PA		PO	
neratinib	Nerlynx	PA		PO	
osimertinib	Tagrisso	PA		PO	
pacritinib	Vonjo	PA		PO	
palbociclib	Ibrance PD	PA		PO	
pemigatinib	Pemazyre	PA		PO	
pralsetinib	Gavreto	PA		PO	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

regorafenib	Stivarga	PA		PO	**Braftovi for unresectable or metastatic melanoma**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • requested quantity is ≤ six units/day; **and**
					  • positive BRAF V600E or V600K mutation; **and**
					  • requested agent will be used in combination with Mektovi (binimetinib).
					Braftovi for metastatic NSCLC
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • requested quantity is ≤ six units/day; **and**
					  • positive BRAF V600E mutation; **and**
					  • requested agent will be used in combination with Mektovi (binimetinib).
					Copiktra for CLL or SLL
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • member is ≥ 18 years of age; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • prior therapy with at least two systemic therapies.
					Cosela
					• Documentation of the following is required:
					  • diagnosis of extensive-stage small cell lung cancer (ES-SCLC); **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • member is ≥ 18 years of age; **and**
					  • requested agent will be used in combination with a platinum/etoposide-containing or topotecan-containing regimen.
					Cotellic for low-grade or high-grade gliomas
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • positive BRAF V600E mutation; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with Zelboraf (vemurafenib) ≤ 960 mg every 12 hours.
					Cotellic for unresectable or metastatic melanoma
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**

ribociclib	Kisqali	PA		PO	
ripretinib	Qinlock	PA		PO	
ruxolitinib tablet	Jakafi	PA		PO	
selpercatinib	Retevmo	PA		PO	
selumetinib	Koselugo	PA		PO	
tepotinib	Tepmetko	PA		PO	
tovorafenib	Ojemda	PA		PO	
trametinib	Mekinist	PA		PO	
trilaciclib	Cosela	PA	MB	IV	

	Clinical Notes
	• prescriber is an oncologist; **and** • requested quantity is ≤ three units/day; **and** • positive BRAF V600E or V600K mutation; **and** • requested agent will be used in combination with Zelboraf (vemurafenib). **Cotellic for histiocytic neoplasms** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • member is ≥ 18 years of age; **and** • requested quantity is ≤ three units/day. **Fruzaqla for mCRC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all of the following regimens: CAPEOX, FOLFOX, FOLFIRI, FOLFOXIRI, irinotecan-based therapy, oxaliplatin-based therapy; **and** • inadequate response or adverse reaction to one or contraindication to both of the following: Lonsurf (trifluridine/tipiracil), Stivarga (regorafenib); **and** • if BRAF/KRAS/NRAS wild-type cancer is present, inadequate response or adverse reaction to one or contraindication to both of the following: Erbitux (cetuximab), Vectibix (panitumumab); **and** • one of the following: • for 1 mg capsule, requested quantity is ≤ four units/day; **or** • for 5 mg capsule, requested quantity is ≤ one unit/day. **Gavreto for advanced or metastatic thyroid cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member is ≥ 12 years of age; **and** • cancer is RET-fusion positive; **and** • requested quantity is ≤ four units/day; **and** • one of the following: • member refractory to radioactive iodine; **or**

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	• radioactive iodine treatment is not appropriate.
	Gavreto for metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ 18 years of age; **and**
	  • cancer is RET-fusion positive; **and**
	  • requested quantity is ≤ four units/day.
	Gilotrif
	• Documentation of the following is required:
	  • diagnosis of metastatic NSCLC; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • member has epidermal growth factor receptor (EGFR) mutations; **or**
	  • inadequate response or adverse reaction to one or contraindication to all platinum-based chemotherapy; **and**
	  • requested quantity is ≤ one unit/day.
	Ibrance for HER2-negative, HR-positive breast cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • the requested agent will be used in combination with an aromatase inhibitor; **or**
	  • the requested agent will be used in combination with fulvestrant; **and**
	  • requested quantity is ≤ one unit/day.
	Inrebic
	• Documentation of the following is required:
	  • diagnosis of one of the following:
	  • intermediate or high-risk primary myelofibrosis (PMF); **or**
	  • intermediate or high-risk post-polycythemia vera myelofibrosis (post-PV MF); **or**
	  • intermediate or high-risk post-essential thrombocythemia myelofibrosis (post-ET MF); **and**
	  • member is ≥ 18 years of age; **and**
	  • inadequate response, adverse reaction, or contraindication to Jakafi (ruxolitinib tablet); **and**

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	• requested quantity is ≤ four units/day.
	Itovebi
	• Documentation of the following is required:
	  • diagnosis of HR-positive, HER2-negative, endocrine-resistant, PIK3CA-mutated, locally advanced or metastatic breast cancer; **and**
	  • prescriber is an oncologist or consult notes from an oncologist are provided; **and**
	  • appropriate dosing; **and**
	  • member has disease that progressed following treatment with endocrine-based therapy; **and**
	  • requested agent will be used in combination with palbociclib and fulvestrant; **and**
	  • one of the following:
	  • for the 3 mg tablet, requested quantity is ≤ two units/day; **or**
	  • for the 9 mg tablet, requested quantity is ≤ 1 unit/day.
	Jakafi for acute graft versus host disease (aGVHD) or chronic graft versus host disease (cGVHD)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 12 years of age; **and**
	  • inadequate response, adverse reaction, or contraindication to systemic glucocorticoids; **and**
	  • requested quantity is ≤ two units/day.
	Jakafi for polycythemia vera (PV)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: Besremi (ropeginterferon alfa-2b-njft), hydroxyurea, Pegasys (peginterferon alfa-2a); **and**
	  • member is ≥ 18 years of age; **and**
	  • requested quantity is ≤ two units/day.
	Jakafi for intermediate or high-risk or symptomatic low-risk PMF, post-PV MF, or post-ET MF
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • requested quantity is ≤ two units/day.
	Kisqali
	• Documentation of the following is required for

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	a diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • requested agent will be used in combination with an aromatase inhibitor; **or** • requested agent will be used in combination with fulvestrant. • Documentation of the following is required for a diagnosis of HR-positive, HER2-negative stage 2 or 3 early breast cancer: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with an aromatase inhibitor. **Koselugo for plexiform neurofibromas (PN) with neurofibromatosis type 1 (NF1)** • Documentation of the following is required for members ≥ two years of age and < 18 years of age at the start of therapy: • appropriate diagnosis; **and** • prescriber is a neurologist or oncologist; **and** • appropriate dosing; **and** • member is ≥ two years of age and < 18 years of age at the start of therapy; **and** • member has at least one measurable PN and complete resection of PN is not feasible without substanstial risk or morbidity. • Documentation of the following is required for members ≥ 18 years of age: • appropriate diagnosis; **and** • prescriber is a neurologist or oncologist; **and** • appropriate dosing; **and** • member is ≥ 18 years of age; **and** • member has at least one measurable PN and complete resection of PN is not feasible without substanstial risk or morbidity. **Lorbrena** • Documentation of the following is required: • diagnosis of metastatic NSCLC; **and** • prescriber is an oncologist; **and**

	Clinical Notes

	• appropriate dosing; **and**
	• cancer is ALK-positive; **and**
	• requested quantity is ≤ one unit/day.
	Lytgobi and Pemazyre for unresectable locally advanced or metastatic cholangiocarcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • tumor has FGFR2 fusion or other rearrangement; **and**
	  • member is ≥ 18 years of age; **and**
	  • member has received at least one prior treatment; **and**
	  • for Lytgobi, one of the following:
	  • for a 20 mg daily dose, requested quantity is ≤ five units/day; **or**
	  • for a 16 mg daily dose, requested quantity is ≤ four units/day; **or**
	  • for a 12 mg daily dose, requested quantity is ≤ three units/day.
	Mekinist for locally advanced or metastatic anaplastic thyroid cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • one of the following:
	  • for 0.5 mg tablet, requested quantity is ≤ three units/day; **or**
	  • for 2 mg tablet, requested quantity is ≤ one unit/day; **and**
	  • positive BRAF V600E mutation; **and**
	  • requested agent will be used in combination with Tafinlar (dabrafenib); **and**
	  • member has no satisfactory locoregional treatment options.
	Mekinist for low-grade glioma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • member is ≥ one year of age; **and**
	  • positive BRAF V600E mutation; **and**
	  • requested agent will be used in combination with Tafinlar (dabrafenib); **and**
	  • one of the following:
	  • for 0.5 mg tablet, requested quantity is ≤ three

	Clinical Notes
	units/day; **or** • for 2 mg tablet, requested quantity is ≤ one unit/day; **or** • for solution, requested quantity is ≤ 40 mL/day. **Mekinist for adjuvant treatment of melanoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • one of the following: • for 0.5 mg tablet, requested quantity is ≤ three units/day; **or** • for 2 mg tablet, requested quantity is ≤ one unit/day; **and** • positive BRAF V600E or V600K mutation; **and** • requested agent will be used in combination with Tafinlar (dabrafenib); **and** • involvement of lymph nodes following complete resection. **Mekinist for unresectable or metastatic melanoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • one of the following: • for 0.5 mg tablet, requested quantity is ≤ three units/day; **or** • for 2 mg tablet, requested quantity is ≤ one unit/day; **and** • positive BRAF V600E or V600K mutation; **and** • one of the following: • requested agent will be used in combination with Tafinlar (dabrafenib); **or** • all of the following: • requested agent will be used as a single agent; **and** • no history of prior therapy with a BRAF inhibitor (i.e., Tafinlar [dabrafenib] or Zelboraf [vemurafenib]); **and** • clinical rationale for bypassing use of a BRAF inhibitor (i.e., Tafinlar [dabrafenib] or Zelboraf [vemurafenib]). **Mekinist for metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • one of the following:

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	• for 0.5 mg tablet, requested quantity is ≤ three units/day; **or** • for 2 mg tablet, requested quantity is ≤ one unit/day; **and** • positive BRAF V600E mutation; **and** • requested agent will be used in combination with Tafinlar (dabrafenib). **Mekinist for low-grade serous carcinoma of the ovary, fallopian tube, or primary peritoneum** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • medical records documenting an inadequate response, adverse reaction, or contraindication to one platinum-containing regimen and one hormonal therapy; **and** • one of the following: • for 0.5 mg tablet, requested quantity is ≤ three units/day; **or** • for 2 mg tablet, requested quantity is ≤ one unit/day. **Mekinist for unresectable or metastatic solid tumors** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • member is ≥ one year of age; **and** • one of the following: • for 0.5 mg tablet, requested quantity is ≤ three units/day; **or** • for 2 mg tablet, requested quantity is ≤ one unit/day; **or** • for solution, requested quantity is ≤ 40 mL/day; **and** • positive BRAF V600E mutation; **and** • requested agent will be used in combination with Tafinlar (dabrafenib). **Mektovi for BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • requested quantity is ≤ six units/day; **and** • positive BRAF V600E or V600K mutation; **and** • requested agent will be used in combination with Braftovi (encorafenib). **Mektovi for metastatic NSCLC** • Documentation of the following is required:

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	• appropriate diagnosis; **and** • prescriber is an oncologist; **and** • requested quantity is ≤ six units/day; **and** • positive BRAF V600E mutation; **and** • requested agent will be used in combination with Braftovi (encorafenib). **Mektovi for low-grade serous carcinoma of the ovary, fallopian tube, or primary peritoneum** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • requested quantity is ≤ six units/day; **and** • medical records documenting an inadequate response, adverse reaction, or contraindication to one platinum-containing regimen and one hormonal therapy. **Mektovi for NRAS mutation-positive unresectable or metastatic melanoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • positive NRAS mutation; **and** • disease progression following immune checkpoint inhibitor therapy; **and** • requested agent will be used as monotherapy; **and** • requested quantity is ≤ six units/day. **Nerlynx for adjuvant therapy for early stage breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member received trastuzumab therapy within the last two years; **and** • requested quantity is ≤ six units/day. **Nerlynx for treatment of advanced or metastatic breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to two anti-HER2-based regimens; **and** • requested agent will be used in combination with capecitabine; **and**

	Clinical Notes
	• requested quantity is ≤ six units/day. **Ojemda** • Documentation of the following is required: • diagnosis of relapsed or refractory pediatric low-grade glioma; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • positive for a BRAF fusion or rearrangement; **or** • positive for a BRAF V600E mutation. **Ojjaara** • Documentation of the following is required: • diagnosis of one of the following: • intermediate or high-risk or symptomatic low-risk PMF; **or** • intermediate or high-risk or symptomatic low-risk post-PV MF; **or** • intermediate or high-risk or symptomatic low-risk post-ET MF; **and** • member is ≥ 18 years of age; **and** • one of the following: • current hemoglobin is ≤ 10 g/dL; **or** • inadequate response, adverse reaction, or contraindication to Jakafi (ruxolitinib tablet); **and** • requested quantity is ≤ one unit/day. **Pemazyre for myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member is ≥ 18 years of age. **Piqray** • Documentation of the following is required: • diagnosis of HR-positive, HER2-negative, PIK3CA-mutated advanced or metastatic breast cancer; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • disease has progressed following treatment with endocrine-based therapy; **and** • requested agent will be used in combination with fulvestrant. **Qinlock** • Documentation of the following is required:

	Clinical Notes
	• diagnosis of gastrointestinal stromal tumor (GIST); **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to at least three prior kinase inhibitor therapies, one of which is imatinib; **and** • requested quantity is ≤ three units/day. **Retevmo for advanced or metastatic medullary thyroid cancer (MTC) or thyroid cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member is ≥ two years of age; **and** • one of the following: • member has medullary thyroid cancer and cancer has a RET mutation; **or** • member has thyroid cancer that is RET fusion-positive, and one of the following: member refractory to radioactive iodine, or radioactive iodine treatment is not appropriate; **and** • one of the following: • for the 40 mg capsule or tablet, requested quantity is ≤ three units/day; **or** • for the 80 mg capsule or tablet, requested quantity is ≤ four units/day; **or** • for the 120 mg or 160 mg tablet, requested quantity is ≤ two units/day. **Retevmo for advanced or metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member is ≥ 18 years of age; **and** • cancer is RET fusion-positive; **and** • one of the following: • for the 40 mg capsule or tablet, requested quantity is ≤ three units/day; **or** • for the 80 mg capsule or tablet, requested quantity is ≤ four units/day; **or** • for the 120 mg or 160 mg tablet, requested quantity is ≤ two units/day. **Retevmo for locally advanced or metastatic solid tumor**

	Clinical Notes

	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ two years of age; **and**
	  • cancer is RET fusion-positive; **and**
	  • requested quantity is ≤ four units/day; **and**
	  • one of the following:
	  • inadequate response or adverse reaction to at least one prior systemic therapy, or contraindication to the use of all systemic therapy; **or**
	  • member has no satisfactory alternative treatment options; **and**
	  • one of the following:
	  • for the 40 mg capsule or tablet, requested quantity is ≤ three units/day; **or**
	  • for the 80 mg capsule or tablet, requested quantity is ≤ four units/day; **or**
	  • for the 120 mg or 160 mg tablet, requested quantity is ≤ two units/day.
	Rezurock
	• Documentation of the following is required:
	  • diagnosis of cGVHD; **and**
	  • member is ≥ 12 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to systemic glucocorticoids; **and**
	  • prior therapy for the treatment of cGVHD with at least one prior line of non-steroid systemic therapy; **and**
	  • requested quantity is ≤ one unit/day.
	Stivarga for GIST
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to both of the following: imatinib and sunitinib.
	Stivarga for HCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**

	Clinical Notes

	• inadequate response, adverse reaction, or contraindication to sorafenib.
	Stivarga for mCRC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following regimens: CAPEOX, FOLFIRI, FOLFOX, FOLFOXIRI, irinotecan-based therapy, oxaliplatin-based therapy; **and**
	  • if BRAF/KRAS/NRAS wild-type cancer is present, inadequate response or adverse reaction to one or a contraindication to both of the following: Erbitux (cetuximab), Vectibix (panitumumab).
	Stivarga for osteosarcoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one or contraindication to both of the following regimens: cisplatin and doxorubicin; high-dose methotrexate, cisplatin, and doxorubicin.
	Tabrecta for MET exon 14 skipping metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer has mutation that leads to MET exon 14 skipping; **and**
	  • requested quantity is ≤ four units/day.
	Tabrecta for MET positive amplification metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer is MET positive amplification; **and**
	  • requested quantity is ≤ four units/day.
	Tafinlar for locally advanced or metastatic anaplastic thyroid cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**

	Clinical Notes
	• prescriber is an oncologist; **and** • for 50 mg and 75 mg capsule, requested quantity is ≤ four units/day; **and** • positive BRAF V600E mutation; **and** • requested agent will be used in combination with Mekinist (trametinib); **and** • member has no satisfactory locoregional treatment options. **Tafinlar for low-grade glioma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • member is ≥ one year of age; **and** • one of the following: • for 50 mg and 75 mg capsule, requested quantity is ≤ four units/day; **or** • for 10 mg tablet for oral solution, requested quantity is ≤ 30 units/day; **and** • positive BRAF V600E mutation; **and** • requested agent will be used in combination with Mekinist (trametinib). **Tafinlar for adjuvant treatment of melanoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • for 50 mg and 75 mg capsule, requested quantity is ≤ four units/day; **and** • positive BRAF V600E or V600K mutation; **and** • requested agent will be used in combination with Mekinist (trametinib); **and** • involvement of lymph nodes following complete resection. **Tafinlar for unresectable or metastatic melanoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • for 50 mg and 75 mg capsule, requested quantity is ≤ four units/day; **and** • for positive BRAF V600K, requested agent will be used in combination with Mekinist (trametinib); **and** • for positive BRAF V600E, one of the following: • requested agent will be used in combination with Mekinist (trametinib); **or** • requested agent will be used as monotherapy.

	Clinical Notes

	Tafinlar for metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • for 50 mg and 75 mg capsule, requested quantity is ≤ four units/day; **and**
	  • positive BRAF V600E mutation; **and**
	  • requested agent will be used in combination with Mekinist (trametinib).
	Tafinlar for unresectable or metastatic solid tumors
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • member is ≥ one year of age; **and**
	  • one of the following:
	  • for 50 mg and 75 mg capsule, requested quantity is ≤ four units/day; **or**
	  • for 10 mg tablet for oral solution, requested quantity is ≤ 30 units/day; **and**
	  • positive BRAF V600E mutation; **and**
	  • requested agent will be used in combination with Mekinist (trametinib).
	Tagrisso for advanced or metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ one unit/day; **and**
	  • one of the following:
	  • cancer displays the EGFR exon 19 deletion or exon 21 L858R mutation; **or**
	  • both of the following:
	  • cancer displays the EGFR mutation and the T790M resistance mutation; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: erlotinib, gefitinib, Gilotrif (afatinib), Vizimpro (dacomitinib).
	Tagrisso for adjuvant treatment for stage IB to IIIA NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ one unit/day; **and**

	Clinical Notes
	• cancer displays the EGFR exon 19 deletion or exon 21 L858R mutation; **and** • requested agent will be used as adjuvant therapy following tumor resection. **Tagrisso for locally advanced, unresectable stage III NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer displays the EGFR exon 19 deletion or exon 21 L858R mutation; **and** • tumor is unresectable; **and** • disease has not progressed on platinum-based chemoradiation therapy; **and** • requested quantity is ≤ one unit/day. **Tagrisso for first-line treatment of locally advanced or metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer displays the EGFR exon 19 deletion or exon 21 L858R mutation; **and** • requested agent will be given in combination with pemetrexed and platinum-based chemotherapy. **Tepmetko for MET exon 14 skipping metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer harbors MET exon 14 skipping alterations; **and** • requested quantity is ≤ two units/day. **Tepmetko for MET positive amplification metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer is MET positive amplification; **and** • requested quantity is ≤ two units/day. **Truqap** • Documentation of the following is required:

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	• diagnosis of HR-positive, HER2-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-mutations; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • disease has progressed following treatment with endocrine-based therapy; **and** • requested agent will be used in combination with fulvestrant; **and** • requested quantity is ≤ four units/day. **Verzenio for HR-positive, HER2-negative early breast cancer (EBC)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • the requested agent will be used in combination with an aromatase inhibitor; **or** • the requested agent will be used in combination with tamoxifen; **and** • requested quantity is ≤ two units/day. **Verzenio for HR-positive, HER2-negative advanced or metastatic breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • the requested agent will be used in combination with an aromatase inhibitor; **or** • the requested agent will be used in combination with fulvestrant; **or** • the requested agent will be used as monotherapy when disease has progressed after both hormonal therapy and chemotherapy; **and** • requested quantity is ≤ two units/day. **Vizimpro** • Documentation of the following is required: • diagnosis of metastatic NSCLC; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has EGFR mutations; **and** • requested quantity is ≤ one unit/day.

	Clinical Notes

	Vonjo
	• Documentation of the following is required:
	  • diagnosis of one of the following:
	  • intermediate or high-risk or symptomatic low-risk PMF; **or**
	  • intermediate or high-risk or symptomatic low-risk post-PV MF; **or**
	  • intermediate or high-risk or symptomatic low-risk post-ET MF; **and**
	  • member is ≥ 18 years of age; **and**
	  • one of the following:
	  • current platelet count is ≤ 50 x 10^9/L; **or**
	  • current hemoglobin is ≤ 10 g/dL; **or**
	  • inadequate response, adverse reaction, or contraindication to Jakafi (ruxolitinib tablet); **and**
	  • requested quantity is ≤ four units/day.
	Zydelig
	• Documentation of the following is required:
	  • diagnosis of CLL; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • relapsed or refractory CLL; **or**
	  • prior therapy with at least one systemic therapy.

Oncology Agents – PD-1/PD-L1 Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

atezolizumab	Tecentriq	PA	MB	IV	**Bavencio, Keytruda, and Zynyz for metastatic Merkel cell carcinoma**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • for Bavencio, an inadequate response, adverse reaction, or contraindication to Keytruda.
					Bavencio for first-line treatment of RCC
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • tumor is clear cell histology; **and**

atezolizumab-hyaluronidase-tqjs	Tecentriq Hybreza	PA	MB	SC	
avelumab	Bavencio	PA	MB	IV	
cemiplimab-rwlc	Libtayo	PA	MB	IV	
dostarlimab-gxly	Jemperli	PA	MB	IV	
durvalumab	Imfinzi	PA	MB	IV	
nivolumab	Opdivo	PA	MB	IV	
nivolumab-hyaluronidase-nvhy	Opdivo Qvantig	PA	MB	IV	
pembrolizumab	Keytruda	PA	MB	IV	
retifanlimab-dlwr	Zynyz	PA	MB	IV	
tislelizumab-jsgr	Tevimbra	PA	MB	IV	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
toripalimab-tpzi	Loqtorzi	PA	MB	IV	• requested agent will be used in combination with Inlyta (axitinib). **Bavencio for locally advanced or metastatic urothelial carcinoma (UC)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • inadequate response or adverse reaction to one or contraindication to all platinum-containing regimens; **or** • disease has not progressed following treatment with four-to-six cycles of first-line platinum-containing regimen. **Imfinzi for primary advanced or recurrent endometrial cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member is ≥ 18 years of age; **and** • cancer is dMMR; **and** • requested agent will be used in combination with carboplatin and paclitaxel every three weeks for six doses, followed by monotherapy of Imfinzi every four weeks. **Imfinzi for extensive stage (ES) SCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has extensive stage disease; **and** • requested agent will be used in combination with etoposide and either carboplatin or cisplatin. **Imfinzi and Keytruda for locally advanced or metastatic BTC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with cisplatin and gemcitabine.

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	Imfinzi for metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with Imjudo (tremelimumab-actl) and platinum-based regimen; **and**
	  • member does not have EGFR or ALK genomic tumor aberrations.
	Imfinzi for unresectable hepatocellular carcinoma (HCC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with Imjudo (tremelimumab-actl).
	Imfinzi for resectable NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with platinum-containing chemotherapy in the neoadjuvant setting followed by monotherapy in the adjuvant setting following surgery; **and**
	  • member does not have EGFR mutations or ALK rearrangements.
	Imfinzi for stage III NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • disease has not progressed following combination therapy with platinum-based chemotherapy and radiation therapy.
	Imfinzi for limited-stage small cell lung cancer (LS-SCLC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
	Jemperli for dMMR recurrent or advanced solid tumors

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	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ 18 years of age; **and**
	  • cancer is dMMR; **and**
	  • inadequate response or adverse reaction to one or contraindication to all other treatments for dMMR.
	Jemperli for recurrent or advanced endometrial cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ 18 years of age; **and**
	  • one of the following:
	  • requested agent will be used in combination with carboplatin and paclitaxel every three weeks for six doses followed by monotherapy of Jemperli every six weeks; **or**
	  • cancer is dMMR and all of the following:
	  • inadequate response or adverse reaction to one or contraindication to all lines of platinum-based regimens; **and**
	  • member is not a candidate for curative surgery or radiation; **and**
	  • requested agent will be used as monotherapy.
	Keytruda for non-muscle invasive bladder cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or urologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to BCG; **and**
	  • disease is high-risk with carcinoma in situ.
	Keytruda for high-risk early stage triple-negative breast cancer (TNBC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with chemotherapy and then continued as a single agent following surgery.
	Keytruda for cervical cancer

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	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • both of the following:
	  • requested agent will be used in combination with chemotherapy, with or without bevacizumab; **and**
	  • tumor expresses PD-L1 (CPS ≥ 1); **or**
	  • both of the following:
	  • requested agent will be used in combination with chemoradiotherapy; **and**
	  • member has FIGO 2014 Stage III-IVA cervical cancer; **or**
	  • all of the following:
	  • disease progression following one systemic chemotherapy regimen; **and**
	  • requested agent will be used as monotherapy; **and**
	  • tumor expresses PD-L1 (CPS ≥ 1).
	Keytruda for MSI-H/dMMR solid tumors or mCRC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing.
	Keytruda for advanced endometrial carcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ 18 years of age; **and**
	  • inadequate response or adverse reaction to one prior line of systemic therapy or contraindication to all systemic therapies; **and**
	  • member is not a candidate for surgery or radiation; **and**
	  • one of the following:
	  • for advanced endometrial carcinoma that is not MSI-H or dMMR, requested agent will be used in combination with Lenvima (lenvatinib); **or**
	  • for advanced endometrial carcinoma that is MSI-H or dMMR, requested agent will be used as monotherapy.
	Keytruda for primary advanced or recurrent endometrial carcinoma
	• Documentation of the following is required:

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	• appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member is ≥ 18 years of age; **and** • requested agent will be used in combination with carboplatin and paclitaxel every three weeks for six doses, followed by monotherapy of Keytruda every six weeks. **Keytruda for advanced, recurrent or metastatic esophageal or EGJ cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • if previously untreated, requested agent will be used in combination with a fluoropyrimidine- and platinum-containing regimen; **or** • requested agent will be used as monotherapy and member had at least one prior line of systemic therapy for squamous cell tumor with PD-L1 (CPS ≥ 10). **Keytruda for locally advanced unresectable or metastatic HER2-positive gastric or GEJ adenocarcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with trastuzumab, fluoropyrimidine-, and platinum-containing regimen. **Keytruda for locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with a fluoropyrimidine- and platinum-containing regimen. **Keytruda for HCC secondary to hepatitis B** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and**

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	• appropriate dosing; **and** • inadequate response or adverse reaction to one, or contraindication to both of the following: Lenvima (lenvatinib), sorafenib. **Keytruda and Opdivo for relapsed or refractory classical Hodgkin lymphoma in adult members** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • member is ≥ 18 years of age; **and** • one of the following: • member has progressed after autologous hematopoietic stem cell transplant with or without brentuximab; **or** • member is ineligible for transplant or inadequate response to two lines of prior chemotherapy; **or** • member has received allogeneic transplant. **Keytruda and Opdivo for relapsed or refractory classical Hodgkin lymphoma in pediatric members** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • member is < 18 years of age; **and** • inadequate response or adverse reaction to two or more lines of prior chemotherapy. **Keytruda for recurrent or metastatic head and neck squamous cell carcinoma (HNSCC)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all platinum-containing regimens; **or** • cancer is non-nasopharyngeal and one of the following: • requested agent is used in combination with a platinum agent (cisplatin, carboplatin) and fluorouracil; **or** • tumor is PD-L1 positive (CPS ≥ 1). **Keytruda, Opdivo, and Opdivo Qvantig for stage IIB, IIC,**

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	or III melanoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used as adjuvant treatment following complete resection.
	Keytruda, Opdivo, and Opdivo Qvantig for unresectable or metastatic melanoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing.
	Keytruda for unresectable advanced or metastatic MPM
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with pemetrexed and platinum chemotherapy.
	Keytruda for resectable NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in the neoadjuvant setting in combination with one of the following:
	  • carboplatin and paclitaxel; **or**
	  • cisplatin and gemcitabine; **or**
	  • cisplatin and paclitaxel; **or**
	  • cisplatin and pemetrexed; **and**
	  • requested agent will be continued as monotherapy as adjuvant treatment after surgery.
	Keytruda for stage IB (T2a ≥4 cm), II, or IIIA NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used as adjuvant treatment following resection and platinum-based regimen.
	Keytruda for stage III NSCLC
	• Documentation of the following is required:

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	• appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • tumor expresses PD-L1 [tumor proportion score (TPS) ≥ 1%]; **and** • member is not a candidate for surgical resection or definitive chemoradiation; **and** • member does not have EGFR or ALK genomic tumor aberrations. **Keytruda for unresectable or metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • for nonsquamous NSCLC in the first-line setting, requested agent will be used in combination with pemetrexed and one of the following: carboplatin, cisplatin; **or** • for squamous NSCLC in the first-line setting, requested agent will be used in combination with carboplatin and one of the following: paclitaxel, albumin-bound paclitaxel ; **or** • PD-L1 expression and one of the following: • both of the following: • inadequate response or adverse reaction to one or contraindication to all platinum-containing regimens; **and** • requested agent will be used as monotherapy; **or** • both of the following: • member does not have EGFR or ALK genomic tumor aberrations; **and** • requested agent will be used as monotherapy in the first-line setting. **Keytruda for primary mediastinal B-cell lymphoma (PMBCL)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to two or contraindication to all systemic chemotherapies. **Keytruda for advanced RCC**

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	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • tumor is clear cell histology and one of the following:
	  • requested agent will be used in combination with Inlyta (axitinib); **or**
	  • requested agent will be used in combination with Lenvima (lenvatinib); **or**
	  • requested agent will be used as adjuvant treatment following nephrectomy; **or**
	  • tumor is non-clear cell histology and one of the following:
	  • requested agent will be used in combination with lenvatinib; **or**
	  • requested agent will be used as monotherapy.
	Keytruda for metastatic ESCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • tumor expresses PD-L1 (CPS ≥ 10); **and**
	  • inadequate response or adverse reaction to one or contraindication to all other lines of systemic therapy.
	Keytruda and Libtayo for metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ 18 years of age; **and**
	  • member is not a candidate for surgery and/or radiation therapy.
	Keytruda for tumor mutational burden-high (TMB-H) cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • tumor has ≥ 10 mutations/megabase.
	Keytruda for unresectable locally advanced or metastatic

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	TNBC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is PD-L1 positive (CPS ≥ 10); **and**
	  • requested agent will be used in combination with one of the following: paclitaxel protein-bound, paclitaxel, or gemcitabine plus carboplatin.
	Keytruda for locally advanced or metastatic UC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • requested agent will be used as monotherapy and an inadequate response or adverse reaction to one or contraindication to all platinum-containing regimens; **or**
	  • requested agent will be used in combination with Padcev (enfortumab vedotin-ejfv).
	Libtayo for basal cell carcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one or contraindication to all hedgehog pathway inhibitors.
	Libtayo for NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • member has locally advanced cancer and is not a candidate for surgical resection or definitive chemoradiation; **or**
	  • member has metastatic disease; **and**
	  • member does not have EGFR, ALK, or ROS1 tumor aberrations; **and**
	  • one of the following:
	  • requested agent will be used in combination with platinum-based regimen; **or**
	  • requested agent will be used as monotherapy in the

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	first-line setting and the tumor has PD-L1 expression ≥ 50%.
	Loqtorzi
	• Documentation of the following is required:
	  • diagnosis of nasopharyngeal carcinoma (NPC); **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ 18 years of age; **and**
	  • one of the following:
	  • cancer is metastatic or recurrent, locally advanced NPC, and requested agent will be used as first-line treatment in combination with cisplatin and gemcitabine; **or**
	  • all of the following:
	  • cancer is recurrent unresectable or metastatic NPC; **and**
	  • member has had disease progression on or after a platinum-containing chemotherapy regimen; **and**
	  • requested agent will be used as monotherapy.
	Opdivo for advanced RCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • tumor is clear cell histology and requested agent will be used in combination with Yervoy (ipilimumab); **or**
	  • tumor is clear cell histology and requested agent will be used in combination with Cabometyx (cabozantinib); **or**
	  • tumor is clear cell histology and member has received prior anti-angiogenic therapy and requested agent will be used as monotherapy; **or**
	  • tumor is non-clear cell histology and one of the following:
	  • requested agent will be used in combination with cabozantinib; **or**
	  • requested agent will be used in combination with ipilimumab; **or**
	  • requested agent will be used as monotherapy.
	Opdivo and Opdivo Qvantig for completely resected esophageal or gastroesophageal junction (GEJ) cancer
	• Documentation of the following is required:

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	• appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has residual pathologic disease; **and** • member has received neoadjuvant chemoradiotherapy (CRT). **Opdivo and Opdivo Qvantig for advanced or metastatic gastric cancer, GEJ cancer or esophageal adenocarcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent is to be used in combination with a fluoropyrimidine- and platinum-containing regimen. **Opdivo for HCC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with Yervoy (ipilimumab); **and** • inadequate response, adverse reaction, or contraindication to sorafenib. **Opdivo and Opdivo Qvantig for recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all platinum-containing regimens. **Opdivo for MPM** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with Yervoy (ipilimumab). **Opdivo and Opdivo Qvantig for MSI-H/dMMR mCRC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and**

	Clinical Notes

	• inadequate response or adverse reaction to one or contraindication to all of the following: fluoropyrimidine-containing regimen, irinotecan-containing regimen, oxaliplatin-containing regimen.
	Opdivo and Opdivo Qvantig for resectable NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used as monotherapy in the adjuvant setting after surgery; **and**
	  • member does not have EGFR mutations or ALK rearrangements; **and**
	  • requested agent will be used in the neoadjuvant setting in combination with one of the following:
	  • carboplatin and paclitaxel; **or**
	  • carboplatin and pemetrexed; **or**
	  • carboplatin and gemcitabine; **or**
	  • cisplatin and gemcitabine; **or**
	  • cisplatin and paclitaxel; **or**
	  • cisplatin and pemetrexed.
	Opdivo for unresectable or metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • inadequate response or adverse reaction to one or contraindication to all platinum-containing regimens; **or**
	  • requested agent will be used in combination with Yervoy (ipilimumab) and one of the following:
	  • paclitaxel and carboplatin; **or**
	  • pemetrexed and carboplatin; **or**
	  • pemetrexed and cisplatin; **or**
	  • tumor has PD-L1 expression ≥ 1% and the requested agent is used in combination with Yervoy (ipilimumab).
	Opdivo for unresectable advanced, recurrent, or metastatic ESCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**

	Clinical Notes

	• one of the following:
	  • member has received prior fluoropyrimidine-based and platinum-based regimen; **or**
	  • requested agent will be used in combination with a fluoropyrimidine- and platinum-based regimen in the first-line setting; **or**
	  • requested agent will be used in combination with Yervoy (ipilimumab) in the first-line setting.
	Opdivo and Opdivo Qvantig for UC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • member with locally advanced or metastatic UC who has disease progression during or following one platinum-containing regimen; **or**
	  • requested agent will be used as adjuvant treatment for members at high risk of recurrence following radical resection of UC; **or**
	  • requested agent will be used in unresectable or metastatic UC as first-line treatment in combination with cisplatin and gemcitabine.
	Opdivo Qvantig for unresectable advanced, recurrent or metastatic ESCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • member has received prior fluoropyrimidine- and platinum-based regimen; **or**
	  • requested agent will be used in combination with a fluoropyrimidine- and platinum-based regimen in the first-line setting.
	Opdivo Qvantig for HCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used as monotherapy following treatment with Opdivo (nivolumab) and Yervoy (ipilimumab); **and**
	  • inadequate response, adverse reaction, or

	Clinical Notes
	contraindication to sorafenib. **Opdivo Qvantig for metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used as monotherapy; **and** • inadequate response or adverse reaction to one or contraindication to all platinum-containing regimens. **Opdivo Qvantig for advanced RCC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • tumor is clear cell histology and requested agent will be used as monotherapy following treatment with Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy; **or** • tumor is clear cell histology and requested agent will be used in combination with Cabometyx (cabozantinib); **or** • tumor is clear cell histology and member has received prior anti-angiogenic therapy and requested agent will be used as monotherapy; **or** • tumor is non-clear cell histology and one of the following: • requested agent will be used in combination with cabozantinib; **or** • requested agent will be used as monotherapy. **Tecentriq and Tecentriq Hybreza for extensive stage (ES) SCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has extensive stage disease; **and** • requested agent will be used in combination with carboplatin and etoposide. **Tecentriq and Tecentriq Hybreza for hepatocellular carcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and**

	Clinical Notes
	• appropriate dosing; **and** • requested agent will be used in combination with bevacizumab; **and** • member has Child-Pugh Class A. **Tecentriq and Tecentriq Hybreza for stage II to IIIA NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • tumor has PD-L1 expression ≥ 1%; **and** • requested agent will be used as adjuvant treatment following complete resection and platinum-based regimen. **Tecentriq and Tecentriq Hybreza for unresectable or metastatic alveolar soft part sarcoma (ASPS)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • for Tecentriq, member is ≥ two years of age; **or** • for Tecentriq Hybreza, member is ≥ 18 years of age. **Tecentriq and Tecentriq Hybreza for unresectable or metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • inadequate response or adverse reaction to one or contraindication to all platinum-containing regimens; **or** • first-line setting for nonsquamous NSCLC and requested agent will be used in combination with all of the following: Avastin (bevacizumab), carboplatin, and paclitaxel; **or** • tumor has PD-L1 expression ≥ 50%; **or** • first-line setting for nonsquamous NSCLC and requested agent will be used in combination with both of the following: albumin-bound paclitaxel and carboplatin. **Tecentriq and Tecentriq Hybreza for unresectable or**

	Clinical Notes

	metastatic melanoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • positive BRAF V600E or V600K mutation; **and**
	  • the requested agent will be used in combination with Cotellic (cobimetinib) and Zelboraf (vemurafenib); **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following:
	  • Braftovi (encorafenib) + Mektovi (binimetinib); **or**
	  • Cotellic (cobimetinib) + Zelboraf (vemurafenib); **or**
	  • Tafinlar (dabrafenib) + Mekinist (trametinib).
	Tevimbra for unresectable or metastatic PD-L1 positive ESCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • tumor expresses PD-L1 (CPS ≥ 1); **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with platinum-containing chemotherapy.
	Tevimbra for unresectable or metastatic ESCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one line of systemic chemotherapy that did not include a PD-1/PD-L1 inhibitor or contraindication to all other lines of systemic therapy.
	Tevimbra for unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • tumor expresses PD-L1 (CPS ≥ 1); **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with both a fluoropyrimidine-containing regimen and platinum-containing regimen.

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

belinostat	Beleodaq	PA	MB	IV	**Beleodaq for peripheral T-cell lymphoma (PTCL)**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • inadequate response or adverse reaction to one or contraindication to all second-line treatment options.
					Istodax (romidepsin lyophilized) and romidepsin non-lyophilized for cutaneous T-cell lymphoma (CTCL)
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist, hematologist, or dermatologist; **and**
					  • appropriate dosing.
					Istodax (romidepsin lyophilized) and romidepsin non-lyophilized for PTCL
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • inadequate response or adverse reaction to one or contraindication to all second-line treatment options.

romidepsin lyophilized	Istodax	PA	MB	IV	
romidepsin non-lyophilized		PA	MB	IV	
vorinostat	Zolinza			PO	

Oncology Agents – Antibody-Drug Conjugates

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

ado-trastuzumab	Kadcyla	PA	MB	IV	**Besponsa**
					• Documentation of the following is required:
					  • diagnosis of ALL; **and**
					  • member is ≥ one year of age; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • one of the following:
					  • both of the following:
					  • Philadelphia chromosome-positive; **and**
					  • inadequate response or adverse reaction to one tyrosine kinase inhibitor for the treatment of ALL; **or**
					  • all of the following:
					  • Philadelphia chromosome-negative; **and**
					  • B-cell precursor ALL; **and**
					  • prior therapy for the treatment of ALL with one systemic therapy.

belantamab mafodotin-blmf	Blenrep	PA		IV	
datopotamab deruxtecan-dlnk	Datroway	PA	MB	IV	
fam-trastuzumab deruxtecan-nxki	Enhertu	PA	MB	IV	
gemtuzumab ozogamicin	Mylotarg	PA	MB	IV	
inotuzumab ozogamicin	Besponsa	PA	MB	IV	
mirvetuximab soravtansine-gynx	Elahere	PA	MB	IV	
sacituzumab govitecan-hziy	Trodelvy	PA	MB	IV	
tisotumab vedotin-tftv	Tivdak	PA	MB	IV	

	Clinical Notes

	Blenrep
	• Documentation of the following is required:
	  • diagnosis of multiple myeloma; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • member has received at least four prior chemotherapy regimens or contraindication to the use of recommended chemotherapy regimens; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following proteasome inhibitors: bortezomib, Kyprolis (carfilzomib), Ninlaro (ixazomib), Velcade (bortezomib); **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following immunomodulatory agents: lenalidomide, Pomalyst (pomalidomide), Thalomid (thalidomide); **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following anti-CD38 monoclonal antibodies: Darzalex (daratumumab), Darzalex Faspro (daratumumab-hyaluronidase-fihj), Sarclisa (isatuximab-irfc).
	Datroway and Trodelvy for HR-positive, HER2-negative unresectable locally advanced or metastatic breast cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one or contraindication to all endocrine-based therapies; **and**
	  • inadequate response or adverse reaction to at least two prior non-endocrine-based systemic therapies in the metastatic setting; **and**
	  • if HER2 IHC 0+, 1+, or 2+/ISH negative (HER2-low) breast cancer, inadequate response, adverse reaction, or contraindication to Enhertu.
	Elahere
	• Documentation of the following is required:
	  • diagnosis of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is folate receptor-alpha positive; **and**
	  • inadequate response or adverse reaction to at least one

	Clinical Notes

	systemic therapy, or contraindication to all systemic therapies for the requested indication.
	Enhertu for locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one trastuzumab-based regimen.
	Enhertu for unresectable or metastatic HER2-positive breast cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one anti-HER2-based regimen.
	Enhertu for unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one prior chemotherapy regimen.
	Enhertu for unresectable or metastatic NSCLC with activating HER2 (ERBB2) mutations
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one prior systemic therapy.
	Enhertu for unresectable or metastatic HER2-positive (IHC 3+) solid tumor
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • inadequate response or adverse reaction to one prior systemic therapy; **or**

	Clinical Notes
	• member has no satisfactory alternative treatment options. **Kadcyla** • Documentation of the following is required: • diagnosis of HER2-positive breast cancer; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • member has recurrent or metastatic breast cancer and an inadequate response or adverse reaction to trastuzumab and a taxane separately or in combination; **or** • member has early breast cancer and residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment. **Mylotarg for newly-diagnosed CD33-positive AML in adults and pediatric members one month of age and older** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ one month of age; **and** • prescriber is an oncologist or hematologist, or consult notes from an oncologist or hematologist are provided; **and** • appropriate dosing; **and** • one of the following: • requested agent will be used in combination with cytarabine and daunorubicin or fludarabine; **or** • member is ≥ 60 years of age; **or** • clinical rationale why combination therapy with cytarabine and daunorubicin or fludarabine is not appropriate. **Mylotarg for relapsed or refractory CD33-positive AML in adults and pediatric members two years of age and older** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ two years of age; **and** • prescriber is an oncologist or hematologist, or consult notes from an oncologist or hematologist are provided; **and** • appropriate dosing; **and** • one of the following: • relapsed or refractory AML; **or** • prior therapy for the treatment of AML with one systemic therapy.

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	Tivdak for recurrent or metastatic cervical cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ 18 years of age; **and**
	  • inadequate response, adverse reaction, or contraindication to one line of platinum-based chemotherapy; **and**
	  • if PD-L1, TMB-H, or MSI-H/dMMR positive, inadequate response, adverse reaction, or contraindication to Keytruda (pembrolizumab).
	Trodelvy for unresectable locally advanced or metastatic triple negative breast cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to at least two prior systemic therapies, at least one for metastatic disease.

Oncology Agents – Bruton's Tyrosine Kinase Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

acalabrutinib	Calquence	PA		PO	**Brukinsa and Calquence for CLL or SLL**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • member is ≥ 18 years of age; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing.
					Brukinsa for FL
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • member is ≥ 18 years of age; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with Gazyva (obinutuzumab); **and**
					  • prior therapy with at least two systemic therapies.
					Brukinsa and Calquence for MCL
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**

ibrutinib	Imbruvica	PA		PO	
pirtobrutinib	Jaypirca	PA		PO	
zanubrutinib	Brukinsa	PA		PO	

	Clinical Notes
	• member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • prior therapy with at least one systemic therapy. **Brukinsa for MZL** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • prior therapy with at least one anti-CD20 monoclonal antibody-based regimen. **Brukinsa for Waldenstrom's macroglobulinemia (WM)** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing. **Calquence for MZL** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • prior therapy with at least one systemic therapy. **Imbruvica for cGVHD** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ one year of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all systemic glucocorticoids. **Imbruvica for CLL, SLL, and WM** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing. **Imbruvica for central nervous system (CNS) lymphoma** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and**

	Clinical Notes
	• appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to a methotrexate-based regimen for the treatment of CNS lymphoma. **Jaypirca for CLL/SLL** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • prior therapy for the treatment of CLL/SLL with at least two lines of systemic therapy, including a Bruton's Tyrosine Kinase Inhibitor and a BCL-2 inhibitor; **and** • requested quantity is ≤ 2 units/day. **Jaypirca for MCL** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • prior therapy for the treatment of MCL with at least two lines of systemic therapy, one of which is a Bruton's Tyrosine Kinase Inhibitor; **and** • requested quantity is ≤ 2 units/day.

Oncology Agents – Topoisomerase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
etoposide capsule			A90	PO	**Etopophos** • Documentation of the following is required: • diagnosis of small cell lung cancer or testicular cancer; **and** • prescriber is an oncologist or hematologist; **and** • member is ≥ 18 years of age; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to an etoposide product available without PA. **Onivyde** • Documentation of the following is required: • diagnosis of metastatic adenocarcinoma of the pancreas; **and** • prescriber is an oncologist or hematologist; **and**
etoposide injection			MB	IV	
etoposide phosphate	Etopophos	PA	MB	IV	
irinotecan	Camptosar		MB	IV	
irinotecan liposome	Onivyde	PA	MB	IV	
topotecan capsule	Hycamtin			PO	
topotecan injection	Hycamtin		MB	IV	

	Clinical Notes

	• appropriate dosing; **and**
	• member is ≥ 18 years of age; **and**
	• one of the following:
	  • requested agent will be used in combination with fluorouracil, leucovorin, and oxaliplatin; **or**
	  • both of the following:
	  • requested agent will be used in combination with fluorouracil and leucovorin; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: a fluoropyrimidine-based chemotherapy regimen, a gemcitabine-based chemotherapy regimen.

Oncology Agents – Antiandrogens

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

abiraterone 125 mg	Yonsa	PA		PO	**abiraterone 250 mg, 500 mg**
					• Documentation of the following is required:
					  • diagnosis of metastatic high-risk castration-sensitive prostate cancer or metastatic castration-resistant prostate cancer (mCRPC); **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with prednisone; **and**
					  • for the 500 mg tablet, medical necessity for use instead of the 250 mg tablet; **and**
					  • one of the following:
					  • requested agent will be used in combination with a gonadotropin-releasing hormone (GnRH) analog; **or**
					  • member had a bilateral orchiectomy.
					Erleada for metastatic castration-sensitive prostate cancer (mCSPC)
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • inadequate response, adverse reaction, or contraindication to abiraterone; **and**
					  • one of the following:
					  • requested agent will be used in combination with a GnRH analog; **or**
					  • member had a bilateral orchiectomy.
					Erleada for non-metastatic castration-resistant prostate

abiraterone 250 mg, 500 mg	Zytiga	PA	A90	PO	
apalutamide	Erleada	PA		PO	
bicalutamide	Casodex		# , A90	PO	
darolutamide	Nubeqa	PA		PO	
enzalutamide	Xtandi	PA		PO	
nilutamide			A90	PO	

	Clinical Notes

	cancer (NM-CRPC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or urologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to Xtandi (enzalutamide); **and**
	  • one of the following:
	  • requested agent will be used in combination with a GnRH analog; **or**
	  • member had a bilateral orchiectomy.
	Nubeqa for NM-CRPC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or urologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to Xtandi (enzalutamide); **and**
	  • one of the following:
	  • requested agent will be used in combination with a GnRH analog; **or**
	  • member had a bilateral orchiectomy.
	Nubeqa for metastatic hormone-sensitive prostate cancer (mHSPC) or mCSPC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or urologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with docetaxel; **and**
	  • one of the following:
	  • requested agent will be used in combination with a GnRH analog; **or**
	  • member had a bilateral orchiectomy.
	Nubeqa for M1 mCRPC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • if no prior docetaxel or no novel hormone therapy, inadequate response, adverse reaction, or contraindication to all of the following: abiraterone, docetaxel, and enzalutamide; **or**
	  • if prior docetaxel but no prior novel hormone

	Clinical Notes
	therapy, inadequate response, adverse reaction, or contraindication to both of the following: abiraterone and enzalutamide; **or** • if prior novel hormone therapy but no prior docetaxel, inadequate response, adverse reaction, or contraindication to docetaxel; **or** • if prior docetaxel and prior novel hormone therapy, inadequate response, adverse reaction, or contraindication to cabazitaxel. **Xtandi for mCSPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to abiraterone; **and** • one of the following: • requested agent will be used in combination with a GnRH analog; **or** • member had a bilateral orchiectomy. **Xtandi for mCRPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • requested agent will be used in combination with a GnRH analog; **or** • member had a bilateral orchiectomy; **and** • one of the following: • requested agent will be used as monotherapy; **or** • requested agent will be used in combination with Talzenna (talazoparib). **Xtandi for NM-CRPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or urologist; **and** • appropriate dosing; **and** • one of the following: • requested agent will be used in combination with a GnRH analog; **or** • member had a bilateral orchiectomy. **Xtandi for NM-CSPC with high risk biochemical recurrence (BCR)**

	Clinical Notes

	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or urologist; **and**
	  • appropriate dosing.
	Yonsa
	• Documentation of the following is required:
	  • diagnosis of mCRPC; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with methylprednisolone; **and**
	  • one of the following:
	  • requested agent will be used in combination with a GnRH analog; **or**
	  • member had a bilateral orchiectomy.

Oncology Agents – Antibiotics

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

bleomycin			MB	IV / IM / SC	**Jelmyto**
					• Documentation of the following is required:
					  • diagnosis of low-grade upper-tract urothelial cancer; **and**
					  • prescriber is an oncologist or urologist; **and**
					  • appropriate dosing.
					• For recertification, documentation that the member achieved a complete response three months after initiation is required.

dactinomycin	Cosmegen		MB	IV	
mitomycin injection			MB	IV	
mitomycin pyelocalyceal solution	Jelmyto	PA	MB	Intravesically	

Oncology Agents – Hedgehog Pathway Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

glasdegib	Daurismo	PA		PO	**Daurismo for acute myeloid leukemia (AML)**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with low dose cytarabine; **and**
					  • one of the following:
					  • member is ≥ 75 years of age; **or**
					  • member is ≥ 60 years of age and one of the

sonidegib	Odomzo	PA		PO	
vismodegib	Erivedge	PA		PO	

	Clinical Notes
	following: • member is not a candidate for intensive induction chemotherapy; **or** • member has significant comorbidities that preclude the use of intensive induction chemotherapy. **Erivedge for metastatic or locally advanced basal cell carcinoma (BCC)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • requested quantity is ≤ one unit/day; **and** • member is ≥ 18 years of age; **and** • one of the following: • member has persistent or recurring basal cell carcinoma following surgery and/or radiation therapy; **or** • member is not a candidate for surgery or radiation therapy. **Odomzo for locally advanced basal cell carcinoma (BCC)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • requested quantity is ≤ one unit/day; **and** • member is ≥ 18 years of age; **and** • one of the following: • member has persistent or recurring basal cell carcinoma following surgery and/or radiation therapy; **or** • member is not a candidate for surgery or radiation therapy.

Oncology Agents – CD123-Directed Cytotoxins

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
tagraxofusp-erzs	Elzonris	PA	MB	IV	**Elzonris** • Documentation of the following is required: • diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN); **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • first infusion will take place in an inpatient setting, and

	Clinical Notes
	subsequent infusions may take place in an outpatient setting with appropriate monitoring.

Oncology Agents – Selective Estrogen Receptor Modulator (SERM)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
toremifene	Fareston		# , A90	PO	

Oncology Agents – Estrogen Receptor Antagonists

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
elacestrant	Orserdu	PA		PO	fulvestrant • Documentation of the following is required: • diagnosis of HR-positive advanced or metastatic breast cancer; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • member is HER2-positive and one of the following: • requested agent will be use as monotherapy; **or** • requested agent will be used in combination with trastuzumab; **or** • member is HER2-negative and one of the following: • requested agent will be used as monotherapy; **or** • requested agent will be used in combination with a CDK inhibitor (abemaciclib, palbociclib, or ribociclib); **or** • requested agent will be used in combination with anastrozole or letrozole. Orserdu • Documentation of the following is required: • diagnosis of ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one line of endocrine therapy containing a CDK4/6 inhibitor; **and** • one of the following: • for Orserdu 86 mg tablets, requested quantity is ≤ three units/day; **or** • for Orserdu 345 mg tablets, requested quantity is ≤ one unit/day.
fulvestrant	Faslodex	PA	MB	IM	

Oncology Agents – Isocitrate Dehydrogenase (IDH) Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
enasidenib	Idhifa	PA		PO	**Idhifa** • Documentation of the following is required: • diagnosis of IDH2-mutated AML; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • requested quantity is ≤ one unit/day; **and** • one of the following: • member is not a candidate for intensive remission induction therapy; **or** • relapsed or refractory IDH2-mutated AML. **Rezlidhia** • Documentation of the following is required: • diagnosis of relapsed or refractory IDH1 mutated AML; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • requested quantity is ≤ two units/day. **Tibsovo for IDH1-mutated AML** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • requested quantity is ≤ two units/day; **and** • one of the following: • member is not a candidate for chemotherapy; **or** • relapsed or refractory IDH1-mutated AML. **Tibsovo for IDH1-mutated cholangiocarcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • requested quantity is ≤ two units/day; **and** • prior treatment of IDH1-mutated cholangiocarcinoma with at least one of the following systemic therapies: • cisplatin, gemcitabine, and pembrolizumab; **or** • cisplatin, durvalumab, and gemcitabine; **or** • single agent and combination chemotherapies involving 5-fluorouracil, capecitabine, cisplatin, gemcitabine, oxaliplatin, or paclitaxel; **or** • entrectinib or larotrectinib (for NTRK gene fusion positive); **or** • nivolumab and ipilimumab (for TMB-H tumors); **or** • pembrolizumab (for MSI-H/dMMR tumors); **or** • pralsetinib or selpercatinib (for RET gene fusion-
ivosidenib	Tibsovo	PA		PO	
olutasidenib	Rezlidhia	PA		PO	
vorasidenib	Voranigo	PA		PO	

	Clinical Notes

	positive).
	Tibsovo for relapsed or refractory IDH1 mutated myelodysplastic syndrome (MDS)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ two units/day.
	Voranigo
	• Documentation of the following is required:
	  • diagnosis of grade 2 or 3 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation; **and**
	  • member is ≥ 12 years of age; **and**
	  • prescriber is an oncologist or neuro-oncologist; **and**
	  • appropriate dosing; **and**
	  • history of surgery (including biopsy, sub-total resection, or gross total resection); **and**
	  • one of the following:
	  • for the 10 mg tablet, requested quantity is ≤ two units/day; **or**
	  • for the 40 mg tablet, requested quantity is ≤ one unit/day.

Oncology Agents – CTLA-4 Blocking Monoclonal Antibodies

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

ipilimumab	Yervoy	PA	MB	IV	**Imjudo for metastatic NSCLC**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with Imfinzi (durvalumab) and platinum-based regimen; **and**
					  • member does not have EGFR or ALK genomic tumor aberrations; **and**
					  • requested quantity is ≤ five doses.
					Imjudo for unresectable hepatocellular carcinoma
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**

tremelimumab-actl	Imjudo	PA	MB	IV	

	Clinical Notes
	• requested agent will be used in combination with Imfinzi (durvalumab); **and** • requested quantity is one dose. **Yervoy for cutaneous melanoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in the adjuvant setting following complete resection, including total lymphadenectomy. **Yervoy for hepatocellular carcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with Opdivo (nivolumab); **and** • inadequate response, adverse reaction, or contraindication to sorafenib. **Yervoy for malignant pleural mesothelioma (MPM)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with Opdivo (nivolumab). **Yervoy for metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • PD-L1 expression ≥ 1% and requested agent will be used in combination with Opdivo (nivolumab); **or** • requested agent will be used in combination with Opdivo (nivolumab) and two cycles of platinum doublet chemotherapy. **Yervoy for microsatellitle instability-high (MSI-H)/mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC)** • Documentation of the following is required: • appropriate diagnosis; **and**

	Clinical Notes
	• prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: fluoropyrimidine-based therapy, irinotecan-based therapy, oxaliplatin-based therapy. **Yervoy for renal cell carcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has clear cell histology; **and** • requested agent will be used in combination with Opdivo (nivolumab). **Yervoy for unresectable advanced or metastatic squamous cell carcinoma of the esophagus (ESCC)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with Opdivo (nivolumab) in the first-line setting. **Yervoy for unresectable or metastatic melanoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • requested agent will be used as monotherapy; **or** • requested agent will be used in combination with Opdivo (nivolumab); **or** • requested agent will be used in combination with Keytruda (pembrolizumab).

Oncology Agents – DNA Methylation Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
azacitidine tablet	Onureg	PA		PO	**Onureg** • Documentation of the following is required: • diagnosis of AML; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following:
azacitidine vial	Vidaza		MB	IV / SC	
decitabine			MB	IV	
decitabine / cedazuridine	Inqovi			PO	

					Clinical Notes
					• achievement of first complete remission (CR) following intensive induction chemotherapy; **or** • complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy; **and** • member is not able to complete intensive curative therapy; **and** • requested quantity is ≤ 14 units/28 days.

Oncology Agents – Antineoplastic Combination

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
daunorubicin / cytarabine	Vyxeos	PA	MB	IV	**Kisqali-Femara Co-Pack** • Documentation of the following is required: • diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer; **and** • prescriber is an oncologist; **and** • appropriate dosing. **Lonsurf for metastatic colorectal cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to at least one or contraindication to all of the following regimens: CAPEOX, FOLFOX, FOLFIRI, FOLFOXIRI, irinotecan-based therapy, oxaliplatin-based therapy; **and** • if BRAF/KRAS/NRAS wild-type cancer is present, inadequate response or adverse reaction to one or contraindication to both of the following: Erbitux (cetuximab), Vectibix (panitumumab). **Lonsurf for metastatic gastric or GEJ adenocarcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to two prior lines of chemotherapy containing one of the following or contraindication to all appropriate chemotherapy and HER2/neu-targeted therapy: fluoropyrimidine-based therapy, platinum-based therapy, either a taxane - or irinotecan-based therapy, and if appropriate, HER2/neu-targeted therapy.
pertuzumab / trastuzumab / hyaluronidase-zzxf	Phesgo	PA	MB	SC	
ribociclib / letrozole	Kisqali-Femara Co-Pack	PA		PO	
trifluridine / tipiracil	Lonsurf	PA		PO	

	Clinical Notes

	Phesgo
	• Documentation of the following is required:
	  • diagnosis of HER2-positive breast cancer; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • for early breast cancer, requested agent will be used in combination with chemotherapy; **or**
	  • for metastatic breast cancer, requested agent will be used in combination with docetaxel.
	Vyxeos
	• Documentation of the following is required:
	  • diagnosis of newly diagnosed therapy-related AML or AML with myelodysplasia-related changes (AML-MRC); **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ one year of age; **and**
	  • inadequate response, adverse reaction, or contraindication to use of separate daunorubicin and cytarabine chemotherapy agents.

Oncology Agents – KRAS Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

adagrasib	Krazati	PA		PO	**Krazati for locally advanced or mCRC**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • cancer has KRAS G12C mutation; **and**
					  • requested agent will be used in combination with Erbitux (cetuximab); **and**
					  • inadequate response or adverse reaction to one or contraindication to all fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; **and**
					  • requested quantity is ≤ six units/day.
					Krazati and Lumakras for metastatic NSCLC
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • cancer has KRAS G12C mutation; **and**
					  • inadequate response or adverse reaction to one or

sotorasib	Lumakras	PA		PO	

	Clinical Notes

	contraindication to all first-line systemic therapies; **and**
	• one of the following:
	  • for Krazati, requested quantity is ≤ six units/day; **or**
	  • for Lumakras 120 mg tablet, requested quantity is ≤ eight units/day; **or**
	  • for Lumakras 240 mg tablet, requested quantity is ≤ four units/day; **or**
	  • for Lumakras 320 mg tablet, requested quantity is ≤ three units/day.
	Lumakras for locally advanced or mCRC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer has KRAS G12C mutation; **and**
	  • requested agent will be used in combination with Vectibux (panitumumab); **and**
	  • inadequate response or adverse reaction to one or contraindication to all fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; **and**
	  • one of the following:
	  • for Lumakras 120 mg tablet, requested quantity is ≤ eight units/day; **or**
	  • for Lumakras 240 mg tablet, requested quantity is ≤ four units/day; **or**
	  • for Lumakras 320 mg tablet, requested quantity is ≤ three units/day.

Oncology Agents – Proteasome Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

bortezomib	Velcade		MB	IV / SC	**Kyprolis**
					• Documentation of the following is required for monotherapy:
					  • diagnosis of multiple myeloma; **and**
					  • appropriate dosing; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • inadequate response or adverse reaction to at least one prior chemotherapy regimen for the requested indication.
					• Documentation of the following is required for combination therapy:
					  • diagnosis of multiple myeloma; **and**

bortezomib			MB	IV	
carfilzomib	Kyprolis	PA	MB	IV	
ixazomib	Ninlaro	PA		PO	

	Clinical Notes
	• appropriate dosing; **and** • prescriber is an oncologist or hematologist; **and** • inadequate response or adverse reaction to at least one prior chemotherapy regimen for the requested indication; **and** • requested agent will be used in combination with dexamethasone with or without additional agents for the treatment of multiple myeloma (excluding proteasome inhibitors). **Ninlaro** • Documentation of the following is required: • diagnosis of multiple myeloma; **and** • appropriate dosing; **and** • prescriber is an oncologist or hematologist; **and** • inadequate response or adverse reaction to at least one prior chemotherapy regimen for the requested indication; **and** • requested agent will be used in combination with dexamethasone with or without additional agents for the treatment of multiple myeloma (excluding proteasome inhibitors); **and** • requested quantity is ≤ three capsules/28 days.

Oncology Agents – Poly-Adenosine Diphosphate Ribose Polymerase (PARP) Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
niraparib	Zejula	PA		PO	**Lynparza for BRCA-mutated high-risk early breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has deleterious or suspected deleterious gBRCAm; **and** • member has been treated with neoadjuvant or adjuvant chemotherapy; **and** • requested quantity is ≤ four units/day. **Lynparza for BRCA-mutated metastatic breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has deleterious or suspected deleterious gBRCAm; **and** • member has been treated with chemotherapy in the
olaparib	Lynparza	PA		PO	
rucaparib	Rubraca	PA		PO	
talazoparib	Talzenna	PA		PO	

	Clinical Notes
	neoadjuvant, adjuvant, or metastatic setting; **and** • if HR-positive breast cancer, member has received prior endocrine therapy or is not a candidate for endocrine therapy; **and** • requested quantity is ≤ four units/day. **Lynparza for BRCA-mutated mCRPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has a deleterious or suspected deleterious germline or somatic mutation in BRCA1 or BRCA2; **and** • requested agent will be used in combination with both of the following: • abiraterone; **and** • prednisone or prednisolone; **and** • requested quantity is ≤ four units/day. **Lynparza for homologous recombination repair (HRR) gene -mutated mCRPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has deleterious or suspected deleterious germline or somatic HRR gene mutation; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: Xtandi (enzalutamide), Yonsa (abiraterone), Zytiga (abiraterone); **and** • requested quantity is ≤ four units/day. **Lynparza for advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer** • For first-line maintenance therapy as monotherapy, documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has deleterious or suspected deleterious gBRCAm or sBRCAm cancer; **and** • member has achieved a partial or complete response to first-line platinum-based chemotherapy; **and** • requested quantity is ≤ four units/day. • For first-line maintenance therapy as combination

	Clinical Notes

	therapy, documentation of the following is required:
	• appropriate diagnosis; **and**
	• prescriber is an oncologist; **and**
	• appropriate dosing; **and**
	• one of the following:
	  • cancer has a deleterious germline or somatic mutation in BRCA1 or BRCA2; **or**
	  • cancer is homologous recombination deficiency (HRD) positive status; **and**
	• member has achieved a partial or complete response to first-line platinum-based chemotherapy; **and**
	• requested agent will be used in combination with bevacizumab; **and**
	• requested quantity is ≤ four units/day.
	• For recurrent disease, documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member has deleterious or suspected deleterious gBRCAm or sBRCAm cancer; **and**
	  • member achieved a partial or complete response to platinum-based chemotherapy; **and**
	  • requested quantity is ≤ four units/day.
	Lynparza for metastatic pancreatic adenocarcinoma (first-line maintenance therapy)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member has deleterious or suspected deleterious gBRCAm; **and**
	  • member has disease which has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen; **and**
	  • requested quantity is ≤ four units/day.
	Lynparza and Talzenna for TNBC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer has deleterious or suspected deleterious gBRCAm; **and**
	  • member has been treated with chemotherapy in the

	Clinical Notes
	neoadjuvant, adjuvant, or metastatic setting; **and** • requested quantity is ≤ four units/day. **Rubraca for BRCA-mutated mCRPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has deleterious gBRCAm or sBRCAm; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: Xtandi (enzalutamide), Yonsa (abiraterone), Zytiga (abiraterone); **and** • inadequate response, adverse reaction, or contraindication to taxane-based chemotherapy; **and** • requested quantity is ≤ four units/day. **Rubraca for advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (maintenance therapy)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has deleterious gBRCAm or sBRCAm cancer; **and** • member has achieved a partial or complete response to platinum-based chemotherapy; **and** • requested quantity is ≤ four units/day. **Talzenna for locally advanced or metastatic breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has deleterious or suspected deleterious gBRCAm; **and** • one of the following: • for the 0.5 mg, 0.75 mg, or 1 mg capsule, requested quantity is ≤ one unit/day; **or** • for the 0.25 mg capsule, requested quantity is ≤ three units/day. **Talzenna for HRR gene-mutated mCRPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and**

	Clinical Notes

	• requested agent will be used in combination with enzalutamide; **and**
	• requested quantity is ≤ one unit/day.
	Zejula for advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer
	• For first-line maintenance therapy, documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member has achieved a partial or complete response to platinum-based chemotherapy; **and**
	  • requested quantity is ≤ one unit/day.
	• For maintenance therapy, documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member has deleterious or suspected deleterious gBRCAm cancer; **and**
	  • member has achieved a partial or complete response to platinum-based chemotherapy; **and**
	  • requested quantity is ≤ one unit/day.

Oncology Agents – Gamma Secretase Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

nirogacestat	Ogsiveo	PA		PO	**Ogsiveo**
					• Documentation of the following is required:
					  • diagnosis of one of the following:
					  • desmoid tumor; **or**
					  • aggressive fibromatosis; **and**
					  • member is ≥ 18 years of age; **and**
					  • prescriber is an oncologist or sarcoma specialist or consult notes from an oncologist or sarcoma specialist are provided; **and**
					  • appropriate dosing; **and**
					  • tumor progression; **and**
					  • inadequate response, adverse reaction, or contraindication to sorafenib; **and**
					  • requested quantity is ≤ two units/day.

Oncology Agents – LAG-3/PD-1 Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

nivolumab / relatlimab-rmbw	Opdualag	PA	MB	IV	**Opdualag**
					• Documentation of the following is required:
					  • diagnosis of unresectable or metastatic melanoma; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • inadequate response or adverse reaction to one or contraindication to all of the following:
					  • Keytruda (pembrolizumab); **or**
					  • Opdivo (nivolumab); **or**
					  • Opdivo Qvantig (nivolumab-hyaluronidase-nvhy); **or**
					  • Opdivo (nivolumab) in combination with Yervoy (ipilimumab); **and**
					  • one of the following:
					  • member is negative for the BRAF V600E or V600K mutation; **or**
					  • member is positive for the BRAF V600E or V600K mutation and inadequate response or adverse reaction to one or contraindication to all of the following:
					  • Braftovi (encorafenib) and Mektovi (binimetinib); **or**
					  • Tafinlar (dabrafenib) and Mekinist (trametinib); **or**
					  • Zelboraf (vemurafenib) and Cotellic (cobimetinib).

Oncology Agents – Nectin-4 Directed Antibody

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

enfortumab vedotin-ejfv	Padcev	PA	MB	IV	**Padcev**
					• Documentation of the following is required:
					  • diagnosis of locally advanced or metastatic urothelial cancer; **and**
					  • prescriber is an oncologist or consult notes from an oncologist are provided; **and**
					  • appropriate dosing; **and**
					  • one of the following:
					  • inadequate response or adverse reaction to both a platinum-based chemotherapy and a PD-1 inhibitor or PD-L1 inhibitor therapy; **or**
					  • member has received at least one prior line of therapy for requested indication and contraindication to all cisplatin-containing

	Clinical Notes
	chemotherapy; **or** • requested agent will be used in combination with Keytruda.

Oncology Agents – Immunomodulator/Immunosuppressant

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
lenalidomide	Revlimid	PA	BP, A90	PO	**lenalidomide** • Documentation of the following is required for FL, MZL, myelodysplastic syndrome, or mantle cell lymphoma (MCL): • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • for the 2.5 mg, 5 mg, or 10 mg capsule, requested quantity is ≤ one unit/day; **or** • for the 15 mg, 20 mg, or 25 mg capsule, requested quantity is ≤ 21 capsules for a 28 day supply; **and** • for previously untreated MZL, clinical rationale for use instead of one of the following: • bendamustine + rituximab; **or** • rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (RCHOP); **or** • rituximab, cyclophosphamide, vincristine, and prednisone (RCVP); **or** • rituximab; **and** • for treatment of FL or MZL, the requested agent will be used in combination with rituximab. • Documentation of the following is required for multiple myeloma: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • for the 2.5 mg, 5 mg, or 10 mg capsule, requested quantity is ≤ one unit/day; **or** • for the 15 mg capsule, one of the following: • requested quantity is ≤ 21 capsules/28 day supply; **or** • requested quantity is ≤ one unit/day and inadequate response to 10 mg daily; **or** • for the 20 mg or 25 mg capsule, requested quantity is ≤ 21 capsules/28 day supply.
pomalidomide	Pomalyst	PA		PO	
thalidomide	Thalomid			PO	

	Clinical Notes
	SmartPA: Claims within quantity limits for lenalidomide will usually process at the pharmacy without a PA request if the member has a MassHealth history of medical claims for multiple myeloma. †

	Pomalyst for multiple myeloma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one or contraindication to both of the following: lenalidomide, Thalomid (thalidomide); **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following proteasome inhibitors: bortezomib, Kyprolis (carfilzomib), Ninlaro (ixazomib), Velcade (bortezomib); **and**
	  • requested quantity is ≤ 21 capsules/28 day supply.
	Pomalyst for Kaposi sarcoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • member has acquired immunodeficiency syndrome (AIDS) and has failed highly active antiretroviral therapy; **or**
	  • member is human immunodeficiency virus (HIV)-negative; **and**
	  • inadequate response, adverse reaction, or contraindication to both of the following: pegylated liposomal doxorubicin, paclitaxel; **and**
	  • requested quantity is ≤ 42 capsules/28 day supply.

Oncology Agents – Tropomyosin Receptor Kinase (TRK) Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

entrectinib	Rozlytrek	PA		PO	**Rozlytrek for solid tumors with neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**

larotrectinib	Vitrakvi	PA		PO	

	Clinical Notes

	• appropriate dosing; **and**
	• for Rozlytrek oral pellet, medical necessity for the use of the oral pellet formulation instead of the oral capsule compounded into a suspension; **and**
	• one of the following:
	  • tumor is metastatic; **or**
	  • member is not a candidate for surgical resection; **and**
	• one of the following:
	  • for the 50 mg oral pellet, requested quantity is ≤ 12 units/day; **or**
	  • for the 100 mg capsule, requested quantity is ≤ one unit/day; **or**
	  • for the 200 mg capsule, requested quantity is ≤ three units/day; **and**
	• one of the following:
	  • requested agent is first-line for the requested indication; **or**
	  • member has no satisfactory alternative treatment options; **or**
	  • disease has progressed following at least one first-line treatment for the requested indication (e.g., chemotherapy, radiation, surgical intervention).
	Rozlytrek for ROS1-positive metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer is ROS1 positive; **and**
	  • for Rozlytrek oral pellet, medical necessity for the use of the oral pellet formulation instead of the oral capsule compounded into a suspension; **and**
	  • one of the following:
	  • for the 50 mg oral pellet, requested quantity is ≤ 12 units/day; **or**
	  • for the 100 mg capsule, requested quantity is ≤ one unit/day; **or**
	  • for the 200 mg capsule, requested quantity is ≤ three units/day.
	Vitrakvi
	• Documentation of the following is required:
	  • diagnosis of solid tumors with NTRK gene fusion without a known acquired resistance mutation; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**

					Clinical Notes

					• one of the following:
					  • tumor is metastatic; **or**
					  • member is not a candidate for surgical resection; **and**
					• one of the following:
					  • requested agent is first-line for the requested indication; **or**
					  • member has no satisfactory alternative treatment options; **or**
					  • disease has progressed following at least one first-line treatment for the requested indication (e.g., chemotherapy, radiation, surgical intervention); **and**
					• one of the following:
					  • for the 100 mg capsule, requested quantity is ≤ two units/day; **or**
					  • for the 25 mg capsule, requested quantity is ≤ six units/day; **or**
					  • for the oral solution, requested quantity is ≤ ten mL/day; **and**
					• if the request is for oral solution formulation, medical necessity for the use of an oral solution formulation (e.g., swallowing disorder) must be provided.
					MassHealth Drug Utilization Review will be reaching out to prescribers after Vitrakvi PA approval to verify clinical effectiveness.

Oncology Agents – Multiple Receptor Antibodies

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

amivantamab-vmjw	Rybrevant	PA	MB	IV	**Rybrevant for locally advanced or metastatic NSCLC**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • one of the following:
					  • cancer has EGFR exon 20 insertion mutation; **or**
					  • cancer displays the EGFR exon 19 deletion or exon 21 L858R mutation; **and**
					  • for EGFR exon 20 insertion mutation, one of the following:
					  • requested agent will be used as monotherapy and disease progression during or following one platinum-containing regimen; **or**
					  • requested agent will be used in combination with carboplatin and pemetrexed; **or**

	Clinical Notes

	• for EGFR exon 19 deletion or exon 21 L858R mutation, one of the following:
	  • inadequate response, adverse reaction, or contraindication to Tagrisso (osimertinib) with or without chemotherapy and requested agent will be used in combination with Lazcluze (lazertinib); **or**
	  • requested agent will be used in combination with carboplatin and pemetrexed and disease progression during or following therapy with an EGFR tyrosine kinase inhibitor (e.g., afatinib, dacomitinib, erlotinib, gefitinib, lazertinib, osimertinib).

Oncology Agents – Antiestrogen

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
tamoxifen solution	Soltamox			PO	
tamoxifen tablet			M90	PO	

Oncology Agents – Retinoids

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
bexarotene	Targretin		BP, A90	PO / Topical	
tretinoin capsule			A90	PO	

Oncology Agents – CLDN18.2 Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

zolbetuximab-clzb	Vyloy	PA	MB	Vyloy
				• Documentation of the following is required:
				  • diagnosis of locally advanced unresectable or metastatic HER-2-negative gastric or gastroesophageal junction adenocarcinoma; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is an oncologist; **and**
				  • tumor expresses CLDN18.2; **and**
				  • appropriate dosing; **and**
				  • requested agent will be used in combination with both of the following: fluoropyrimidine-containing chemotherapy and platinum-containing chemotherapy.

Oncology Agents – Anthracenediones

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
mitoxantrone			MB	IV	

Oncology Agents – Vinca Alkaloid

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
vinblastine			MB	IV	
vincristine			MB	IV	
vinorelbine				IV	

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Cancer

Non-FDA-approved, for example:

- Cancer

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.

- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Please see clinical criteria for agents requiring PA in the table above under the Clinical Notes section.

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 58 - Anticoagulants and Antiplatelet Agents

Drug Category: Blood and Circulation

Medication Class/Individual Agents: Anticoagulants and Antiplatelet Agents

I. Prior-Authorization Requirements

Platelet Aggregation Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
anagrelide	Agrylin		# , A90
aspirin / extended-release dipyridamole			M90
cilostazol			A90
clopidogrel	Plavix		# , A90
dipyridamole			M90
prasugrel	Effient		# , A90
ticagrelor	Brilinta		# , A90
vorapaxar	Zontivity	PA	

Intravenous/Subcutaneous Anticoagulants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dalteparin	Fragmin		
enoxaparin	Lovenox		#
fondaparinux	Arixtra		#
heparin			
heparin lock flush			

Oral Anticoagulants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
apixaban	Eliquis		
dabigatran capsule	Pradaxa		BP, M90
dabigatran oral pellet	Pradaxa	PA	
edoxaban	Savaysa	PA	
rivaroxaban 10 mg, 15 mg, 20 mg tablet, starter pack	Xarelto		BP
rivaroxaban 2.5 mg tablet	Xarelto	PA - > 2 units/day	BP, A90
rivaroxaban suspension	Xarelto	PA - ≥ 18 years	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Antiplatelet Agents:

- Antiplatelet agents play a major role in the management of cardiovascular (CV), cerebrovascular, and peripheral vascular diseases. The recommendation for use of these agents as monotherapy or combination therapy depends on the specific clinical indication and the member's risk for thromboembolic events and/or bleeding events.
- Vorapaxar is the first in a new class of antiplatelet agents called protease-activated receptor-1 (PAR-1) antagonists. This drug is FDA approved for the reduction of thrombotic cardiovascular events in members with a history of myocardial infarction or with peripheral arterial disease. Vorapaxar has been studied only as an addition to aspirin and/or clopidogrel. There is no experience with the use of vorapaxar administered as monotherapy.

Anticoagulant Agents:

- There are several oral and injectable anticoagulants commercially available for the management of a variety of medical conditions. The oral anticoagulants include apixaban, dabigatran, edoxaban, rivaroxaban, and warfarin.

Oral Anticoagulants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
warfarin			A90

Salicylates			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aspirin 325 mg, 500 mg, 650 mg			*, A90
aspirin 81 mg			*, M90
aspirin suppository			*
aspirin with buffers			*, A90

Clinical Notes

- Warfarin is a vitamin K antagonist that works by interfering with the synthesis of vitamin K dependent clotting factors (II, VII, IX, and X) as well as the anticoagulant proteins C and S. It is dosed once daily. Due to its narrow therapeutic window and various food and drug interactions, it requires frequent monitoring of international normalized ratios (INR) to monitor for safety and efficacy. Warfarin does not require dosage adjustments in members with renal impairment.
- The direct oral anticoagulants (DOACs) target a single enzyme involved in the coagulation cascade. Dabigatran is a prodrug that is converted to dabigatran, a potent, competitive inhibitor of thrombin. Apixaban, edoxaban and rivaroxaban all selectively inhibit factor Xa, thereby preventing the generation of thrombin and ultimately preventing platelet activation and the formation of fibrin clots. These agents require dose adjustments in members with renal impairment. When used for non-valvular atrial fibrillation, apixaban may be used in severe renal impairment, including members on hemodialysis.
- Edoxaban and rivaroxaban are both approved for once-daily dosing (with the exception of the first 21 days for treatment of a deep vein thrombosis [DVT] or pulmonary embolism [PE] with rivaroxaban) whereas dabigatran and apixaban are both administered twice daily. In addition, these DOACs are not associated with the same food and drug interactions as with warfarin treatment. Available antidotes are currently FDA-approved for apixaban, dabigatran, rivaroxaban, and warfarin.

#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Myocardial infarction (Zontivity)

- Nonvalvular atrial fibrillation (Savaysa)
- Peripheral artery disease (PAD) (Zontivity)
- Reduction of risk of major CV events in chronic coronary artery disease (CAD)/PAD (rivaroxaban 2.5 mg)
- Treatment of DVT and/or PE (Savaysa)
- Treatment or reduction of risk of recurrent DVT and/or PE in pediatric members (Pradaxa oral pellet)

non FDA-approved, for example:

- Nonvalvular atrial fibrillation (Xarelto suspension)
- Reduction of risk of major thrombotic vascular events in CAD/PAD (Xarelto suspension)
- Treatment or reduction of risk of recurrent DVT and/or PE (Xarelto suspension)

Note: The above lists may not include all FDA-approved and non FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Pradaxa oral pellet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ three months of age and < 12 years of age; **and**
  - member has received or will receive ≥ five days of injectable or intravenous anticoagulation prior to starting the requested agent; **and**
  - inadequate response, adverse drug reaction, or contraindication to one of the following: Xarelto oral suspension, Xarelto tablets **and**
  - appropriate dosing; **and**
  - if the member is ≥ eight years of age, one of the following:
    - inadequate response, adverse drug reaction, or contraindication to dabigatran capsule; **or**
    - medical necessity for the requested formulation instead of the capsule formulation available without PA as noted by one of the following:
      - member has a swallowing disorder or condition affecting the ability to swallow; **or**
      - member is unable to swallow capsules.

rivaroxaban 2.5 mg tablet over quantity limits

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding FDA recommended dosing.

Savaysa

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response, adverse drug reaction, or contraindication to all of the following: Eliquis, dabigatran capsule, and Xarelto.

Xarelto suspension for members ≥ 18 years of age

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the suspension formulation as noted by one of the following:
    - member utilizes tube feeding (NG or gastric tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **and**
  - appropriate dosing.

Zontivity

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ one tablet/day; **and**
  - member does not have a history of stroke, transient ischemic attack, or intracranial hemorrhage; **and**
  - requested agent will be used in combination with one of the following: aspirin, clopidogrel.

†Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 59 - Anesthetics - Topical

Drug Category: Dermatological Agents

Medication Class/Individual Agents: Local Anesthetics

I. Prior-Authorization Requirements

Topical Anesthetics – Ophthalmic Topical Anesthetics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
chloroprocaine ophthalmic gel	Iheezo	PA	
fluorescein / benoxinate			A90
lidocaine ophthalmic gel	Akten		
proparacaine			A90
tetracaine			A90

Topical Anesthetics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
capsaicin high dose patch	Qutenza	PA	MB
chloroprocaine injection	Clorotekal		MB
chloroprocaine vial	Nesacaine		MB
lidocaine / prilocaine			A90
lidocaine 1.8% patch	Ztlido	PA	
lidocaine 4% patch		PA - > 4 patches/day	A90
lidocaine 5% patch	Lidoderm	PA - > 3 patches/day	# , A90
lidocaine ointment			A90
lidocaine topical jelly, solution			
lidocaine viscous solution			

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Lidocaine/prilocaine is indicated as a topical anesthetic on normal intact skin for local analgesia and on genital mucous membranes for superficial minor surgery and pre -treatment for infiltration anesthesia.
- Lidocaine/prilocaine may have improved dermal analgesia compared to other topical lidocaine products due to its eutectic mixture formulation. However, this agent is indicated only as short term anesthesia and should not be used chronically.

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA

status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Dermatological procedure requiring local analgesia (lidocaine/prilocaine)
- Neurologic pain condition (lidocaine 4% patch)
- Ocular surface anesthesia (Iheezo)
- Pain associated with diabetic peripheral neuropathy (Qutenza)
- Pain associated with post-herpetic neuralgia (lidocaine 5% patch, Qutenza, Ztlido)
- Surface anesthesia and temporary pain relief (lidocaine ointment)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Iheezo

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an ophthalmologist or consult notes from an ophthalmologist are provided; **and**
  - inadequate response or adverse reaction to one, or contraindication to all of the following: Akten, fluorescein/benoxinate, proparacaine, tetracaine.

lidocaine 4% patch > four patches/day

- Documentation of all the following is required:
  - appropriate diagnosis; **and**

- medical necessity for the use of > four patches/day.

lidocaine 5% patch > three patches/day

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the use of > three patches/day.

lidocaine 5 % ointment, lidocaine/prilocaine

- Available without PA. However, requests for members with a diagnosis code for premature ejaculation will deny at the pharmacy as PA required.
- Please note: The MassHealth agency does not pay for any drug when used for the treatment of sexual dysfunction as described in 130 CMR 406.413(B) "Limitations on Coverage of Drugs – Drug Exclusions" (see link below).

https://www.mass.gov/regulations/130-CMR-406000-pharmacy-services

Qutenza for diabetic peripheral neuropathy

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: topical capsaicin agent, lidocaine patch; **and**
  - one of the following:
    - medical necessity for transdermal formulation as noted by one of the following:
      - member utilizes tube feeding (G-tube/J-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
      - member is < 13 years of age; **or**
    - inadequate response, adverse reaction, or contraindication to all of the following classes of oral agents:
      - tricyclic antidepressant; **and**
      - anticonvulsant (gabapentin at a dose of at least 1,200 mg/day for two weeks, or pregabalin); **and**
      - venlafaxine or duloxetine.

Qutenza for post-herpetic neuralgia

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: topical capsaicin agent, lidocaine patch; **and**
  - one of the following:
    - medical necessity for transdermal formulation as noted by one of the following:
      - member utilizes tube feeding (G-tube/J-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
      - member is < 13 years of age; **or**
    - inadequate response, adverse reaction, or contraindication to both of the following classes of oral agents:
      - tricyclic antidepressant; **and**
      - anticonvulsant (gabapentin at a dose of at least 1,200 mg/day for two weeks, or pregabalin).

Ztlido

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: 4% lidocaine patch, 5% lidocaine patch; **and**
  - one of the following:
    - requested quantity is ≤ three patches/day; **or**

- medical necessity for > three patches/day.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 60 - Hereditary Angioedema Agents

Drug Category: Complement Inhibitors

Medication Class/Individual Agents: Hereditary Angioedema Agents

I. Prior-Authorization Requirements

Hereditary Angioedema Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
berotralstat	Orladeyo	PA	
c1 esterase inhibitor, human-Berinert	Berinert	PA	
c1 esterase inhibitor, human-Cinryze	Cinryze	PA	
c1 esterase inhibitor, human-Haegarda	Haegarda	PA	
c1 esterase inhibitor, recombinant-Ruconest	Ruconest	PA	
ecallantide	Kalbitor	PA	MB
icatibant	Firazyr	PA	
lanadelumab-flyo	Takhzyro	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Berotralstat, Cinryze (c1 esterase inhibitor, human), Haegarda (c1 esterase inhibitor, human), and lanadelumab-flyo are approved for the routine prophylaxis against angioedema attacks in adolescents 12 years of age and older and adult patients with hereditary angioedema (HAE). Cinryze (c1 esterase inhibitor, human) and Haegarda (c1 esterase inhibitor, human) are also approved in children six years of age and older. Lanadelumab-flyo is also approved in children two years of age and older.
  - Prophylaxis may be administered short-term in anticipation of exposure to known triggers such as a procedure or period of stress, or long-term for the reduction of attack rates. Long-term prophylaxis should be considered based upon multiple parameters, including attack frequency, comorbidities, patient preferences, access to emergency care.[1-3]
  - In patients six years of age and older who are receiving prophylaxis with lanadelumab-flyo and have been HAE attack free for six months, every four-week dosing should be considered instead of every two-week dosing. Patients two to less than six years of age are only recommended to receive lanadelumab-flyo every four weeks.

	Clinical Notes
	• Berinert (c1 esterase inhibitor, human), ecallantide, icatibant, and Ruconest (c1 esterase inhibitor, recombinant) are all FDA approved for the acute attacks of HAE. • Berinert (c1 esterase inhibitor, human), Cinryze (c1 esterase inhibitor, human), Haegarda (c1 esterase inhibitor, human), icatibant, lanadelumab-flyo, and Ruconest (c1 esterase inhibitor, recombinant) are approved for patient self-administration after training by a healthcare professional. • Ecallantide is not approved for self- administration and should only be administered by a doctor or nurse with medical support to manage serious allergic reactions and HAE. [1] Zuraw B, Farkas H. Hereditary angioedema (due to C1 inhibitor deficiency): General care and long-term prophylaxis. In Saini S (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2025 [cited 2025 March 5]. Available from: http://www.utdol.com/utd/index.do. [2] Busse PJ, Christiansen SC, Riedl MA, Banerji A, Bernstein JA, Castaldo AJ, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021;9(1):132-150.e3. [3] Maurer M, Magerl M, Betschel S, Aberer W, Ansotegui IJ, Aygören-Pürsün E, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2021 revision and update. Allergy. 2022;77(7):1961-1990.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Treatment of acute attacks of hereditary angioedema (HAE) (Berinert, icatibant, Kalbitor, Ruconest)

- Prophylaxis against angioedema attacks in patients with HAE (Cinryze, Haegarda, Orladeyo, Takhzyro)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Berinert, icatibant, Kalbitor, Ruconest

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an allergist or immunologist or consult notes from an allergist or immunologist regarding the diagnosis are provided; **and**
  - appropriate dosing.
- For recertification, documentation of the use or expiration of a previously approved product is required.

Cinryze, Haegarda, Orladeyo, Takhzyro

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an allergist or immunologist or consult notes from an allergist or immunologist regarding the diagnosis are provided; **and**
  - one of the following:
    - member has > one HAE attack/30 days; **or**
    - member has a history of recurrent laryngeal attacks; **and**
  - appropriate dosing.
- For recertification of Takhzyro, documentation of one of the following is required:
  - requested dosing is every four weeks; **or**
  - requested dosing is every two weeks and one of the following:
    - member has had ≥ one HAE attack in the last six months; **or**
    - both of the following:
      - member has been HAE attack free for ≥ six months; **and**

- clinical rationale for every two-week dosing instead of every-four week dosing.

MassHealth Evaluation Criteria

Table 61 - Gastrointestinal Drugs – Antidiarrheals, Constipation, and Miscellaneous Gastrointestinal Agents

Drug Category: Gastrointestinal

Medication Class/Individual Agents: Antidiarrheals, Antispasmodics, Bile Acid Agents, Bowel Preparations, Constipation Agents

I. Prior-Authorization Requirements

Gastrointestinal Drugs – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bezlotoxumab	Zinplava	PA	
bifidobacterium infantis	Align	PA - ≥ 21 years	
fecal microbiota spores, live-brpk	Vowst	PA	
fecal microbiota, live-jslm	Rebyota	PA	
lactobacillus rhamnosus GG	Culturelle	PA - ≥ 21 years	
saccharomyces boulardii	Florastor	PA - ≥ 21 years	
teduglutide injection	Gattex	PA	BP

Gastrointestinal Drugs – Constipation Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aluminum hydroxide			*, A90
bisacodyl enema, suppository			*, A90
bisacodyl tablet			*, M90
calcium polycarbophil			*, M90
dextrin			*, A90
docusate / benzocaine enema	Enemeez Plus		A90
docusate sodium capsule, tablet			*, M90
docusate sodium enema	Enemeez		A90
docusate sodium solution, syrup			*, A90
lactulose packet		PA	
lactulose solution			A90
linaclotide	Linzess		
lubiprostone	Amitiza	PA	M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Alosetron

- Alosetron is a selective 5-HT3 receptor antagonist used to treat irritable bowel syndrome (IBS).
- Due to the risk of serious gastrointestinal complications, providers prescribing alosetron must be enrolled in Lotronex Prescribing Program and document a signed physician-patient agreement.

Opium tincture

- Opium tincture is not recommended for use in children and caution is recommended for use in the elderly.

Bowel Preparation Agents

- All preparations are considered equally efficacious; however, certain products may have the advantage of reduced side effects or lower fluid requirements.

Gastrointestinal Drugs – Constipation Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
magnesium salts			*, A90
methylcellulose			*, A90
methylnaltrexone	Relistor	PA	
mineral oil			*, A90
naldemedine	Symproic	PA	
naloxegol	Movantik	PA	
plecanatide	Trulance	PA	
polyethylene glycol 3350			*, A90
prucalopride	Motegrity	PA	BP
psyllium capsule			A90
psyllium powder			*, A90
sennosides syrup			*, A90
sennosides tablet			*, M90
tenapanor 50 mg tablet	Ibsrela	PA	

Gastrointestinal Drugs – Antispasmodics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dicyclomine	Bentyl		# , A90
hyoscyamine oral			A90

Gastrointestinal Drugs – Bile Acid Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
chenodiol		PA	A90
cholic acid	Cholbam	PA	
elafibranor	Iqirvo	PA	
maralixibat	Livmarli	PA	
obeticholic acid	Ocaliva	PA	
odevixibat	Bylvay	PA	
seladelpar	Livdelzi	PA	
ursodiol 200 mg, 400 mg capsule		PA	A90
ursodiol 250 mg tablet	Urso		# , A90
ursodiol 300 mg capsule			A90
ursodiol 500 mg tablet	Urso Forte		# , A90

Gastrointestinal Drugs – Bowel Preparation Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
polyethylene glycol / sodium sulfate / potassium chloride / magnesium sulfate / sodium chloride	Suflave	PA	
polyethylene glycol-electrolyte solution			A90
polyethylene glycol-electrolyte solution-Golytely	Golytely		# , A90
polyethylene glycol-electrolyte solution-Moviprep	Moviprep		BP, A90
polyethylene glycol-electrolyte solution-Plenvu	Plenvu		
sodium picosulfate / magnesium oxide / anhydrous citric acid-Clenpiq	Clenpiq	PA	
sodium sulfate / magnesium sulfate / potassium chloride	Sutab	PA	
sodium sulfate / potassium sulfate / magnesium sulfate	Suprep		BP, A90

Gastrointestinal Drugs – Antidiarrhea Medications			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alosetron	Lotronex	PA	A90
bismuth subsalicylate			*, A90
crofelemer	Mytesi	PA	
difenoxin / atropine	Motofen		
diphenoxylate / atropine	Lomotil		#
eluxadoline	Viberzi	PA	
loperamide			*
opium tincture		PA	

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Alagille syndrome (Bylvay, Livmarli)
- Bile acid synthesis disorders due to single enzyme defects with or without familial hypertriglyceridemia (Cholbam)
- Bowel preparation prior to colonoscopy procedure or surgery (Clenpiq, Suflave, Sutab)
- Chronic idiopathic constipation (lactulose packet, lubiprostone, prucalopride, Trulance)
- Gallstones (chenodiol, ursodiol)
- IBS with constipation (Ibsrela, lactulose packet, lubiprostone, Trulance)
- Opioid-induced constipation in adults with chronic, non-cancer pain (lubiprostone, Movantik, Relistor, Symproic)
- Opioid-induced constipation in palliative care members (lactulose packet, Relistor)
- Peroxisomal disorders with or without familial hypertriglyceridemia (Cholbam)
- Prevention of gallstone formation (ursodiol)
- Prevention of recurrent Clostridium difficile infection (Rebyota, Vowst)
- Primary biliary cholangitis (Iqirvo, Livdelzi, Ocaliva)
- Progressive familial intrahepatic cholestasis (Bylvay, Livmarli)
- Severe and chronic diarrhea-predominant IBS (alosetron, Viberzi)
- Short bowel syndrome (Gattex)
- Symptomatic relief of non-infectious diarrhea in adult members with HIV/AIDS on anti-retroviral therapy (Mytesi)
- Treatment of chronic diarrhea (opium tincture)
- Recurrent Clostridium difficile infection (Zinplava)

Non-FDA-approved, for example:

- Cerebrotendinous xanthomatosis (chenodiol)
- Hepatic encephalopathy (lactulose packet)
- Pediatric requests for chronic idiopathic constipation or irritable bowel syndrome with constipation (lubiprostone)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.

- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Align, Culturelle, Florastor ≥ 21 years of age

- Documentation of the following is required for the diagnosis of antibiotic associated diarrhea (prophylaxis):
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to two or contraindication to all of the following: alosetron, bismuth subsalicylate, diphenoxylate/atropine, loperamide; **and**
  - current antibiotic therapy.
- Documentation of the following is required for the diagnosis of bacterial overgrowth:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to one of the following: amoxicillin-clavulanic acid, ciprofloxacin, doxycycline, metronidazole, neomycin, tetracycline, trimethoprim-sulfamethoxazole, rifaximin.
- Documentation of the following is required for the diagnosis of chronic constipation:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to three or contraindication to all of the following: docusate, fiber supplementation/bulk-forming laxatives, lubiprostone or Linzess or prucalopride or Trulance, osmotic laxatives, saline laxatives, stimulant laxatives.
- Documentation of the following is required for the diagnosis of C. difficile associated diarrhea:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to one or contraindication to all of the following: fidaxomicin, metronidazole, rifaximin, oral vancomycin.
- Documentation of the following is required for the diagnosis of irritable bowel syndrome associated with constipation (IBS-C):
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to two or contraindication to all of the following: docusate, fiber supplementation/bulk-forming laxatives, lubiprostone or Linzess or Trulance, osmotic laxatives, saline laxatives, stimulant laxatives.
- Documentation of the following is required for the diagnosis of irritable bowel syndrome associated with diarrhea (IBS-D):
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to two or contraindication to all of the following: antibiotic (rifaximin), anti-diarrheal, antispasmodic, bile acid sequestrant, tricyclic antidepressant (TCA).
- Documentation of the following is required for the diagnosis of recurrent vaginitis:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to two or contraindication to all of the following: butoconazole, clindamycin, clotrimazole, fluconazole, metronidazole, miconazole, terconazole.

alosetron

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a gastroenterologist or consultation notes from a gastroenterologist are provided; **and**
  - appropriate dosing (0.5 mg twice daily initial, up to 1 mg twice daily maintenance); **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: antispasmodics, bile acid sequestrant, bismuth subsalicylate, bulk-forming agent, diphenoxylate/atropine, loperamide, TCAs.

Bylvay

- Documentation of the following is required for diagnosis of progressive familial intrahepatic cholestatis (PFIC):
  - appropriate diagnosis; **and**
  - genetic testing does not indicate PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of BSEP-3; **and**
  - member is ≥ three months of age; **and**
  - presence of moderate to severe pruritus; **and**
  - no evidence of portal hypertension or decompensated cirrhosis; **and**
  - no history of liver transplant; **and**
  - no history of biliary diversion surgery within the past six months; **and**
  - inadequate response, adverse reaction, or contraindication to ursodiol 30 mg/kg/day; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: cholestyramine 4 g/day, rifampin 10 mg/kg/day; **and**
  - member's current weight; **and**
  - appropriate dosing.

- Documentation of the following is required for diagnosis of Alagille syndrome:
  - appropriate diagnosis; **and**
  - member is ≥ one year of age; **and**
  - genetic testing documenting JAG1 or NOTCH2 deletion or genetic testing confirming mutation in GAA gene; **and**
  - member has moderate to severe pruritus caused by cholestasis; **and**
  - prescriber is a specialist (hepatologist, gastroenterologist, or Alagille syndrome specialist) or consult notes from a specialist are provided; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: bile acid sequestrant, naltrexone, rifampin, sertraline, ursodiol; **and**
  - inadequate response, adverse reaction, or contraindication to Livmarli; **and**
  - member's current weight; **and**
  - appropriate dosing.

chenodiol

- Documentation of the following is required for a diagnosis of cerebrotendinous xanthomatosis (CTX):
  - appropriate diagnosis; **and**
  - results of molecular genetic testing confirming the diagnosis of cerebrotendinous xanthomatosis; **and**
  - appropriate dosing or documentation that the member is stable on a lower or higher dose; **and**
  - member’s current weight.

- Documentation of the following is required for a diagnosis of gallstones:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to an ursodiol product; **and**
  - member's current weight.

Cholbam

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ three weeks of age; **and**
  - member's current weight.

Clenpiq, Suflave, Sutab

- Documentation of the following is required:
  - one of the following:
    - inadequate response or adverse reaction to one bowel prep product available without PA; **or**
    - medical necessity for the requested product.

Gattex

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ one year of age; **and**
  - dependence on parenteral nutrition or intravenous fluids for at least one year; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: anti-diarrheal, H2 antagonist, octreotide, proton pump inhibitor, ursodiol; **and**
  - prescriber is a gastroenterologist or consult notes from a gastroenterologist are provided; **and**
  - appropriate dosing.

Ibsrela

- Documentation of the following is required for diagnosis of IBS with constipation:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ two units/day; **and**
  - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk-forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
  - inadequate response, adverse reaction, or contraindication to lubiprostone; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Linzess and Trulance.

Iqirvo, Livdelzi

- Documentation of the following is required:
  - appropriate diagnosis of primary biliary cholangitis supported by laboratory testing results and medical records documenting two of the following:
    - alkaline phosphatase elevation; **or**
    - presence of antimitochondrial antibody; **or**
    - histopathologic evidence of cholangitis and destruction of small or medium-sized bile ducts on biopsy, if performed; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one unit/day; **and**
  - one of the following:
    - alkaline phosphatase ≥ 1.67 x upper limit of normal; **or**
    - total bilirubin > upper limit of normal; **and**
  - one of the following:
    - inadequate response to ursodiol at a dose of 13 to 15 mg/kg/day for at least one year and request is for use with ursodiol 13 to 15 mg/kg/day; **or**
    - adverse reaction or contraindication to ursodiol; **and**

- for Iqirvo, requested agent will not be used concurrently with Livdelzi or Ocaliva; **and**
- for Livdelzi, requested agent will not be used concurrently with Iqirvo or Ocaliva.

- For recertification, documentation of one of the following is required:
  - if alkaline phosphatase was > upper limit of normal at baseline, current alkaline phosphatase <1.67-times upper limit of normal; **or**
  - ≥15% decrease in alkaline phosphatase; **or**
  - if total bilirubin was > upper limit of normal at baseline, current total bilirubin ≤ upper limit of normal.

lactulose packet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an adverse reaction or contraindication to lactulose solution.

Livmarli

- Documentation of the following is required for diagnosis of progressive familial intrahepatic cholestatis (PFIC):
  - appropriate diagnosis; **and**
  - genetic testing does not indicate PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of BSEP-3; **and**
  - member is ≥ 12 months of age; **and**
  - presence of moderate to severe pruritus; **and**
  - no evidence of portal hypertension or decompensated cirrhosis; **and**
  - no history of liver transplant; **and**
  - no history of biliary diversion surgery within the past six months; **and**
  - inadequate response, adverse reaction, or contraindication to ursodiol 30 mg/kg/day; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: cholestyramine 4 g/day, rifampin 10 mg/kg/day; **and**
  - inadequate response, adverse reaction, or contraindication to Bylvay; **and**
  - member's current weight; **and**
  - appropriate dosing.

- Documentation of the following is required for diagnosis of Alagille syndrome:
  - appropriate diagnosis; **and**
  - member is ≥ three months of age; **and**
  - genetic testing documenting JAG1 or NOTCH2 deletion or genetic testing confirming mutation in GAA gene; **and**
  - member has moderate to severe pruritus caused by cholestasis; **and**
  - prescriber is a specialist (hepatologist, gastroenterologist, or Alagille syndrome specialist) or consult notes from a specialist are provided; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: bile acid sequestrant, naltrexone, rifampin, sertraline, ursodiol; **and**
  - member's current weight; **and**
  - appropriate dosing.

lubiprostone

- Documentation of the following is required for members ≥ 18 years of age:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk-forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
  - for a diagnosis of IBS with constipation or chronic idiopathic constipation, inadequate response or adverse reaction to one or

contraindication to both of the following: Linzess and Trulance; **and**
  - appropriate dosing.
- Documentation of the following is required for members ≥ three years of age and <18 years of age:
  - diagnosis of chronic idiopathic constipation or irritable bowel syndrome with constipation; **and**
  - prescriber is a specialist in gastroenterology; **and**
  - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk-forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
  - appropriate dosing.

Movantik, prucalopride, Symproic
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one unit/day; **and**
  - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk-forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
  - inadequate response, adverse reaction, or contraindication to lubiprostone; **and**
  - for prucalopride, inadequate response or adverse reaction to one or contraindication to both of the following: Linzess and Trulance; **and**
  - for a compounded formulation of prucalopride, appropriate dosing.

Mytesi
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: bismuth subsalicylate, diphenoxylate/atropine, loperamide; **and**
  - requested quantity is ≤ two units/day.

Non-preferred Probiotics
- Documentation of the following is required:
  - Diagnosis of one of the following:
    - antibiotic associated diarrhea (prophylaxis); **or**
    - bacterial overgrowth; **or**
    - chronic constipation; **or**
    - C. difficile associated diarrhea; **or**
    - irritable bowel syndrome with constipation; **or**
    - irritable bowel syndrome with diarrhea; **or**
    - recurrent vaginitis; **and**
  - member must meet all criteria as written above for the listed diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: Align, Culturelle, Florastor.

Ocaliva
- Documentation of the following is required:
  - appropriate diagnosis of primary biliary cholangitis supported by laboratory testing results and medical records documenting two of the following:
    - alkaline phosphatase elevation; **or**
    - presence of antimitochondrial antibody; **or**

- histopathologic evidence of cholangitis and destruction of small or medium-sized bile ducts on biopsy, if performed; **and**
- member is ≥ 18 years of age; **and**
- one of the following:
  - alkaline phosphatase ≥ 1.67 x upper limit of normal; **or**
  - total bilirubin > upper limit of normal; **and**
- one of the following:
  - inadequate response to ursodiol at a dose of 13 to 15 mg/kg/day for at least one year and request is for use with ursodiol 13 to 15 mg/kg/day; **or**
  - adverse reaction or contraindication to ursodiol; **and**
- requested quantity is ≤ one unit/day; **and**
- requested agent will not be used concurrently with Iqirvo or Livdelzi; **and**
- one of the following:
  - request is for initiation of treatment and requested dose is 5 mg once daily; **or**
  - request is for continuation of treatment beyond three months and both of the following:
    - if request is for continuation of treatment beyond 12 months, one of the following:
      - if alkaline phosphatase was > upper limit of normal at baseline, alkaline phosphatase < 1.67-times upper limit of normal; **or**
      - ≥15% decrease in alkaline phosphatase; **or**
      - if total bilirubin was > upper limit of normal at baseline, total bilirubin ≥ upper limit of normal; **or**
      - clinical rationale for continued treatment; **and**
    - one of the following:
      - requested dose is 10 mg once daily; **or**
      - requested dose and/or frequency is ≤ 10 mg once daily and one of the following:
        - positive response to therapy at current dose (defined as alkaline phosphatase < 1.67-times upper limit of normal, total bilirubin ≤ upper limit of normal, and ≥ 15% decrease in alkaline phosphatase); **or**
        - clinical rationale for not titrating the dose to 10 mg once daily.

opium tincture

- Documentation of the following is required:
  - diagnosis of chronic diarrhea; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: bismuth subsalicylate, diphenoxylate/atropine, loperamide; **and**
  - requested quantity is ≤ 2.4 mL/day.

Rebyota

- Documentation of the following is required:
  - indication for prevention of recurrent Clostridium difficile infection with ≥ one episode of Clostridium difficile infection following initial infection (≥ two total episodes of CD including initial infection); **and**
  - prescriber is an infectious disease specialist or gastroenterologist or consult notes from a specialist are provided; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: Dificid, vancomycin capsule or oral solution, Zinplava; **and**
  - medical necessity for requested agent instead of fecal microbiota transplant via other methods (e.g., IND protocol, stool banks); **and**
  - requested quantity is ≤ single dose.

Relistor

- Documentation of the following is required for diagnosis of opioid induced constipation with advanced illness receiving palliative care:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk-forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
  - for the injection formulation, medical necessity for the requested formulation instead of tablet formulation.
- Documentation of the following is required for diagnosis of opioid induced constipation with chronic non-cancer pain:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk-forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Movantik and Symproic; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Linzess and lubiprostone; **and**
  - for the injection formulation, medical necessity for the requested formulation instead of tablet formulation.

Trulance
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one unit/day; **and**
  - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk-forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
  - inadequate response, adverse reaction, or contraindication to Linzess.

ursodiol 200 mg, 400 mg
- Documentation of the following is required for the diagnosis of gallstones:
  - appropriate diagnosis; **and**
  - member is not a candidate for cholecystectomy; **and**
  - medical necessity for the requested agent instead of an ursodiol product available without PA; **and**
  - member's current weight.
- Documentation of the following is required for the prevention of gallstone formation:
  - appropriate diagnosis; **and**
  - medical necessity for the requested agent instead of an ursodiol product available without PA.

Viberzi
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a gastroenterologist or provides consult notes from a gastroenterologist; **and**
  - requested quantity is ≤ two units/day; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: antispasmodics, bile acid sequestrant, bismuth subsalicylate, bulk-forming agent, diphenoxylate/atropine, loperamide, TCAs.

Vowst
- Documentation of the following is required:

- indication for prevention of recurrent Clostridium difficile infection with ≥ one episode of Clostridium difficile infection following initial infection (≥ two total episodes of CD including initial infection); **and**
- member is ≥ 18 years of age; **and**
- prescriber is an infectious disease specialist or gastroenterologist or consult notes from a specialist are provided; **and**
- inadequate response or adverse reaction to two or contraindication to all of the following: Dificid, vancomycin capsule or oral solution, Zinplava; **and**
- inadequate response, adverse reaction, or contraindication to Rebyota; **and**
- medical necessity for requested agent instead of fecal microbiota transplant via other methods (IND protocol, stool banks); **and**
- requested quantity is ≤ 12 capsules for one course of therapy.

Zinplava

- Documentation of the following is required:
  - diagnosis of recurrent Clostridium difficile infection with ≥ 1 episode of Clostridium difficile infection following initial infection; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - requested quantity is ≤ a single dose; **and**
  - requested medication will be used in combination with an antibiotic being used for the treatment of Clostridium difficile infection including at least one of the following: fidaxomicin, metronidazole, rifaximin, or vancomycin.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 62 - Gout Agents

Drug Category: Gout Agents

Medication Class/Individual Agents: Gout Agents

I. Prior-Authorization Requirements

Anti-Gout Agents				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
allopurinol 100 mg, 300 mg tablet	Zyloprim		# , M90	**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** **allopurinol:** • This agent can be started during an acute attack if appropriate anti-inflammatory prophylaxis has been started or after the acute flare has resolved. • If a patient is already being treated with allopurinol, the agent should not be discontinued during an acute attack. • Serum urate levels begin to fall within two days of allopurinol administration and reach stable levels in one to two weeks. • The therapeutic goal of urate lowering therapy is to promote urate dissolution and prevent crystal formation. This is achieved by maintaining the serum urate level at ≤ 6 mg/dL. **colchicine capsule, solution:** • FDA approved for prophylaxis of gout flares in adults. **colchicine tablet:** • FDA approved for treatment of acute gout flares in adults, prophylaxis of gout flares in adults, and treatment of Familial Mediterranean Fever. • The FDA approved dosing for acute gout is: 1.2 mg orally at the first sign of a flare followed by 0.6 mg one hour later; maximum dose is 1.8 mg over 1 hour (3
allopurinol 200 mg tablet		PA	M90	
colchicine capsule	Mitigare	PA	BP, A90	
colchicine solution	Gloperba	PA		
colchicine tablet	Colcrys		# , A90	
febuxostat	Uloric	PA	M90	
pegloticase	Krystexxa	PA	MB	
probenecid			M90	
probenecid / colchicine			M90	

	Clinical Notes
	tablets per acute attack). **febuxostat:** • A xanthine oxidase inhibitor but unlike allopurinol, it is not a purine-based analogue. • Elimination occurs through hepatic metabolism and renal dose adjustment is unnecessary in patients with mild to moderate renal dysfunction. **pegloticase:** • A recombinant modified mammalian uricase enzyme indicated for the treatment of chronic gout in adults refractory to conventional therapy. • This agent is not recommended for the treatment of asymptomatic hyperuricemia. **probenecid:** • A uricosuric agent that promotes renal clearance of uric acid in the proximal tubule. • The agent is known to increases urinary calcium excretion in gout patients and should be avoided in patients with prior nephrolithiasis.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Gout (allopurinol 200 mg tablet, colchicine capsule, febuxostat, Gloperba, Krystexxa)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

allopurinol 200 mg tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical necessity for use of the requested agent instead of two allopurinol 100 mg tablets available without PA; **and**
  - medical records documenting inadequate response or adverse reaction to two allopurinol 100 mg tablets available without PA.

colchicine capsule

- Documentation of all of the following is required for gout prophylaxis in combination with urate lowering therapy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - member will be initiated on a urate lowering treatment with allopurinol, febuxostat, or probenecid; **and**
  - clinical rationale for use of the requested agent instead of colchicine tablet.
- Documentation of all of the following is required for gout prophylaxis without urate lowering therapy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to allopurinol 800 mg/day for four weeks; **or**
    - adverse reaction or contraindication to allopurinol; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to febuxostat 80 mg/day, or 40 mg/day if creatinine clearance (CrCL) < 30 mL/min, for four weeks; **or**
    - adverse reaction or contraindication to febuxostat; **and**
  - clinical rationale for use of the requested agent instead of colchicine tablet.
- For recertification, documentation of a diagnosis of tophaceous gout is required.

febuxostat

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**

- member is ≥ 18 years of age; **and**
- one of the following:
  - inadequate response (defined by serum urate levels > 6.0 mg/dL) to allopurinol 800 mg/day for four weeks; **or**
  - adverse reaction or contraindication to allopurinol; **and**
- one of the following:
  - requested quantity is ≤ one tablet/day; **or**
  - medical necessity for exceeding quantity limit.

Gloperba

- Documentation of all of the following is required for gout prophylaxis in combination with urate lowering therapy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - member will be initiated on a urate lowering treatment with allopurinol, febuxostat, or probenecid; **and**
  - medical necessity for the use of a solution formulation.
- Documentation of all of the following is required for gout prophylaxis without urate lowering therapy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to allopurinol 800 mg/day for four weeks; **or**
    - adverse reaction or contraindication to allopurinol; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to febuxostat 80 mg/day, or 40 mg/day if CrCL < 30 mL/min, for four weeks; **or**
    - adverse reaction or contraindication to febuxostat; **and**
  - medical necessity for the use of a solution formulation.
- For recertification, documentation of a diagnosis of tophaceous gout is required.

Krystexxa

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to allopurinol 800 mg/day for four weeks; **or**
    - adverse reaction or contraindication to allopurinol; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to febuxostat 80 mg/day, or 40 mg/day if CrCL < 30 mL/min, for four weeks; **or**
    - adverse reaction or contraindication to febuxostat; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to a uricosuric agent in combination with allopurinol or febuxostat for four weeks; **or**
    - adverse reaction or contraindication to a uricosuric agent.

MassHealth Evaluation Criteria

Table 63 - Dermatologic Agents - Topical Chemotherapy, Genital Wart Treatment, and Miscellaneous Dermatologic Agents

Drug Category: Dermatologic Agents

Medication Class/Individual Agents: Topical Chemotherapy, Genital Wart Treatment, and Miscellaneous Dermatologic Agents

I. Prior-Authorization Requirements

Dermatologic Agents – Actinic Keratosis			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aminolevulinic acid	Ameluz	PA	MB
aminolevulinic acid	Levulan	PA	MB
diclofenac 3% gel			A90
fluorouracil 0.5% cream	Carac		BP, A90

Dermatologic Agents – Genital Wart Treatment			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
podofilox gel	Condylox		BP, A90
podofilox solution			A90
sinecatechins	Veregen	PA	

Dermatologic Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aluminum chloride	Drysol	PA	
cantharidin	Ycanth PD	PA	MB
doxepin cream-Prudoxin	Prudoxin	PA	
doxepin cream-Zonalon	Zonalon	PA	
glycopyrronium cloth	Qbrexza	PA	
sofpironium	Sofdra	PA	

Dermatologic Agents – Actinic Keratosis and Superficial Basal Cell Carcinoma			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fluorouracil 5%	Efudex		BP, A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Actinic keratosis:

- Treatment includes destructive therapies, topical medications, and photodynamic therapy.

Basal Cell Carcinoma:

- The NCCN guideline on Basal Cell and Squamous Cell Skin Cancers recommends that in patients with low-risk, superficial basal cell skin cancer, where surgery or radiation is contraindicated or impractical, topical therapies such as fluorouracil, imiquimod, photodynamic therapy, or cryotherapy can be considered. The guideline does not specify any agent as preferred.[1]

Genital Warts:

- Treatment involves one of three major approaches: chemical or physical destruction, immunologic therapy, or surgical excision.
- The preferred approach depends upon the number and extent of the lesions.
- In general, no one treatment appears to be significantly more efficacious versus another.

Moderate pruritus:

- Doxepin cream is FDA-approved for the short-term (up

Dermatologic Agents – Actinic Keratosis and Superficial Basal Cell Carcinoma			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cream			
fluorouracil solution			A90

Dermatologic Agents – Actinic Keratosis and Genital Wart Therapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
imiquimod 2.5%, 3.75% cream	Zyclara	PA	BP, A90

Dermatologic Agents – Actinic Keratosis, Superficial Basal Cell Carcinoma and Genital Wart Therapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
imiquimod 5% cream			A90

Clinical Notes

to eight days) management of moderate pruritus in adults with atopic dermatitis or lichen simplex chronicus.

[1]NCCN Clinical Practice Guidelines in Oncology. Basal Cell Skin Cancer [guideline on the Internet]. 2017 Sept 18 [cited 2018 *May 30*]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Actinic keratosis (Ameluz, imiquimod 3.75% cream, Levulan, Zyclara)
- External genital/perianal warts (imiquimod 3.75% cream, Veregen)
- Hyperhydrosis (Drysol)
- Moderate-to-severe pruritus (doxepin cream)
- Molluscum contagiosum (Ycanth)

- Primary axillary hyperhidrosis (Sofdra, Qbrexza)

non-FDA-approved, for example:

- Craniofacial hyperhidrosis (Sofdra, Qbrexza)
- Palmar or plantar hyperhidrosis (Sofdra, Qbrexza)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Ameluz and Levulan

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a dermatologist or consult notes from a dermatologist are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: topical fluorouracil, topical imiquimod, cryosurgery; **and**
  - requested agent will be used in conjunction with photodynamic therapy; **and**
  - for Ameluz, inadequate response, adverse reaction, or contraindication to Levulan used in conjunction with photodynamic therapy.
- For recertification, medical necessity for use beyond 12 weeks.

doxepin cream

- Documentation of all of the following is required:
  - diagnosis of moderate-to-severe pruritus; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: capsaicin cream, lidocaine patch, one potent or superpotent topical corticosteroid, systemic therapy (antihistamines, SSRIs, SNRIs, anticonvulsants), topical calcineurin inhibitor (tacrolimus, pimecrolimus); **and**
  - one of the following:

- requested quantity is ≤ 45 grams/30 days; **or**
- all of the following:
  - requested quantity is > 45 grams/30 days; **and**
  - adverse reaction or inadequate response to one systemic therapy; **and**
  - medical necessity for exceeding the quantity limit.

Drysol
- Documentation of all of the following is required:
  - diagnosis of hyperhidrosis; **and**
  - inadequate response, adverse reaction, or contraindication to an OTC antiperspirant.

imiquimod 3.75% cream for External Genital/Perianal Warts
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to topical imiquimod 5% cream; **or**
    - medical necessity for use of imiquimod 3.75% instead of imiquimod 5%; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: topical podofilox, podophyllum resin applied by a provider.

imiquimod 3.75% cream and Zyclara for Actinic Keratosis
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to topical imiquimod 5% cream; **or**
    - medical necessity for use of imiquimod 2.5% or 3.75% instead of imiquimod 5%; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: topical fluorouracil solution, topical fluorouracil cream; **or**
    - medical necessity for use of the requested agent instead of topical fluorouracil.

Sofdra
- Documentation of all of the following is required:
  - diagnosis of craniofacial hyperhidrosis, primary axillary hyperhidrosis, or palmar or plantar hyperhidrosis; **and**
  - member is ≥ nine years of age; **and**
  - inadequate response, adverse reaction, or contraindication to aluminum chloride solution; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to Botox; **or**
    - clinical rationale for use of the requested agent instead of Botox; **and**
  - one of the following:
    - requested quantity is ≤ 40.2 mL/30 days; **or**
    - medical necessity for exceeding the quantity limit.

Qbrexza
- Documentation of all of the following is required:
  - diagnosis of craniofacial hyperhidrosis, primary axillary hyperhidrosis, or palmar or plantar hyperhidrosis; **and**
  - member is ≥ nine years of age; **and**
  - inadequate response, adverse reaction, or contraindication to aluminum chloride solution; **and**

- one of the following:
  - inadequate response, adverse reaction, or contraindication to Botox; **or**
  - clinical rationale for use of the requested agent instead of Botox; **and**
- requested quantity is ≤ one unit/day.

Veregen for External Genital/Perianal Warts

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: topical podofilox, podophyllum resin applied by a provider.

Ycanth

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - itching, pain, or bleeding associated with lesions; **or**
    - member is immunocompromised; **or**
    - concomitant bacterial infection; **or**
    - risk of spread to contacts (i.e., siblings, daycare); **and**
  - member is ≥ two years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: cryotherapy, curettage, podofilox; **and**
  - requested dose is ≤ eight applicators/12 weeks.

MassHealth Evaluation Criteria
Table 64 - Asthma/Allergy Monoclonal Antibodies

Drug Category: Respiratory Tract Agents

Medication Class/Individual Agents: Immunologic Agents

I. Prior-Authorization Requirements

Asthma/Allergy Monoclonal Antibodies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
benralizumab	Fasenra	PA	
dupilumab	Dupixent PD	PA	
mepolizumab	Nucala	PA	
nemolizumab-ilto	Nemluvio	PA	
omalizumab	Xolair	PA	
reslizumab	Cinqair	PA	MB
tezepelumab-ekko	Tezspire	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Benralizumab

- Benralizumab is a humanized monoclonal antibody (IgG1, κ-class) that directly binds to the alpha subunit of the human interleukin-5 receptor (IL-5Rα). It is indicated for the add-on maintenance treatment of members aged 6 years and older with severe asthma, and with an eosinophilic phenotype.
- It is also approved for the treatment of adults with eosinophilic granulomatosis with polyangiitis (EGPA).
- This agent is initially administered subcutaneously (SC) under the care of a health care professional. Thereafter, this injectable medication can be self-administered using the autoinjector.

Dupilumab

- Dupilumab is a human monoclonal IgG4 antibody that inhibits interleukin (IL)-4 and IL-13 signaling by binding to the IL-4Rα subunit for these complexes. Blocking IL-4Rα with dupilumab inhibits IL-4 and IL-13 cytokine-induced inflammatory responses, including the release of proinflammatory cytokines, chemokines, nitric oxide, and immunoglobulin E (IgE); however, the exact mechanism

	Clinical Notes

	of action for dupilumab in treating asthma has not been definitively identified.
	• It is indicated in:
	  • members aged six years and older with moderate-to-severe eosinophilic asthma as add-on maintenance therapy, oral corticosteroid (OC)-dependent asthma as add-on maintenance therapy;
	  • members aged six months and older with moderate-to-severe atopic dermatitis (AD) not controlled with topical therapies;
	  • add-on therapy in members 12 years of age and older with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP);
	  • members one year and older, weighing at least 15 kg with eosinophilic esophagitis;
	  • adults with prurigo nodularis;
	  • add-on maintenance therapy for adults with inadequately controlled chronic obstructive pulmonary disease and an eosinophilic phenotype.
	• Dupilumab is initially administered SC under the care of a health care professional. Thereafter, this injectable medication can be self-administered.
	
	Nemolizumab-ilto
	• Nemolizumab-ilto is an IL-31 receptor antagonist indicated for:
	  • the treatment of adults with prurigo nodularis (PN);
	  • the treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.
	• This agent is initially administered SC under the care of a health care professional. Thereafter, this injectable medication can be self-administered.
	
	Omalizumab
	• Omalizumab is a recombinant monoclonal antibody that selectively binds to human immunoglobulin E (IgE).
	• It is indicated:
	  • for moderate-to-severe persistent asthma in members ≥ six years of age with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled

	Clinical Notes
	corticosteroids (ICS); • for chronic idiopathic urticaria in members ≥ 12 years of age who remain symptomatic despite histamine-1 (H1) antihistamine treatment; • for add-on maintenance treatment of nasal polyps in adults with inadequate response to intranasal corticosteroids; • for the reduction of allergic reactions (Type 1), including anaphylaxis, that may occur with accidental exposure to one or more foods in members one year of age and older with IgE-mediated food allergy. • Omalizumab carries a black-box warning highlighting the risk of anaphylaxis and thus should be administered by a health care professional initially for three doses before determining if individuals are appropriate for self-administration. Mepolizumab • Mepolizumab is a humanized interleukin-5 (IL-5) antagonist monoclonal antibody. • It is indicated: • for add-on maintenance treatment of members aged six years and older with severe asthma, and with an eosinophilic phenotype; • for the treatment of adults with EGPA; • for the treatment of adult and pediatric members aged 12 years and older with hypereosinophilic syndrome (HES) for ≥ six months without an identifiable non-hematologic secondary cause; • for add-on maintenance treatment of chronic rhinosinusitis with nasal polyps in adults with inadequate response to intranasal corticosteroids. • This medication is administered by SC injection every four weeks. • It is suggested that this agent be administered by a health care professional for anyone < 12 years of age. Members aged 12 years and older should initially receive their injection under the guidance of a health care professional. Following proper training, members can then self-inject using the prefilled autoinjector or prefilled syringe. Reslizumab • Reslizumab is another humanized IL-5 antagonist monoclonal antibody indicated for add-on maintenance treatment of adults aged 18 years and older with severe

	Clinical Notes
	asthma, and with an eosinophilic phenotype. • This agent should be administered in a health care setting by a health care professional. • It is given via an intravenous infusion at a dosage of 3 mg/kg once every four weeks. • Reslizumab carries a black-box warning highlighting the risk of anaphylaxis. **Tezepelumab** • Tezepelumab is a first-in-class monoclonal antibody that blocks the action of thymic stromal lymphopoietin (TSLP). This agent is approved as add-on maintenance treatment of individuals 12 years of age and older with severe asthma. **Treatment Guidelines for the Management of Persistent Severe Asthma** • The National Heart, Lung, and Blood Institute (NHLBI) guidelines recommend consideration of omalizumab as an adjunctive therapy in members five to 11 years of age with persistent asthma that is inadequately controlled with daily and as needed combination of low-to-medium dose ICS-formoterol. In addition, it recommends that members who are being considered for omalizumab therapy are referred to an asthma specialist.[1] • According to the 2014 International European Respiratory Society/American Thoracic Society (ERS/ATS) guidelines, persistent severe asthma afflicts five to ten percent of all asthma members.[2] It is important to differentiate these individuals based on their subgroups or phenotypes whenever possible. Eosinophilic asthma is one such subgroup of severe asthma. Members with severe asthma with an eosinophilic phenotype have both recurrent exacerbations and eosinophilic airway inflammation, which plays a significant part in airway remodeling, hyperresponsiveness, and mucus accumulation. • Currently, the Global Initiative for Asthma (GINA) guidelines recommend the use of ICS-formoterol as the preferred maintenance treatment for adults and adolescents ≥ 12 years of age. • GINA recommends the use of low-dose ICS for children ≤ 11 years of age. The addition of a leukotriene receptor agonist (LTRA) can be considered for some children. However, the risks of potential neuropsychiatric events

	Clinical Notes
	should be discussed with parents/caregivers prior to prescribing. • For children six to 11 years of age inadequately controlled with low-dose ICS or low-dose ICS plus LTRA, consideration can be given to starting low-dose ICS-formoterol, increasing ICS to medium dose, or starting very low-dose ICS-formoterol. • GINA also recommends consideration for phenotypic assessment for potential add-on biologic (e.g., anti-IgE, anti-IL5/5R, or anti-IL4R therapy) in severe cases of asthma not adequately controlled on maintenance inhalers.[3] **Treatment Guidelines for the Management of Chronic Urticaria** • The European Academy of Allergy and Clinical Immunology/Global Allergy and Asthma European Network/European Dermatology Forum/World Allergy Organization (2021) and the American Academy of Allergy, Asthma and Immunology (2014) recommend that omalizumab be considered in members with refractory chronic urticaria who have failed first-line treatment options.[4,5] **Treatment Guidelines for the Management of CRSwNP** • Current guidelines for management of CRSwNP highlight intranasal corticosteroids (INS) as the cornerstone of maintenance treatment. Nasal saline irrigations or short courses of oral corticosteroids can be used as adjunctive therapy to INS. Sinus surgery is generally reserved for those who have failed to respond to medical therapy. The Allergy-Immunology Joint Task Force has noted that the biologics dupilumab, omalizumab, and mepolizumab are the most beneficial for the most patient important outcomes. The choice of a biologic may be directed by other comorbid diseases and dual indication use.[6] The EPOS 2020 steering group advises to use dupilumab or mepolizumab in individuals with CRSwNP who have not improved despite other medical or surgical options. Data was not sufficient to advise on the use of anti-IgE in CRSwNP at the time of publication.[7] **Treatment Guidelines for the Management of PN**

Clinical Notes

- Prurigo nodularis is a rare chronic skin disorder affecting primarily older adults and is characterized by symmetrically distributed, multiple, firm, pruritic nodules. This disorder is often associated with a history of atopic dermatitis.[8]
- First-generation sedating antihistamines at bedtime and/or selective serotonin reuptake inhibitors or tricyclic antidepressants may be used for chronic pruritus. Individuals with a limited number of nodular lesions may trial topical calcineurin inhibitors, or potent/superpotent topical corticosteroids. Intralesional injection of corticosteroids may be a treatment option in patients who have only a few large PN nodules.[9]
- For individuals with widespread disease or disease resistant to topical or intralesional corticosteroids, narrowband ultraviolet B (NBUVB) phototherapy is an option. For patients with widespread or recalcitrant PN who fail to respond to phototherapy or for those whom this therapy is not feasible, there are two FDA-approved systemic therapies available, dupilumab and nemolizumab-ilto.[9]

[1]National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group: 2020 Focused Updates to the Asthma Management Guidelines. National Heart Lung and Blood Institute. 2020 Dec [cited 2022 Mar 31]. Available from: https://www.nhlbi.nih.gov/health-topics/all-publications-and-resources/2020-focused-updates-asthma-management-guidelines.

[2]Chung KF, Wenzel SE, Brozek JL, Bush A, Castro M, Sterk PJ, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. Feb 2014;43(2):343-73.

[3]Global Strategy for Asthma Management and Prevention. [guideline on the internet]. Bethesda (MD): Global Initiative for Asthma (GINA); 2024 [cited 2024 Dec 6]. Available from: https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf.

[4]Bernstein JA, Lang DM, Khan DA, Craig T, Dreyfus D, Hsieh F, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol. 2014;133(5):1270-7.

	Clinical Notes
	[5]Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy. 2022; 77: 734–766. doi:10.1111/all.15090. [6]Rank MA, Chu DK, Bognanni A, Oykhman P, Bernstein JA, Ellis AK, Golden DBK, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. J of Allerg and Clin Immun. 2023; 151(2):386-398. doi.org/10.1016/j.jaci.2022.10.026. [7]Fokkens WJ, Lund VJ, Hopkins C, Hellings PW, Kern R, Reitsma S, et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2020. 2020 Feb;58(29): 1-481. Available from: https://www.rhinologyjournal.com/Rhinology_issues/manuscript_2353.pdf. [8]Wasky K. Prurigo nodularis. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2024 [cited 2024 Dec 6]. Available from: http://www.utdol.com/utd/index.do. [9]Elmariah S, Kim B, Berger T, et al. Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus. J Am Acad Dermatol. 2021;84(3):747-760. doi:10.1016/j.jaad.2020.07.025.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Chronic idiopathic urticaria
- Chronic obstructive pulmonary disease
- Eosinophilic granulomatosis with polyangiitis
- Hypereosinophilic syndrome
- IgE-mediated food allergy
- Moderate-to-severe allergy-related asthma

- Moderate-to-severe eosinophilic asthma
- Moderate-to-severe atopic dermatitis (AD)
- Nasal polyps
- Oral corticosteroid (OCS)-dependent asthma
- Prurigo nodularis
- Severe Asthma

non-FDA-approved, for example:

- systemic mastocytosis

Note: The above list may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Cinqair

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - member is symptomatic despite receiving **one** of the following:
    - combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
    - combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as separate inhalers; **or**
    - chronic oral corticosteroids; **and**
  - evidence of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥ 400 cells/μL, elevated sputum eosinophils or FeNO); **and**
  - prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - appropriate dosing.

Dupixent

- Documentation of all of the following is required for moderate-to-severe AD:

- appropriate diagnosis; **and**
- member is ≥ six months of age; **and**
- prescriber is a specialist (e.g., allergist, immunologist, or dermatologist) or consult notes from a specialist are provided; **and**
- appropriate dosing (not exceeding 2.28 units every 28 days for Dupixent 200 mg/1.14 mL, and four units every 28 days for Dupixent 300 mg/2 mL); **and**
- one of the following:
  - total body surface area (BSA) to be treated is ≥ 10%; **or**
  - inadequate response or adverse reaction to one other systemic immunomodulatory agent or contraindication to all other systemic immunomodulatory agents for the treatment of atopic dermatitis; **or**
  - both of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: topical tacrolimus, Eucrisa; **and**
    - one of the following:
      - inadequate response or adverse reaction to one superpotent or potent topical corticosteroid, or contraindication to all superpotent or potent topical corticosteroids; **or**
      - treatment area is sensitive area (face or groin); **or**
      - member is < 12 years of age.
- Documentation of all of the following is required for chronic rhinosinusitis with nasal polyps:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - prescriber is a specialist (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - one of the following:
    - inadequate response or adverse reaction to one oral corticosteroid; **or**
    - inadequate response or adverse reaction to one intranasal corticosteroid; **or**
    - inadequate response or adverse reaction to prior nasal surgery; **or**
    - contraindication to both oral corticosteroids and intranasal corticosteroids; **and**
  - appropriate dosing (not exceeding four units every 28 days for Dupixent 300 mg/2 mL); **and**
  - requested agent will be used as adjunctive therapy.
- Documentation of all of the following is required for moderate-to-severe eosinophilic asthma or OCS-dependent asthma:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - member is symptomatic despite receiving **one** of the following:
    - combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
    - combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as separate inhalers; **or**
    - chronic oral corticosteroids; **and**
  - one of the following:
    - evidence of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥ 150 cells/μL, elevated sputum eosinophils or FeNO); **or**
    - member is receiving chronic oral corticosteroids; **or**
    - member has concomitant AD or CRSwNP; **and**
  - prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - appropriate dosing (not exceeding 2.28 units every 28 days for Dupixent 200 mg/1.14 mL, and four units every 28 days for Dupixent 300 mg/2 mL).
- Documentation of all the following is required for prurigo nodularis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., allergist, immunologist, dermatologist) or consult notes from a specialist are provided; **and**

- one of the following:
  - inadequate response or adverse reaction to one or contraindication to all potent or superpotent topical corticosteroids; **or**
  - inadequate response or adverse reaction to one or contraindication to all intralesional corticosteroids; **or**
  - inadequate response, adverse reaction, or contraindication to phototherapy; **and**
- appropriate dosing (not exceeding four units every 28 days for Dupixent 300 mg/2 mL).

- Documentation of all the following is required for eosinophilic esophagitis:
  - appropriate diagnosis; **and**
  - member is ≥ one year of age; **and**
  - prescriber is a specialist (e.g., allergist, hematologist, immunologist, gastroenterologist) or consult notes from a specialist are provided; **and**
  - member weighs ≥ 15 kg; **and**
  - inadequate response (defined as ≥ 60 days of therapy) or adverse reaction to one or contraindication to all proton pump inhibitors; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to both of the following: budesonide, fluticasone propionate; **and**
  - appropriate dosing (not exceeding four units every 28 days for Dupixent 300 mg/2 mL).
- Documentation of all the following is required for moderate-severe chronic obstructive pulmonary disease (COPD):
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., pulmonologist, allergist, or immunologist) or consult notes from a specialist are provided; **and**
  - one of the following:
    - both of the following:
      - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) or adverse reaction to one of the following or any combination of separate inhalers equivalent to one of the following: Bevespi, Duaklir, Stiolto, umeclidinium/vilanterol; **and**
      - contraindication to the use of an inhaled corticosteroid; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) or adverse reaction to one or any combination of separate inhalers equivalent to one of the following or contraindication to both of the following: Breztri, Trelegy; **and**
  - evidence of an eosinophilic phenotype (i.e. peripheral blood eosinophil count ≥ 300 cells/μL); **and**
  - requested agent will be used as adjunctive therapy with either dual or triple inhaled therapy; **and**
  - appropriate dosing.

SmartPA: Claims for Dupixent (dupilumab) 300 mg/2 mL at a quantity ≤ four units/28 days will usually process and pay at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for Dupixent for at least 84 days out of the last 120 days and a MassHealth history of medical claims for moderate to severe atopic dermatitis, moderate to severe eosinophilic asthma, nasal polyps, or prurigo nodularis. Claims for Dupixent (dupilumab) 300 mg/2 mL at a quantity ≤ eight units/28 days will usually process and pay at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for Dupixent for at least 84 days out of the last 120 days and a MassHealth history of medical claims for eosinophilic esophagitis. Claims for Dupixent (dupilumab) 200 mg/1.14 mL at a quantity ≤ 2.28 units/28 days will usually process and pay at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for Dupixent for at least 84 days out of the last 120 days and a MassHealth history of medical claims for moderate to severe atopic dermatitis or moderate to severe eosinophilic asthma.

Fasenra

- Documentation of all of the following is required for severe eosinophilic asthma:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - member is symptomatic despite receiving **one** of the following:

    - combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
    - combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as separate inhalers; **or**
    - chronic oral corticosteroids; **and**
  - evidence of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥ 150 cells/μL, elevated sputum eosinophils or FeNO); **and**
  - prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - appropriate dosing.
- Documentation of all of the following is required for eosinophilic granulomatosis with polyangiitis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to all systemic glucocorticoids; **and**
  - prescriber is a specialist (e.g., allergist, cardiologist, hematologist, immunologist, pulmonologist, rheumatologist, etc.) or consult notes from a specialist are provided; **and**
  - appropriate dosing (not exceeding one unit every 28 days).

SmartPA: Claims for Fasenra will usually pay at the pharmacy without a PA request if the member has a history of medical claims for severe eosinophilic asthma and paid MassHealth pharmacy claims for Fasenra for at least 84 days out of the last 120 days. Claims for Fasenra 30 mg/mL at a quantity ≤ one unit/28 days will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for Fasenra for at least 84 days out of the last 120 days and a MassHealth history of medical claims for eosinophilic granulomatosis with polyangiitis or hypereosinophillic syndrome. †

Nemluvio

- Documentation of all of the following is required for moderate-to-severe AD:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., allergist, immunologist, dermatologist) or consult notes from a specialist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to two or contraindicated to all of the following: Adbry, Dupixent, Ebglyss; **and**
  - one of the following:
    - total body surface area (BSA) to be treated is ≥ 10%; **or**
    - inadequate response or adverse reaction to one or contraindicated to all other systemic immunomodulatory agents for the treatment of atopic dermatitis; **or**
    - both of the following:
      - inadequate response or adverse reaction to one or contraindication to both of the following: Eucrisa, topical tacrolimus; **and**
      - one of the following:
        - inadequate response or adverse reaction to one potent or superpotent topical corticosteroid or contraindication to all potent or superpotent topical corticosteroids; **or**
        - treatment area is a senstive area (face/groin).
- For recertification, documentation of positive response to therapy is required; **and**
- one of the following:
  - request is for every eight-week dosing (after week 16 of therapy); **or**
  - request is for continued every four-week dosing (after week 16 of therapy) and one of the following:
    - partial response to therapy; **or**
    - failed trial with every eight-week dosing.
- Documentation of all of the following is required for prurigo nodularis:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., allergist, immunologist, dermatologist) or consult notes from a specialist are provided; **and**

- member is ≥ 18 years of age; **and**
- one of the following:
  - inadequate response or adverse reaction to one potent or superpotent topical corticosteroid or contraindication to all potent or superpotent topical corticosteroids; **or**
  - inadequate response or adverse reaction to one or contraindication to all intralesional corticosteroids; **or**
  - inadequate response or adverse reaction or contraindication to phototherapy; **and**
- inadequate response or adverse reaction or contraindication to Dupixent; **and**
- appropriate dosing.

Nucala

- Documentation of all of the following is required for severe eosinophilic asthma:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - member is symptomatic despite receiving **one** of the following:
    - combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
    - combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as separate inhalers; **or**
    - chronic oral corticosteroids; **and**
  - evidence of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥ 150 cells/μL, elevated sputum eosinophils or FeNO); **and**
  - prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - appropriate dosing (not exceeding one unit every 28 days for Nucala 100 mg/mL and 0.4 units every 28 days for Nucala 40 mg/0.4 mL).
- Documentation of all of the following is required for eosinophilic granulomatosis with polyangiitis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to all systemic glucocorticoids; **and**
  - inadequate response, adverse reaction, or contraindication to Fasenra; **and**
  - prescriber is a specialist (e.g., allergist, cardiologist, hematologist, immunologist, pulmonologist, rheumatologist, etc.) or consult notes from a specialist are provided; **and**
  - appropriate dosing (not exceeding three units every 28 days for Nucala 100 mg/mL).
- Documentation of all of the following is required for hypereosinophilic syndrome:
  - appropriate diagnosis; **and**
  - diagnosis without an identifiable non-hematologic secondary cause; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to all systemic glucocorticoids; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to all of the following: hydroxyurea, methotrexate, interferon alfa; **and**
  - prescriber is a specialist (e.g., allergist, cardiologist, GI, hematologist, immunologist, pulmonologist, etc.) or consult notes from a specialist are provided; **and**
  - appropriate dosing (not exceeding three units every 28 days for Nucala 100 mg/mL).
- Documentation of all of the following is required for chronic rhinosinusitis with nasal polyps:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or consult notes from a specialist are provided; **and**

- one of the following:
  - inadequate response or adverse reaction to one or contraindication to both of the following:
    - intranasal corticosteroids; **or**
    - oral corticosteroids; **or**
  - inadequate response or adverse reaction to prior nasal surgery; **and**
- appropriate dosing; **and**
- requested agent will be used as adjunctive therapy.

SmartPA: Claims for Nucala 100 mg/mL at a quantity ≤ one unit/28 days and claims for Nucala 40 mg/0.4 mL at a quantity ≤ 0.4 units/28 days, will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for Nucala for at least 84 days out of the last 120 days and a MassHealth history of medical claims for severe eosinophilic asthma. Claims for Nucala 100 mg/mL at a quantity ≤ three units/28 days will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for Nucala for at least 84 days out of the last 120 days and a MassHealth history of medical claims for eosinophilic granulomatosis with polyangiitis or hypereosinophillic syndrome. †

Tezspire

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - member is symptomatic despite receiving **one** of the following:
    - combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
    - combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as separate inhalers; **or**
    - chronic oral corticosteroids; **and**
  - prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - appropriate dosing.

SmartPA: Claims for Tezspire will usually pay at the pharmacy without a PA request if the member has a history of medical claims for severe persistent asthma and paid MassHealth pharmacy claims for Tezspire for at least 84 days out of the last 120 days. †

Xolair

- Documentation of all of the following is required for chronic idiopathic urticaria:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to at least two or contraindication to all histamine$_1$ antihistamines; **and**
  - inadequate response (defined as ≥ 14 days of therapy); adverse reaction, or contraindication to a histamine$_1$ antihistamine in combination with a histamine$_2$ antihistamine; **and**
  - for the 150 mg or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial formulation; **and**
  - appropriate dosing; **and**
  - prescriber is a specialist (e.g., allergist, immunologist, or dermatologist) or consult notes from a specialist are provided.
- Documentation of all of the following is required for IgE-mediated food allergy:
  - appropriate diagnosis; **and**
  - prescriber is an allergist or immunologist or consult notes from an allergist or immunologist are provided; **and**
  - member is ≥ one year of age; **and**
  - baseline serum IgE between 30 IU/mL to 1,850 IU/mL; **and**
  - evidence of specific allergic sensitivity (i.e., positive skin test or radioallergosorbent test [RAST] for IgE); **and**
  - appropriate dosing; **and**
  - for the 150 mg or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial

formulation.

- Documentation of all of the following is required for moderate-to-severe allergy-related asthma:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - member is symptomatic despite receiving **one** of the following:
    - combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
    - combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as separate inhalers; **or**
    - chronic oral corticosteroids; **and**
  - baseline serum IgE between 30 IU/mL to 700 IU/mL; **and**
  - evidence of specific allergic sensitivity (i.e., positive skin test or radioallergosorbent test [RAST] for IgE); **and**
  - prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - for the 150 mg or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial formulation; **and**
  - appropriate dosing (not exceeding six units every 28 days for the 150 mg vial, four units every 28 days for the 150 mg or 300 mg syringe/auto-injection, and two units every 28 days for the 75 mg syringe/auto-injection).
- Documentation of all of the following is required for chronic rhinosinusitis with nasal polyps:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following:
      - intranasal corticosteroids; **or**
      - oral corticosteroids; **or**
    - inadequate response or adverse reaction to prior nasal surgery; **and**
  - appropriate dosing; **and**
  - for the 150 mg or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial; **and**
  - requested agent will be used as adjunctive therapy.
- Documentation of all of the following is required for systemic mastocytosis:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., hematologist, oncologist, allergist/immunologist) or consult notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - for the 150 mg or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: corticosteroids, histamine$_1$ antihistamine and histamine$_2$ antihistamine.

SmartPA: Claims for Xolair at a quantity ≤ six units/28 days for the 150 mg vial, and ≤ two units/28 days for the 75 mg syringe/auto-injection, will usually process at the pharmacy without a PA request if the member has a MassHealth history of medical claims for moderate-to-severe allergy-related asthma and a history of paid MassHealth pharmacy claims for Xolair for at least 84 days out of the last 120 days. †

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 65 - Enzyme and Metabolic Disorder Therapies

Drug Category: Endocrine and Metabolic Agents

Medication Class/Individual Agents: Enzyme and Metabolic Disorder Therapies

I. Prior-Authorization Requirements

Enzyme and Metabolic Disorder Therapies – Injectable Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ADAMTS13, recombinant-krhn	Adzynma	PA	
agalsidase beta	Fabrazyme	PA	
alglucosidase alfa	Lumizyme	PA	MB
asfotase alfa	Strensiq	PA	
avalglucosidase alfa-ngpt	Nexviazyme	PA	MB
cipaglucosidase alfa-atga	Pombiliti	PA	MB
elapegademase-lvlr	Revcovi	PA	
elosulfase alfa	Vimizim	PA	MB
galsulfase	Naglazyme	PA	MB
idursulfase	Elaprase	PA	MB
imiglucerase	Cerezyme	PA	MB
laronidase	Aldurazyme	PA	MB
olipudase alfa-rpcp	Xenpozyme	PA	MB
pegunigalsidase alfa-iwxj	Elfabrio	PA	
pegvaliase-pqpz	Palynziq	PA	
plasminogen, human-tvmh	Ryplazim	PA	
taliglucerase alfa	Elelyso	PA	MB
velaglucerase alfa	Vpriv	PA	MB
velmanase alfa-tycv	Lamzede	PA	MB
vestronidase alfa-vjbk	Mepsevii	PA	MB

Enzyme and Metabolic Disorder Therapies – Oral Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alpelisib-Vijoice	Vijoice	PA	
arimoclomol	Miplyffa	PA	
carglumic acid	Carbaglu [PD]	PA	BP, A90
glycerol phenylbutyrate	Ravicti	PA	BP

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Please note: One-time cell and gene therapies are part of the ACPP and MCO unified pharmacy policy. PA requests for one-time cell and gene therapies for members with ACPP and MCO plans are reviewed by the MassHealth Drug Utilization Review (DUR) Program.

- Lysosomal storage disorders are caused by a deficiency or absence of required enzymes. The consequence is an accumulation of compounds that are normally degraded, causing cell and organ dysfunction. Before the development of enzyme replacement therapy, management of these conditions consisted of supportive care and treatment of the complications.
- A number of exogenously supplied enzymes are available for lysosomal storage disorders, including adenosine deaminase (ADA) deficiency, Gaucher disease, Fabry disease, Hunter syndrome, hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthetase, hypophosphatasia, lysosomal acid lipase deficiency, mucopolysaccharidosis type I, IVA, VI, and VII, non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) type B or A/B and Pompe disease.
- Pancreatic enzyme replacement is indicated for the

Enzyme and Metabolic Disorder Therapies – Oral Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
leniolisib	Joenja	PA	
levacetylleucine	Aqneursa	PA	
migalastat	Galafold	PA	
miglustat 65 mg	Opfolda	PA	
mitapivat	Pyrukynd	PA	
pancrelipase-Creon DR	Creon DR		
pancrelipase-Pertzye DR	Pertzye DR		
pancrelipase-Viokace	Viokace		
pancrelipase-Zenpep DR	Zenpep DR		
penicillamine capsule	Cuprimine		BP, A90
penicillamine tablet	Depen		BP, A90
sacrosidase	Sucraid	PA	
sapropterin	Kuvan	PA	
sodium phenylbutyrate granules	Pheburane	PA	
sodium phenylbutyrate pellets for suspension	Olpruva	PA	
sodium phenylbutyrate powder, tablet	Buphenyl		BP, A90
trientine 250 mg capsule	Syprine		BP, A90
trientine 300 mg tablet	Cuvrior	PA	
trientine 500 mg capsule		PA	A90
triheptanoin	Dojolvi	PA	
uridine triacetate	Xuriden	PA	

Enzyme and Metabolic Disorder Therapies – Substrate Replacement/Reduction Therapies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
eliglustat	Cerdelga	PA	
fosdenopterin	Nulibry	PA	MB
miglustat 100 mg	Zavesca	PA	BP
sebelipase alfa	Kanuma	PA	MB

Clinical Notes

treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions. Multiple formulations of pancreatic enzymes exist with different combinations of lipase, protease, and amylase; however, these enzymes may differ in their effects. Members should be reevaluated after any changes in enzyme preparation or dose.

- Molybdenum cofactor deficiency (MoCD) is a rare genetic disorder that results from one of several single gene defects in the biosynthetic pathway of molybdenum cofactor. About two-thirds of members have MoCD type A, which involves mutations in molybdenum cofactor synthesis gene 1 (MOSC1). Prior to the approval of fosdenopterin, the only available treatment options included supportive care and therapies directed towards complications arising from the disease.
- Pyruvate kinase deficiency is an inherited red blood cell enzyme disorder that causes chronic hemolysis. Affected individuals are either homozygous for a single pathogenic mutation or compound heterozygous for two different pathogenic variants affecting the function of the pyruvate kinase enzyme in red blood cells and liver. Mitapivat is a pyruvate kinase activator that acts by allosterically binding to the pyruvate kinase tetramer and increasing pyruvate kinase activity.
- PIK3CA-Related Overgrowth Spectrum (PROS) is considered a rare disease that includes a group of genetic disorders, which leads to overgrowth of various body parts due to PIK3CA mutations. Alpelisib is small-molecule inhibitor of phosphatidylinositol-3 kinase (PI3K). Mutations in the gene for PI3K lead to PI3Ka and Akt activation, tumor generation, and cellular transformation. Activating these mutations lead to a range of malformations and overgrowths known as PROS. Alpelisib can inhibit the phosphorylation of PI3K and Akt to prevent further activity in the pathway.
- ASMD is a rare autosomal recessive liposomal storage disease that results in a deficiency in the enzyme acid sphingomyelinase (ASM), which is required to metabolize sphingomyelin, a fatty acid. As a result, sphingomyelin accumulates in cells within major organs. Prior to the approval of olipudase alpha-rpcp, the only available treatment options included supportive care and therapies directed towards complications arising from the disease. Olipudase alfa-rpcp is the first and only FDA-

Enzyme and Metabolic Disorder Therapies - Gene Therapy				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
eladocagene exuparvovec-tneq	Kebilidi	PA	CO	approved drug to treat the underlying pathology of ASMD. This drug does not cross the blood-brain barrier; therefore, it is not expected to modulate the CNS manifestations of ASMD. • Plasminogen deficiency (PLGD) type 1, also referred to as hypoplasminogenemia, is an ultra-rare, autosomal recessive disorder that can impair normal tissue and organ function which can lead to blindness. Individuals with PLGD type 1 lack the enzyme plasminogen and develop thick lesions in the mucous membranes of their body. There have been no standardized treatments for patients with PLGD due to the rarity of the disease, and plasminogen human-tvhm is the first and only product FDA-approved for the treatment of PLGD type 1. • Niemann-Pick disease type C (NPC) is a subtype of Niemann-Pick disease (NPD) caused by variants of the NPC1 and NPC2 genes, which result in impaired cellular processing and transport of low-density lipoprotein (LDL) cholesterol and other macromolecules. Llevacetylleucine is indicated for the treatment of neurological manifestations of NPC in adults and pediatric patients weighing ≥15 kg. Arimoclomol is indicated for use in combination with miglustat for the treatment of neurological manifestations of NPC in adult and pediatric patients 2 years of age and older. These two are the first agents FDA-approved for use in NPC. Previously, miglustat was standard of care and the only disease-modifying therapy for use in NPC, though used off-label. • Aromatic L-amino acid decarboxylase (AADC) deficiency is an ultra-rare, inherited neurometabolic genetic disorder caused by defects in the dopa decarboxylase (DDC) gene which impacts the ability to produce neurotransmitters like serotonin and dopamine. Eladocagene exuparvovec-tneq is the first agent approved to treat AADC deficiency.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

CO Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements. All requests for one-time cell and gene therapies (as listed on the Acute Hospital Carve-Out Drug List), including for members enrolled in an Accountable Care Partnership Plan (ACPP) or Managed Care Organization (MCO), will be reviewed by the MassHealth Drug Utilization Review (DUR) Program.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Acid sphingomyelinase deficiency (ASMD) (Xenpozyme)
- Activated phosphoinositide 3-kinase delta (PI3Kd) syndrome (APDS) (Joenja)
- Adenosine deaminase severe combined immunodeficiency (ADA-SCID) (Revcovi)
- Alpha-mannosidosis (Lamzede)
- Aromatic L-amino acid decarboxylase (AADC) deficiency (Kebilidi)
- Congenital sucrase-isomaltase deficiency (Sucraid)
- Congenital thrombocytopenic purpura (cTTP) (Adzynma)
- Fabry disease (Elfabrio, Fabrazyme, Galafold)
- Gaucher Disease Type 1 (Cerdelga, Cerezyme, Elelyso, miglustat 100 mg, Vpriv)
- Hemolytic anemia with pyruvate kinase deficiency (Pyrukynd)
- Hereditary orotic aciduria (Xuriden)
- Hunter Syndrome (Elaprase)
- Hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthetase (NAGS) (carglumic acid)
- Hyperammonemia due to propionic aciduria (PA) or methylmalonic aciduria (MMA) (carglumic acid)
- Hypophosphatasia (Strensiq)
- Late-onset Pompe Disease (Opfolda, Pombiliti)
- Long-chain fatty acid oxidation disorders (LC-FAOD) (Dojolvi)
- Lysosomal acid lipase deficiency (Kanuma)
- Molybdenum cofactor deficiency (MoCD) Type A (Nulibry)
- Mucopolysaccharidosis I (Aldurazyme)
- Mucopolysaccharidosis IVA (Morquio A syndrome) (Vimizim)
- Mucopolysaccharidosis VI (Naglazyme)
- Mucopolysaccharidosis VII (Sly syndrome) (Mepsevii)
- Niemann-Pick disease type C (NPC) (Aqneursa, Miplyffa)
- Phenylketonuria (Palynziq, sapropterin)
- PIK3CA-Related Overgrowth Spectrum (PROS) (Vijoice)
- Plasminogen deficiency (PLGD), Type 1 (Ryplazim)
- Pompe disease (Lumizyme, Nexviazyme)
- Urea cycle disorder (Olpruva, Pheburane, Ravicti)
- Wilson’s disease (Cuvrior, trientine 500 mg capsule)

Non-FDA-approved, for example:

- Acute hyperammonemia in isovaleric aciduria (carglumic acid)
- Niemann-Pick disease type C (NPC) (miglustat 100 mg)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Adzynma

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - prescriber is a hematologist, oncologist, or intensive care specialist or consult notes from a specialist are provided; **and**
  - results from genetic test confirming diagnosis of cTTP; **and**
  - requested agent will not be used concurrently with fresh frozen plasma; **and**
  - appropriate dosing; **and**
  - member's current weight.

Aldurazyme

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic testing showing mutations in IDUA gene or an enzyme assay test showing reduced lysosomal alpha-L-iduronidase activity in peripheral blood leukocytes, plasma, or cultured fibroblasts; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight.

Aqneursa

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., medical geneticist or specialist familiar with lysosomal storage disorders) or consult notes from a specialist are provided; **and**
  - one of the following:
    - results from genetic testing confirming mutations in both alleles of NPC1 or NPC2; **or**
    - results from genetic testing confirming mutation in one allele of NPC1 or NPC2 and either a positive filipin-staining or elevated cholestane triol/oxysterols (> 2x the upper limit of normal); **and**
  - member has neurological manifestations of NPC; **and**
  - member's weight is ≥ 15 kg; **and**

- requested agent will not be used in combination with Miplyffa; **and**
- appropriate dosing.

- For recertification, documentation of the following is required:
  - positive response to therapy; **and**
  - updated member weight.

carglumic acid

- Documentation of all of the following is required for hyperammonemia due to NAGS deficiency:
  - appropriate diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - results from genetic test or an enzyme assay test supporting the diagnosis.
- Documentation of all of the following is required for hyperammonemia due to PA or MMA:
  - appropriate diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - results from genetic testing, medical records, or lab results supporting the diagnosis; **and**
  - elevated ammonia levels > 60 μmol/L.
- Documentation of all of the following is required for acute hyperammonemia in isovaleric aciduria (IVA):
  - appropriate diagnosis; **and**
  - medical records and/or laboratory testing results supporting the diagnosis of IVA; **and**
  - abnormally elevated baseline ammonia levels (e.g., > 60 μmol/L); **and**
  - appropriate dosing.

Cerdelga

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - results from enzyme assay test showing reduced activity of glucocerebrosidase; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member is not currently receiving enzyme replacement therapy.

Cerezyme and Vpriv

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic test confirming mutation in GBA gene or an enzyme assay test showing reduced activity of the enzyme glucocerebrosidase; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

Cuvrior

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥18 years of age; **and**
  - member has stable disease; **and**
  - member is tolerant to penicillamine; **and**
  - contraindication to penicillamine; **and**
  - inadequate response, adverse reaction, or contraindication to trientine capsule; **and**
  - requested medication will not be taken concurrently with penicillamine; **and**
  - requested quantity is ≤ ten units/day; **and**
  - appropriate dosing.

Dojolvi

- Documentation of all of the following is required:
  - diagnosis of long-chain fatty acid oxidation disorders (LC-FAOD); **and**
  - results from genetic testing or molecular analysis to confirm diagnosis (e.g., CPT I or II, LCHAD, TFP, VLCAD deficiency); **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - trial with a diet consisting of low-fat, high-carbohydrates, and avoidance of fasting; **and**
  - member's current caloric intake.

Elaprase

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic testing confirming mutation in IDS gene or iduronate-2-sulfatase assay test showing reduced or absent activity in the serum, white blood cells, or fibroblasts; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

Elelyso

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic test confirming mutation in GBA gene or an enzyme assay test showing reduced activity of the enzyme glucocerebrosidase; **and**
  - member is ≥ four years of age; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

Elfabrio and Fabrazyme

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - results from an enzyme assay test showing reduced or absent α-galactosidase A (α-GAL) enzyme activity in plasma, leukocytes, tears, or biopsied tissue; **or**
    - Genetic testing confirming mutation in GAL gene; **or**
    - Biomarker demonstrating an increase in Gb3 concentration; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight; **and**
  - for Elfabrio, inadequate response, adverse reaction, or contraindication to Fabrazyme.

Joenja

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - prescriber is a specialist (e.g., pediatrician, hematologist/oncologist, or allergist/immunologist), or consult notes from a specialist are provided; **and**
  - results from genetic testing confirming mutation in the PIK3CD or PIK3R1 genes; **and**
  - member's weight is ≥ 45 kg; **and**
  - appropriate dosing.

Galafold

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - results from an enzyme assay test showing reduced or absent α-galactosidase A (α-GAL) enzyme activity in plasma, leukocytes, tears, or biopsied tissue; **and**

- member has GLA variants which are amenable to treatment with the requested agent; **and**
- requested quantity is ≤ 15 units/30 days.

Kanuma

- Documentation of all of the following is required:
  - diagnosis of lysosomal acid lipase deficiency; **and**
  - one of the following:
    - lab assay documenting low lysosomal acid lipase activity; **or**
    - genetic testing confirming full or partial loss of LAL gene; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

Kebilidi

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic test confirming diagnosis of AADC deficiency (e.g., biallelic mutation of DDC gene); **and**
  - member is ≥ 16 months of age; **and**
  - prescriber is a neurologist or consult notes from a neurologist are provided; **and**
  - member has achieved skull maturity required for stereotactic surgical administration; **and**
  - medical records documenting both of the following:
    - member is unable to ambulate independently; **and**
    - member is experiencing neurological defects despite treatment with a dopamine agonist, monoamine oxidase inhibitor and/or vitamin B6; **and**
  - appropriate dosing and treatment dates; **and**
  - infusion will take place in a qualified treatment facility; **and**
  - member has not received any prior gene therapy for AADC deficiency; **and**
  - laboratory test results documenting one of the following:
    - decreased AADC enzyme activity in plasma; **or**
    - cerebrospinal fluid showing both of the following:
      - decreased levels of 5-HIAA, HV, and MHPG; **and**
      - increased levels of 3-OMD, L-Dopa, and 5-HTP.

Lamzede

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 3 years of age; **and**
  - results from a genetic test confirming diagnosis of alpha-mannosidosis (e.g., mutation of MAN2B1 gene); **and**
  - baseline measurements for all of the following tests:
    - one of the following motor function tests:
      - 3-minute stair climb test; **or**
      - 6-minute walk test; **and**
    - serum oligosaccharides; **and**
    - forced vital capacity; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

Lumizyme

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - results from acid maltase enzyme alpha-glucosidase (GAA) assay test showing reduced or absent activity from cultured skin

fibroblasts; **or**
    - lymphocyte testing; **or**
    - blood spot assay; **or**
    - genetic testing confirming mutation in GAA gene; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

Mepsevii

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic testing showing mutations in the beta glucuronidase gene; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

miglustat 100 mg

- Documentation of all of the following is required for the diagnosis of Gaucher disease type I:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - results from enzyme assay test showing reduced activity of glucocerebrosidase; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - contraindication to enzyme replacement therapy.
- Documentation of all of the following is required for the diagnosis of NPC:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., medical geneticist or specialist familiar with lysosomal storage disorders) or consult notes from a specialist are provided; **and**
  - one of the following:
    - results from genetic testing confirming mutations in both alleles of NPC1 or NPC2; **or**
    - results from genetic testing confirming mutation in one allele of NPC1 or NPC2 and either a positive filipin-staining or elevated cholestane triol/oxysterols (> 2x the upper limit of normal); **and**
  - member has neurological manifestations of NPC; **and**
  - requested quantity is ≤ six units/day.
- For recertification for the diagnosis of NPC, documentation of the following is required:
  - positive response to therapy; **and**
  - updated member weight.

Miplyffa

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., medical geneticist or specialist familiar with lysosomal storage disorders) or consult notes from a specialist are provided; **and**
  - one of the following:
    - results from genetic testing confirming mutations in both alleles of NPC1 or NPC2; **or**
    - results from genetic testing confirming mutation in one allele of NPC1 or NPC2 and either a positive filipin-staining or elevated cholestane triol/oxysterols (> 2x the upper limit of normal); **and**
  - member has neurological manifestations of NPC; **and**
  - member is ≥ 2 years of age; **and**
  - member’s weight is ≥ 8 kg; **and**
  - one of the following:
    - inadequate response to Aqneursa for at least three months*; **or**
    - adverse reaction or contraindication to Aqneursa; **and**
  - requested agent will be used in combination with miglustat; **and**

- requested agent will not be used in combination with Aqneursa; **and**
- appropriate dosing.

- For recertification, documentation of the following is required:
  - positive response to therapy; **and**
  - updated member weight.

*Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to this agent.

Naglazyme

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from an enzyme assay test showing reduced arylsulfatase B (ASB) enzyme activity in leukocytes or fibroblasts along with elevated urine glycosaminoglycan (GAG) levels; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

Nexviazyme

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - results from GAA assay test showing reduced or absent activity from cultured skin fibroblasts; **or**
    - lymphocyte testing; **or**
    - blood spot assay; **or**
    - genetic testing confirming mutation in GAA gene; **and**
  - member is ≥ one year of age; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight; **and**
  - for members weighing < 30 kg, contraindication to Lumizyme.

Nulibry

- Documentation of all of the following is required:
  - appropriate diagnosis confirmed by genetic testing; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - member's current weight.

Olpruva

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic test or an enzyme assay test supporting the diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: sodium phenylbutyrate powder, sodium phenylbutyrate tablet; **and**
  - inadequate response, adverse reaction, or contraindication to Pheburane.

Opfolda

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight is ≥ 40 kg; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**

- one of the following:
  - results from GAA assay test showing reduced or absent activity from cultured skin fibroblasts; **or**
  - lymphocyte testing; **or**
  - blood spot assay; **or**
  - genetic testing confirming mutation in GAA gene; **and**
- inadequate response or adverse reaction to one or contraindication to both of the following: Lumizyme, Nexviagzyme; **and**
- requested agent will be used in combination with Pombiliti.

Palynziq

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - blood phenylalanine concentrations > 600 micromol/L; **and**
  - medication will be used in conjunction with a phenylalanine-restricted diet; **and**
  - inadequate response, adverse reaction, or contraindication to sapropterin.

Pheburane

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic test or an enzyme assay test supporting the diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: sodium phenylbutyrate powder, sodium phenylbutyrate tablet.

Pombiliti

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight is ≥ 40 kg; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - one of the following:
    - results from GAA assay test showing reduced or absent activity from cultured skin fibroblasts; **or**
    - lymphocyte testing; **or**
    - blood spot assay; **or**
    - genetic testing confirming mutation in GAA gene; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Lumizyme, Nexviagzyme; **and**
  - requested agent will be used in combination with Opfolda.

Pyrukynd

- Documentation of all of the following is required:
  - diagnosis of hemolytic anemia with pyruvate kinase deficiency; **and**
  - member is ≥ 18 years of age; **and**
  - results from genetic testing confirming mutation in PKLR gene or lab testing showing reduced or absent activity of pyruvate kinase; **and**
  - prescriber is a specialist in genetic diseases, hematology, or metabolic diseases or consult notes from a specialist are provided; **and**
  - hemoglobin (Hb) ≤ 10 g/dL (dated within the last 60 days); **and**
  - requested quantity is ≤ two units/day.

Ravicti

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic test or an enzyme assay test supporting the diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: sodium phenylbutyrate powder, sodium phenylbutyrate tablet, Olpruva, Pheburane.

Revcovi

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - laboratory results documenting one of the following:
    - absent ADA enzymatic activity in lysed erythrocytes; **or**
    - elevated levels of adenosine and deoxyadenosine in the urine and plasma; **or**
    - a marked increase in deoxyadenosine triphosphate (dATP) levels in erythrocyte lysates; **or**
    - a significant decrease in ATP concentration in red blood cells; **or**
    - absent or extremely low levels of N adenosylhomocysteine hydrolase in red blood cells; **or**
    - severe T cell deficiency manifested by lymphopenia and poor T cell responses to mitogens and antigens; **or**
    - absent thymic shadow on chest radiograph; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

Ryplazim

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - history of lesions (external and/or internal) and symptoms consistent with a diagnosis of PLGD type 1; **and**
  - baseline plasminogen activity level ≤ 45%; **and**
  - one of the following:
    - results from genetic testing showing mutations in PLG gene; **or**
    - member has plasminogen antigen levels ≤ 9 mg/dL; **and**
  - requested dose is ≤ 6.6 mg/kg every two to four days.

sapropterin

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - documentation that medication will be used in conjunction with a phenylalanine-restricted diet; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

Strensiq

- Documentation of all of the following is required:
  - diagnosis of perinatal-onset, infantile-onset, or juvenile-onset hypophosphatasia; **and**
  - genetic testing confirming mutation in ALPL gene; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

Sucraid

- Documentation of all of the following is required:
  - diagnosis of congenital sucrase-isomaltase deficiency (CSID); **and**
  - results from small bowel biopsy or breath hydrogen test showing reduced or absent enzyme activity or sucrase breath test; **and**
  - prescriber is a specialist in genetic or metabolic diseases, a gastroenterologist, or consult notes from a specialist or gastroenterologist are provided; **and**
  - member's current weight.

trientine 500 mg capsule

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to penicillamine; **and**
  - medical necessity for the 500 mg capsule instead of trientine 250 mg capsule; **and**
  - requested medication will not be taken concurrently with penicillamine; **and**
  - requested quantity is ≤ four units/day.

Vijoice

- Documentation of all of the following is required:
  - diagnosis of PROS with congenital or early childhood onset; **and**
  - member is ≥ two years of age; **and**
  - overgrowth is sporadic and mosaic (i.e., patchy, irregular); **and**
  - results from genetic testing showing evidence of a mutation in the PIK3CA gene; **and**
  - appropriate dosing; **and**
  - medical records documenting one of the following:
    - spectrum categorization defined as having at least two of the following:
      - adipose, muscle, nerve, or skeletal overgrowth; **or**
      - capillary, venous, arteriovenous, or lymphatic vascular malformations; **or**
      - epidermal nevus; **or**
    - isolated features defined as having one of the following:
      - large isolated lymphatic malformation; **or**
      - isolated macrodactyly or overgrown splayed feet/hands, overgrown limbs; **or**
      - truncal adipose overgrowth; **or**
      - bilateral hemimegalencephaly/dysplastic megalencephaly/focal cortical dysplasia type 2; **or**
      - epidermal nevus; **or**
      - seborrheic keratoses; **or**
      - benign lichenoid keratoses.

Vimizim

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ five years of age; **and**
  - results from an enzyme assay test showing reduced N-acetylgalactosamine-6-sulfatase activity in blood and/or skin cells; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

Xenpozyme

- Documentation of all of the following is required:
  - diagnosis of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) type B or ASMD type A/B; **and**
  - prescriber is a specialist (e.g., medical geneticist or a specialist familiar with lysosomal storage disorders) or consult notes from a specialist are provided; **and**
  - one of the following:
    - for members ≥ 18 years of age, both of the following:
      - DLco ≤ 70% of predicted normal value; **and**
      - spleen volume ≥ 6 MN; **or**
    - for members < 18 years of age, spleen volume ≥ 5 MN; **and**
  - member does not have acute or rapidly progressing neurologic abnormalities; **and**
  - both of the following:
    - member does not require invasive ventilatory support; **and**

    - member does not require noninvasive ventilatory support while awake for > 12 hours a day; **and**
  - member's current weight; **and**
  - appropriate dosing.
- For recertification, documentation of all of the following is required:
  - improvement from baseline in DLco and spleen volume; **and**
  - updated member weight.

Xuriden

- Documentation of all of the following is required:
  - diagnosis of hereditary orotic aciduria (HOA); **and**
  - genetic testing confirming mutation in UMPS gene; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

MassHealth Evaluation Criteria
Table 66 - Antibiotics and Anti-Infectives – Injectable

Drug Category: Infectious Disease Agents

Medication Class/Individual Agents: Antibiotics and Anti-Infectives – Injectable

I. Prior-Authorization Requirements

Antibiotics: Injectable – Fluoroquinolones

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
ciprofloxacin injection, suspension, 250 mg, 500 mg, 750 mg tablet	Cipro		# , A90	Delafloxacin requires PA because of safety concerns and to ensure appropriate utilization.
delafloxacin injection	Baxdela	PA		
levofloxacin			A90	
moxifloxacin injection	Avelox			

Antibiotics: Injectable – Cephalosporins

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
cefazolin				Cefiderocol, ceftazidime/avibactam, and ceftolozane/tazobactam require PA because of safety concerns and to ensure appropriate utilization.
cefepime				
cefiderocol	Fetroja	PA		
cefotaxime	Claforan		#	
cefotetan				
cefoxitin				
ceftaroline	Teflaro		BP	
ceftazidime				
ceftazidime / avibactam	Avycaz	PA		
ceftolozane / tazobactam	Zerbaxa	PA		
ceftriaxone				
cefuroxime sodium				

Anti-Infectives: Injectable – Not Otherwise Classified

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
artesunate		PA		• Dalbavancin, dalfopristin/quinupristin, lefamulin, linezolid, oritavancin, tedizolid, telavancin, and tigecycline require PA to ensure appropriate utilization and due to safety concerns. • These antibiotics are approved for indications such as
azithromycin	Zithromax		# , A90	
aztreonam injection	Azactam		#	
chloramphenicol			MB	
clindamycin capsule, injection,	Cleocin		# , A90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
oral solution				complicated and uncomplicated skin and skin structure infections, intra-abdominal infections, pneumonia, bacteremia, endocarditis along with vancomycin-resistant *Enterococci* (VRE) infections. • In addition, many of the agents have activity against methicillin-resistant *Staphylococcus aureus* (MRSA) infection. • Intravenous (IV) artesunate is the recommended treatment for severe malaria. It is given at a dose of 2.4 mg/kg at 0, 12 and 24 hours. Artesunate should be continued until parasite density is ≤ 1% and the patient is able to tolerate oral medications. If IV artesunate is not readily available, oral antimalarials such as artemether/lumefantrine or atovaquone/proguanil are recommended until IV artesunate is procured. [1] 1. Centers for Disease Control and Prevention. Malaria Treatment Guidelines, 2021 [guideline on the Internet]. Atlanta (GA): CDC; 2021 [cited 2021 Nov 19]; Available from: https://www.cdc.gov/malaria/diagnosis_treatment/clinicians1.html.
colistimethate sodium injection	Coly-Mycin M		#	
dalbavancin	Dalvance	PA		
daptomycin	Cubicin		#	
daptomycin				
erythromycin injection	Erythrocin			
isoniazid			A90	
lincomycin	Lincocin		#	
linezolid injection	Zyvox	PA		
metronidazole injection	Metro		#	
oritavancin	Kimyrsa	PA		
oritavancin	Orbactiv	PA		
rifampin	Rifadin		# , A90	
sulfamethoxazole / trimethoprim injection				
taurolidine/heparin	Defencath	PA	MB	
tedizolid injection	Sivextro	PA		
telavancin	Vibativ	PA		
tigecycline	Tygacil	PA		
vancomycin injection				

Antibiotics: Injectable – Penicillins

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
ampicillin			A90	
ampicillin / sulbactam	Unasyn		#	
nafcillin				
oxacillin				
penicillin G 0.6 million, 1.2 million, 2.4 million units	Bicillin LA			
penicillin G 5 million, 20 million units	Pfizerpen		#	
penicillin G benzathine / penicillin G procaine	Bicillin CR			
piperacillin / tazobactam	Zosyn		#	

Antibiotics: Injectable – Carbapenems

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
ertapenem	Invanz		#	Imipenem/cilastatin/relebactam and meropenem/vaborbactam require PA because of safety concerns and to ensure appropriate utilization.
imipenem / cilastatin	Primaxin		#	
imipenem / cilastatin / relebactam	Recarbrio	PA		
meropenem				
meropenem / vaborbactam	Vabomere	PA		

Antibiotics: Injectable – Tetracyclines

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
doxycycline hyclate injection				Eravacycline and omadacycline require PA because of safety concerns and to ensure appropriate utilization.
eravacycline	Xerava	PA		
minocycline injection	Minocin			
omadacycline injection	Nuzyra	PA		

Antibiotics: Injectable – Aminoglycosides

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amikacin				Plazomicin requires prior authorization (PA) because of safety concerns and to ensure appropriate utilization.
gentamicin injection				
plazomicin	Zemdri	PA		
streptomycin				
tobramycin injection				

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Infections (site and location vary by indication for requested agent)

Non-FDA-approved, for example:

- Infections (site and location vary by indication for requested agent)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

artesunate for the treatment of malaria

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dose and frequency.

Avycaz, Fetroja, Recarbrio, and Zerbaxa for the treatment of hospital-acquired (nosocomial) bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP) infections caused by susceptible Gram-negative organisms

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication (e.g., culture is not susceptible) to all of the following:
    - aminoglycosides (gentamicin, amikacin, tobramycin); **or**
    - aztreonam; **or**
    - cefepime; **or**
    - ceftazidime; **or**
    - ciprofloxacin or levofloxacin; **or**
    - imipenem/cilastatin; **or**
    - meropenem; **or**
    - piperacillin/tazobactam.

Avycaz, Fetroja, Recarbrio, and Vabomere for the treatment of carbapenem-resistant enterobacterales

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- one of the following:
  - culture is resistant to ertapenem and meropenem (if cultures can be obtained); **or**
  - suspected resistance to ertapenem and meropenem and susceptibility testing is not able to be performed.

Avycaz, Recarbrio, tigecycline, Xerava, and Zerbaxa for the treatment of complicated intra-abdominal infections (cIAI)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for tigecycline or Zerbaxa, member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication (e.g., culture is not susceptible) to all of the following:
    - combination therapy with aztreonam and metronidazole and vancomycin; **or**
    - combination therapy with metronidazole and cefepime; **or**
    - combination therapy with metronidazole and cefotaxime; **or**
    - combination therapy with metronidazole and ceftazidime; **or**
    - combination therapy with metronidazole and ceftriaxone; **or**
    - combination therapy with metronidazole and ciprofloxacin; **or**
    - combination therapy with metronidazole and levofloxacin; **or**
    - doripenem; **or**
    - ertapenem; **or**
    - imipenem/cilastatin; **or**
    - meropenem; **or**
    - moxifloxacin; **or**
    - piperacillin/tazobactam; **and**
  - for Avycaz or Zerbaxa, the requested agent is being utilized concurrently with metronidazole.

Avycaz, Fetroja, Recarbrio, Vabomere, Zemdri, and Zerbaxa for the treatment of complicated urinary tract infections (cUTI)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for Vabomere, Zemdri, or Zerbaxa, member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication (e.g., culture is not susceptible) to all of the following:
    - amikacin; **or**
    - ampicillin/sulbactam; **or**
    - aztreonam; **or**
    - cefepime; **or**
    - ceftazidime; **or**
    - ceftriaxone; **or**
    - ciprofloxacin or levofloxacin; **or**
    - ertapenem; **or**
    - gentamicin; **or**
    - imipenem/cilastatin; **or**
    - meropenem; **or**
    - piperacillin/tazobactam.

Baxdela injection and Nuzyra injection for the treatment of non-MRSA community acquired bacterial pneumonia (CABP) infections

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to Teflaro; **and**
  - inadequate response or adverse reaction to a regimen containing one or contraindication to all of the following:
    - amoxicillin; **or**
    - amoxicillin/clavulanate; **or**
    - ampicillin/sulbactam; **or**

- azithromycin; **or**
- cefotaxime; **or**
- cefpodoxime; **or**
- ceftriaxone; **or**
- cefuroxime; **or**
- clarithromycin; **or**
- doxycycline; **or**
- levofloxacin; **or**
- moxifloxacin.

Baxdela injection, Kimyrsa, Nuzyra injection, and Orbactiv for the treatment of non-MRSA skin and soft tissue infections (SSTIs)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - organism susceptibility to the requested agent; **or**
    - culture cannot be obtained due to the nature of the infection; **and**
  - for Kimyrsa or Orbactiv, inadequate response, adverse reaction, or contraindication (e.g., culture not susceptible) to all of the following: ceftaroline, daptomycin, vancomycin; **and**
  - for Kimyrsa, clinical rationale for use instead of Orbactiv; **and**
  - for Baxdela or Nuzyra, both of the following:
    - inadequate response, adverse reaction, or contraindication to Teflaro; **and**
    - one of the following:
      - inadequate response to one regimen available without PA; **or**
      - adverse reaction, contraindication, or culture is resistant to all regimens available without PA.

Baxdela injection, Dalvance, Kimyrsa, linezolid injection, Nuzyra injection, Orbactiv, Sivextro injection, tigecycline, and Vibativ for the treatment of MRSA SSTIs

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for Baxdela, Kimyrsa, Nuzyra, Orbactiv, Sivextro, or Vibativ, member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication (e.g., culture not susceptible) to all of the following: ceftaroline, daptomycin, vancomycin; **and**
  - for tigecycline, one of the following:
    - inadequate response, adverse reaction, or contraindication to all other available agents that treat MRSA SSTIs; **or**
    - culture is resistant to all other available agents that treat MRSA SSTIs (if cultures can be obtained); **and**
  - for Kimyrsa, clinical rationale for use instead of Orbactiv.

Please note: Adverse events caused by vancomycin, such as red-man syndrome (rate-related infusion reaction) or renal (kidney) adverse events, such as increased serum creatinine or microalbuminuria, are also associated with Vibativ, and renal events in particular are higher with Vibativ. Thus, these specific adverse reactions are not appropriate clinical rationale for selecting Vibativ over vancomycin.

Dalvance for MRSA osteomyelitis or MRSA bacteremia

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale for use of requested agent instead of vancomycin.

Dalvance, linezolid injection, Sivextro injection, tigecycline, and Vibativ for the treatment of non-MRSA/non-VRE infections

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for Sivextro or Vibativ, member is ≥ 18 years of age; **and**
  - one of the following:

    - organism susceptibility to the requested agent; **or**
    - culture cannot be obtained due to the nature of the infection; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to vancomycin; **or**
    - culture is resistant to vancomycin (if cultures can be obtained).

Please note: Adverse events caused by vancomycin, such as red-man syndrome (rate-related infusion reaction) or renal (kidney) adverse events, such as increased serum creatinine or microalbuminuria, are also associated with Vibativ, and renal events in particular are higher with Vibativ. Thus, these specific adverse reactions are not appropriate clinical rationale for selecting Vibativ over vancomycin.

Dalvance or Vibativ for VRE infection or suspected VRE infection

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to linezolid; **or**
    - culture is resistant to linezolid (if cultures can be obtained).

Defencath for the prevention of catheter-related bloodstream infections (CRBSI)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is receiving chronic hemodialysis through a central venous catheter; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all other clinically appropriate less costly antimicrobials in combination with heparin; **and**
  - one of the following:
    - member has history of CRBSIs; **or**
    - member is a nasal carrier of Staphylococcus aureus.

linezolid injection for the treatment of MRSA bone/joint infections

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to vancomycin; **or**
    - culture is resistant to vancomycin (if cultures can be obtained); **or**
    - member has a history of MRSA infections that have not responded to vancomycin in the past.

linezolid injection, Sivextro injection, and tigecycline for the treatment of VRE infections

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for Sivextro, member is is ≥ 18 years of age; **and**
  - for Sivextro or tigecycline, one of the following:
    - inadequate response, adverse reaction, or contraindication to linezolid; **or**
    - culture is resistant to linezolid (if cultures can be obtained).

linezolid injection for the treatment of MRSA central nervous system (CNS) infections

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to vancomycin; **or**
    - culture is resistant to vancomycin (if cultures can be obtained); **or**
    - member has a history of MRSA infections that have not responded to vancomycin in the past.

linezolid injection and Vibativ for the treatment of HABP infections caused by MRSA or suspected MRSA

- Documentation of the following is required:

- appropriate diagnosis; **and**
- one of the following:
  - inadequate response, adverse reaction, or contraindication to vancomycin; **or**
  - culture is resistant to vancomycin (if cultures can be obtained); **or**
  - member has a history of MRSA infections that have not responded to vancomycin in the past; **and**
- if the request is for Vibativ, both of the following:
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to linezolid; **or**
    - culture is resistant to linezolid (if cultures can be obtained); **or**
    - member has a history of MRSA infections that have not responded to linezolid in the past.

Please note: Adverse events caused by vancomycin, such as red-man syndrome (rate-related infusion reaction) or renal (kidney) adverse events, such as increased serum creatinine or microalbuminuria, are also associated with Vibativ, and renal events in particular are higher with Vibativ. Thus, these specific adverse reactions are not appropriate clinical rationale for selecting Vibativ over vancomycin.

Vibativ for the treatment of VABP infections caused by MRSA or suspected MRSA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to vancomycin; **or**
    - culture is resistant to vancomycin (if cultures can be obtained); **or**
    - member has a history of MRSA infections that have not responded to vancomycin in the past; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to linezolid; **or**
    - culture is resistant to linezolid (if cultures can be obtained); **or**
    - member has a history of MRSA infections that have not responded to linezolid in the past.

Please note: Adverse events caused by vancomycin, such as red-man syndrome (rate-related infusion reaction) or renal (kidney) adverse events, such as increased serum creatinine or microalbuminuria, are also associated with Vibativ, and renal events in particular are higher with Vibativ. Thus, these specific adverse reactions are not appropriate clinical rationale for selecting Vibativ over vancomycin.

MassHealth Evaluation Criteria
Table 67 - Antiviral Agents

Drug Category: Antiviral Agents

Medication Class/Individual Agents: Antiviral Agents

I. Prior-Authorization Requirements

Antiviral Agents – Topical			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acyclovir / hydrocortisone	Xerese		
acyclovir cream	Zovirax		BP
acyclovir ointment	Zovirax		#
penciclovir	Denavir		BP

Antiviral Agents – Oral and Injectable			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acyclovir capsule, tablet			A90
acyclovir injection			
acyclovir suspension	Zovirax		# , A90
cidofovir			
famciclovir			A90
foscarnet			MB
ganciclovir injection			
letermovir	Prevymis	PA	
maribavir	Livtencity	PA	
valacyclovir	Valtrex		# , A90
valganciclovir powder for oral solution	Valcyte	PA	A90
valganciclovir tablet	Valcyte		# , A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- The 2015 Centers for Disease Control and Prevention (CDC) sexually transmitted diseases treatment guidelines state that topical antiviral therapy offers minimal clinical benefit for the treatment of genital herpes and does not recommend their use.[1]
- The CDC guidelines recommend the use of oral antiviral agents, including acyclovir, famciclovir, and valacyclovir for recurrent and suppressive therapy in genital herpes.[1]
- Oral antiviral agents (acyclovir, famciclovir and valacyclovir) are available without PA.
- Acyclovir is also available as an oral suspension.
- Letermovir therapy is limited to 100 days post-transplant.

[1]Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines [homepage on the Internet]. Atlanta: Centers for Disease Control and Prevention: 2015 [updated 2015 Jun 5]; [cited 2018 May 31]. Available from: https://www.cdc.gov/std/tg2015/tg-2015-print.pdf

\# This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (Prevymis, valganciclovir powder for oral solution)
- Prophylaxis of CMV infection post-solid organ transplant (valganciclovir powder for oral solution)
- Prophylaxis of CMV infection post-kidney transplant (Prevymis)
- Treatment of CMV infection post-transplant that is refractory to standard treatment in adult and pediatric patients ≥ 12 years of age and who weigh ≥ 35 kg (Livtencity)
- Treatment of CMV retinitis (valganciclovir powder for oral solution)

non-FDA-approved, for example:

- Prophylaxis of CMV infection post-solid organ transplant (non-kidney, non-hematopoietic stem cell transplant) (Prevymis)

Note: The above list may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, application frequency, and tube size.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member’s condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member’s current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Livtencity

- Documentation of the following is required:

- appropriate diagnosis; **and**
- member is ≥ 12 years of age; **and**
- member weight is ≥35 kg; **and**
- prescriber is an infectious disease specialist or consultation notes from an infectious disease specialist are provided; **and**
- appropriate dosing; **and**
- member will not be receiving concurrent antiviral therapy with cidofovir, foscarnet, ganciclovir, or valganciclovir; **and**
- one of the following:
  - inadequate response or adverse reaction to ganciclovir or valganciclovir; **or**
  - contraindication to cidofovir, foscarnet, ganciclovir, and valganciclovir; **or**
  - both of the following:
    - contraindication to both ganciclovir and valganciclovir; **and**
    - inadequate response or adverse reaction to cidofovir or foscarnet.

Prevymis

- Documentation of the following is required for prophylaxis of cytomegalovirus (CMV) infection post-allogeneic hematopoietic stem cell transplant:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is an infectious disease specialist, hematologist, or transplant specialist or consult notes are provided; **and**
  - member is at high risk for CMV reactivation; **and**
  - for 240 mg tablet, the requested agent will be used in combination with cyclosporine; **and**
  - for tablet, requested quantity is ≤ one tablet/day; **and**
  - for the injection formulation, medical necessity for use of the requested formulation instead of the tablet formulation.
- Documentation of the following is required for prophylaxis of CMV infection post-kidney transplant:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is an infectious disease specialist, hematologist, or transplant specialist or consult notes are provided; **and**
  - member is at high risk for CMV reactivation; **and**
  - inadequate response, adverse reaction, or contraindication to valganciclovir; **and**
  - for 240 mg tablet, the requested agent will be used in combination with cyclosporine; **and**
  - for tablet, requested quantity is ≤ one tablet/day; **and**
  - for the injection formulation, medical necessity for use of the requested formulation instead of the tablet formulation.
- Documentation of the following is required for prophylaxis of CMV infection post-solid organ (non-kidney, non-HSCT) transplant:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is an infectious disease specialist, hematologist, or transplant specialist or consult notes are provided; **and**
  - member is at high risk for CMV reactivation; **and**
  - inadequate response, adverse reaction, or contraindication to valganciclovir; **and**
  - for 240 mg tablet, the requested agent will be used in combination with cyclosporine; **and**
  - for tablet, requested quantity is ≤ one tablet/day; **and**
  - for the injection formulation, medical necessity for use of the requested formulation instead of the tablet formulation.

valganciclovir powder for oral solution

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for a diagnosis of CMV retinitis, member is ≥ 18 years of age; **and**
  - medical necessity for the use of a solution formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**

- member has a swallowing disorder or condition affecting ability to swallow; **or**
- member is < 13 years of age; **and**

- requested quantity is ≤ 18 mL/day.

MassHealth Evaluation Criteria
Table 68 - Thrombocytopenic Agents

Drug Category: Blood and Circulation

Medication Class/Individual Agents: Thrombocytopenic Agents

I. Prior-Authorization Requirements

Thrombocytopenic Agents – Thrombopoietin Agonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
avatrombopag	Doptelet	PA	
eltrombopag choline	Alvaiz	PA	
eltrombopag olamine	Promacta	PA	BP
lusutrombopag	Mulpleta	PA	
romiplostim	Nplate	PA	MB

Thrombocytopenic Agents – Monoclonal Antibody			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
caplacizumab-yhdp	Cablivi	PA	

Thrombocytopenic Agents – Tyrosine Kinase Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fostamatinib	Tavalisse	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Thrombopoietin agonists are approved for the treatment of refractory thrombocytopenia in those patients who have had an insufficient response to corticosteroids, immunoglobulin, or splenectomy.
- Eltrombopag is also approved for the treatment of severe aplastic anemia and thrombocytopenia in the setting of hepatitis C.
- Romiplostim is also approved for the treatment of hematopoietic syndrome of acute radiation syndrome.
- These agents are not approved for the normalization of platelet counts and should only be used in those whose clinical condition is associated with a high risk of bleeding.
- Fostamatinib is a tyrosine kinase inhibitor with demonstrated activity against spleen tyrosine kinase (SYK). It is approved for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.
- Avatrombopag and lusutrombopag are indicated for the treatment of thrombocytopenia in adults with chronic liver disease (CLD) who are scheduled to undergo a procedure.
  - For avatrombopag, dosing should begin 10-to-13 days

	Clinical Notes
	before scheduled procedure. Patients should undergo their procedure five-to-eight days after the last dose. • For lusutrombopag, dosing should begin eight-to-14 days before scheduled procedure. Patients should undergo their procedure two-to-eight days after the last dose. • Avatrombopag is also indicated for thrombocytopenia in adults with chronic ITP who have had insufficient response to a previous treatment. • Caplacizumab-yhdp is a novel humanized immunoglobulin (nanobody) that works by targeting platelet (PLT) aggregation through binding to von Willebrand factor (vWF) and inhibiting interaction between vWF and PLTs. It is approved for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange (PEX) and immunosuppressive therapy. This agent should be administered upon initiation of PEX and continued once daily for 30 days following the last daily PEX.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- aTTP (Cablivi)
- Chronic, relapsed, or refractory ITP (Alvaiz, Doptelet, Nplate, Promacta, Tavalisse)
- Hematopoietic syndrome of acute radiation ayndrome (HS-ARS)/acute exposure to myelosuppressive doses of radiation (Nplate)
- Severe aplastic anemia (Alvaiz, Promacta)
- Thrombocytopenia due to CLD in a member scheduled to undergo a procedure (Doptelet, Mulpleta)
- Thrombocytopenia in the setting of hepatitis C with interferon therapy (Alvaiz, Promacta)

Non-FDA-approved, for example:

- Chemotherapy-induced thrombocytopenia (Nplate)
- Thrombocytopenia in the setting of hepatitis C independent of interferon therapy (Promacta)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Alvaiz

- Documentation of the following is required for a diagnosis of chronic, relapsed, or refractory ITP:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - one of the following:
    - platelet count < 30,000 cells/mcL; **or**
    - medical necessity for platelet elevation (upcoming surgery, peptic ulcer disease or condition that may predispose member to bleeding); **and**
  - requested dose is ≤ 54 mg/day; **and**
  - medical necessity for the requested agent instead of Promacta; **and**
  - for the 9 mg tablet, requested quantity is ≤ one unit/day; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: corticosteroid, immunoglobulin; **or**
    - member has had a splenectomy.

- Documentation of the following is required for a diagnosis of severe aplastic anemia:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - platelet count < 50,000 cells/mcL; **and**
  - requested dose is ≤ 108 mg/day; **and**
  - medical necessity for the requested agent instead of Promacta; **and**
  - for the 9 mg tablet, requested quantity is ≤ one unit/day; **and**
  - inadequate response, adverse reaction, or contraindication to immunosuppressive therapy with anti-thymocyte globulin (ATG); **and**
  - inadequate response, adverse reaction, or contraindication to immunosuppressive therapy with cyclosporine.

- Documentation of the following is required for a diagnosis of thrombocytopenia in the setting of hepatitis C with interferon therapy:

- appropriate diagnosis; **and**
- member is ≥ 18 years of age; **and**
- requested dose is ≤ 72 mg/day; **and**
- medical necessity for the requested agent instead of Promacta; **and**
- for the 9 mg tablet, requested quantity is ≤ one unit/day; **and**
- one of the following:
  - member intends to initiate therapy with interferon and current platelet count is ≤ 75,000 cells/mcL; **or**
  - both of the following:
    - member has already begun interferon therapy and platelet count supports continued use; **and**
    - member has met criteria for continued interferon therapy based on treatment futility protocols per most recent PA for hepatitis antiviral agents.

Cablivi

- Documentation of the following is required for a diagnosis of aTTP:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested agent will be used initially in conjunction with immunosuppressive therapy; **and**
  - requested quantity is ≤ one unit/day after initial bolus injection.

Doptelet

- Documentation of the following is required for a diagnosis of chronic, relapsed, or refractory ITP:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - platelet count < 30,000 cells/mcL; **or**
    - medical necessity for platelet elevation (upcoming surgery, peptic ulcer disease or condition that may predispose member to bleeding); **and**
  - inadequate response, adverse reaction, or contraindication to eltrombopag; **and**
  - requested quantity is ≤ two units/day; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: corticosteroid, immunoglobulin; **or**
    - member has had a splenectomy.

- Documentation of the following is required for a diagnosis of thrombocytopenia due to CLD in a member scheduled to undergo a procedure:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - platelet count < 50,000 cells/mcL; **and**
  - one of the following:
    - if platelet count is 40,000 to < 50,000 cells/mcL, requested dose is 40 mg (two tablets) once daily for five days; **or**
    - if platelet count is less than 40,000 cells/mcL, requested dose is 60 mg (three tablets) once daily for five days.

Mulpleta

- Documentation of the following is required for a diagnosis of thrombocytopenia due to CLD in a member scheduled to undergo a procedure:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - platelet count < 50,000 cells/mcL; **and**

- inadequate response, adverse reaction, or contraindication to Doptelet; **and**
- requested dose is 3 mg once daily for a maximum of seven days.

Nplate

- Documentation of the following is required for a diagnosis of chronic, relapsed, or refractory ITP:
  - appropriate diagnosis; **and**
  - member is ≥ one year of age; **and**
  - one of the following:
    - platelet count < 30,000 cells/mcL; **or**
    - medical necessity for platelet elevation (upcoming surgery, peptic ulcer disease or condition that may predispose member to bleeding); **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: corticosteroid, immunoglobulin; **or**
    - member has had a splenectomy; **and**
  - inadequate response, adverse reaction, or contraindication to eltrombopag.

- Documentation of the following is required for a diagnosis of HS-ARS/acute exposure to myelosuppressive doses of radiation:
  - appropriate diagnosis; **and**
  - requested dose is 10 mcg/kg for a one-time administration.

- Documentation of the following is required for a diagnosis of chemotherapy-induced thrombocytopenia :
  - appropriate diagnosis; **and**
  - platelet count < 100,000 cells/µL; **and**
  - treatment plan, including target platelet count goal; **and**
  - requested dose is ≤ 10 mcg/kg weekly.
- For recertification, prescriber provides documentation of both of the following:
  - positive response to therapy as indicated by an increase in platelets from baseline; **and**
  - one of the following:
    - platelet count < 100,000 cells/ µL; **or**
    - both of the following:
      - platelet count ≥ 100,000 cells/µL; **and**
      - medical necessity for continued use of requested agent.

Promacta

- Documentation of the following is required for a diagnosis of chronic, relapsed, or refractory ITP:
  - appropriate diagnosis; **and**
  - member is ≥ one year of age; **and**
  - one of the following:
    - platelet count < 30,000 cells/mcL; **or**
    - medical necessity for platelet elevation (upcoming surgery, peptic ulcer disease or condition that may predispose member to bleeding); **and**
  - requested dose is ≤ 75 mg/day; **and**
  - for the 12.5 mg tablet or packet, requested quantity is ≤ one unit/day; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: corticosteroid, immunoglobulin; **or**
    - member has had a splenectomy.

- Documentation of the following is required for a diagnosis of severe aplastic anemia:

- appropriate diagnosis; **and**
- member is ≥ two years of age; **and**
- platelet count < 50,000 cells/mcL; **and**
- requested dose is ≤ 150 mg/day; **and**
- for the 12.5 mg tablet or packet, requested quantity is ≤ one unit/day; **and**
- one of the following:
  - inadequate response, adverse reaction, or contraindication to immunosuppressive therapy with anti-thymocyte globulin (ATG) and cyclosporine; **or**
  - member is treatment naïve and the requested agent will be used in combination with ATG and cyclosporine.

- Documentation of the following is required for a diagnosis of thrombocytopenia in the setting of hepatitis C with interferon therapy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is ≤100 mg/day; **and**
  - for the 12.5 mg tablet or packet, requested quantity is ≤ one unit/day; **and**
  - one of the following:
    - member intends to initiate therapy with interferon and current platelet count is ≤ 75,000 cells/mcL; **or**
    - both of the following:
      - member has already begun interferon therapy and platelet count supports continued use; **and**
      - member has met criteria for continued interferon therapy based on treatment futility protocols per most recent PA for hepatitis antiviral agents.

- Documentation of the following is required for a diagnosis of thrombocytopenia in the setting of hepatitis C independent of interferon therapy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is ≤100 mg/day; **and**
  - for the 12.5 mg tablet or packet, requested quantity is ≤ one unit/day; **and**
  - current platelet count is ≤ 75,000 cells/mcL; **and**
  - member is not currently using interferon therapy and does not intend to begin therapy; **and**
  - inadequate response, adverse reaction, or contraindication to immunoglobulin.

Tavalisse

- Documentation of the following is required for a diagnosis of chronic, relapsed, or refractory ITP:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - platelet count < 30,000 cells/mcL; **or**
    - medical necessity for platelet elevation (upcoming surgery, peptic ulcer disease or condition that may predispose member to bleeding); **and**
  - inadequate response, adverse reaction, or contraindication to eltrombopag; **and**
  - requested quantity is ≤ two units/day; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: corticosteroid, immunoglobulin; **or**
    - member has had a splenectomy.

MassHealth Evaluation Criteria

Table 69 - Barbiturates, Benzodiazepines, and Miscellaneous Antianxiety Agents

Drug Category: Central Nervous System

Medication Class/Individual Agents: Barbiturates, Benzodiazepines, and Miscellaneous Antianxiety Agents

I. Prior-Authorization Requirements

Benzodiazepines

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
alprazolam extended-release	Xanax XR	PA - < 6 years and PA > 2 units/day	#	• Extended-release and orally disintegrating benzodiazepine formulations require prior authorization (PA) due to the availability of less-costly dosage formulations. • For additional information regarding the management of benzodiazepine powders for compounding, please see: Table 79 - Pharmaceutical Compounds.
alprazolam orally disintegrating tablet		PA		
alprazolam solution		PA - < 6 years and ≥ 13 years		
alprazolam tablet	Xanax	PA - < 6 years	#	
chlordiazepoxide		PA - < 6 years		
clonazepam 0.125 mg, 0.25 mg, 0.5 mg, 1 mg orally disintegrating tablet		PA - < 6 years and PA > 3 units/day		
clonazepam 2 mg orally disintegrating tablet		PA - < 6 years and PA > 2 units/day		
clonazepam tablet	Klonopin	PA - < 6 years	#	
clorazepate		PA		
diazepam 25 mg/5 mL solution		PA		
diazepam 5 mg/5 mL solution, tablet	Valium	PA - < 6 years	#	
diazepam injection				
estazolam		PA - < 6 years and PA > 1 unit/day		
flurazepam		PA		
lorazepam extended-release	Loreev XR	PA		
lorazepam injection	Ativan		#	
lorazepam solution		PA - < 6 years and ≥ 13 years		
lorazepam tablet	Ativan	PA - < 6 years	#	
midazolam injection			MB	
midazolam syrup		PA - < 6 years		
oxazepam		PA		
quazepam	Doral	PA		
remimazolam	Byfavo	PA	MB	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
temazepam 22.5 mg	Restoril	PA	
temazepam 7.5 mg, 15 mg, 30 mg	Restoril	PA - < 6 years and PA > 1 unit/day	#
triazolam	Halcion	PA - < 6 years and PA > 1 unit/day	#

Antianxiety Agents – Not Otherwise Classified

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amitriptyline / chlordiazepoxide		PA		
buspirone		PA - < 6 years	A90	
chlordiazepoxide / clidinium	Librax	PA		
meprobamate		PA		

Barbiturates

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
phenobarbital 100 mg injection	Sezaby		MB	
phenobarbital 65 mg / mL, 130 mg / mL injection			MB	
phenobarbital tablet, solution				

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Alcohol withdrawal syndrome (alprazolam ER, clorazepate, oxazepam)
- Anxiety, panic disorder, skeletal muscle spasm, or seizure (benzodiazepines excluding chlordiazepoxide/clidinium)
- Anxiety (Loreev XR, meprobamate)
- Emotional and somatic factors in gastrointestinal disorders (chlordiazepoxide/clidinium)
- Adjunctive therapy in peptic ulcer, irritable bowel syndrome, and acute enterocolitis (chlordiazepoxide/clidinium)
- Induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less (Byfavo)

- Insomnia (estazolam, flurazepam, quazepam, temazepam, triazolam)
- Seizure disorder (alprazolam, clorazepate, diazepam, lorazepam, oxazepam)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

alprazolam extended-release > two units/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - requested dose cannot be consolidated; **and**
  - medical records documenting titration of medication up to current dose; **and**
  - clinical rationale for dosing higher than FDA approved limits.

alprazolam orally disintegrating tablet and diazepam 25 mg/5 mL oral solution

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for requested formulation instead of solid oral formulations as noted by one of the following:
    - member utilizes tube feeding (G-tube or J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age; **and**
  - for alprazolam orally disintegrating tablets, the requested dose cannot be consolidated; **and**
  - for diazepam 25 mg/5 mL, medical necessity for the concentrated formulation instead of the 5 mg/5 mL solution.

alprazolam and lorazepam oral solution ≥ 13 years of age

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for requested formulation instead of solid oral formulations as noted by one of the following:
    - member utilizes tube feeding (G-tube or J-tube); **or**

- member has a swallowing disorder or condition affecting ability to swallow.

Byfavo

- Documentation of all of the following is required:
  - the agent will be used for induction and maintenance of procedural sedation; **and**
  - inadequate response, adverse reaction, or contraindication to intravenous midazolam; **and**
  - appropriate dosing.

chlordiazepoxide/amitriptyline

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the use of the combination product instead of the commercially available separate agents.

SmartPA: Claims for chlordiazepoxide/amitriptyline will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent for at least 90 days of therapy out of the last 120 days.†

chlordiazepoxide/clidinium

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ eight units/day; **and**
  - prescriber is a gastrointestinal specialist or consult notes from a gastroenterology office are provided; **and**
  - inadequate response or adverse reaction to two or contraindication to all anticholinergic/antispasmodics; **and**
  - inadequate response or adverse reaction to one or contraindication to all SSRIs; **and**
  - inadequate response or adverse reaction to one or contraindication to all non-benzodiazepine anxiolytics; **and**
  - inadequate response or adverse reaction to one other benzodiazepine; **and**
  - requested medication will be used as an adjunctive therapy; **and**
  - for a diagnosis of peptic ulcer, all of the following:
    - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to two proton pump inhibitors, or contraindication to all proton pump inhibitors; **and**
    - requested treatment duration is ≤ 12 weeks; **and**
    - for H. pylori-positive peptic ulcer, an inadequate response to one four-week course of appropriate combination therapy; **or**
  - for a diagnosis of irritable bowel syndrome with constipation, both of the following:
    - inadequate response or adverse reaction to two or contraindication to all of the following: Linzess, lubiprostone, Trulance; **and**
    - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **or**
  - for a diagnosis of irritable bowel syndrome with diarrhea, inadequate response or adverse reaction to five or contraindication to all of the following: bile acid sequestrants, bismuth subsalicylate, bulk-forming laxatives, diphenoxylate/atropine, loperamide, Xifaxan; **or**
  - for a diagnosis of acute enterocolitis, all of the following:
    - inadequate response, adverse reaction, or contraindication to both of the following: bismuth subsalicylate, loperamide; **and**
    - requested treatment duration ≤ three days.

clonazepam 0.125 mg, 0.25 mg, 0.5 mg, and 1 mg orally disintegrating tablet > three units/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or psychiatrist, or consult notes from a neurologist or psychiatrist are provided; **and**
  - requested dose cannot be consolidated within quantity limits; **and**
  - medical records documenting titration of medication up to current dose; **and**
  - clinical rationale for dosing higher than the FDA approved limits.

clonazepam 2 mg orally disintegrating tablet > two units/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or psychiatrist, or consult notes from a neurologist or psychiatrist are provided; **and**
  - requested dose cannot be consolidated within the quantity limit; **and**
  - medical records documenting titration of medication up to current dose; **and**
  - clinical rationale for dosing higher than the FDA approved limits.

clorazepate and oxazepam

- Documentation of all of the following is required
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all benzodiazepines: alprazolam, chlordiazepoxide, clonazepam, diazepam, lorazepam.

SmartPA: Claims for clorazepate and oxazepam will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days of therapy out of the last 120 days.†

estazolam, flurazepam, quazepam, temazepam 7.5 mg, 15 mg, and 30 mg, and triazolam 0.125 mg > one unit/day

- For all requests, individual drug PA criteria must be met first where applicable within established quantity limits for the individual drug.
- Documentation of all of the following is required:
  - diagnosis of insomnia; **and**
  - requested dose cannot be consolidated; **and**
  - medical necessity for exceeding the quantity limit noted by all of the following:
    - inadequate response to the established quantity limit; **and**
    - higher dose was effective in alleviating symptoms; **and**
    - for requests exceeding the FDA-approved maximum dose, inadequate response or adverse reaction to two alternatives for sleep (one must be a non-benzodiazepine hypnotic):
      - non-benzodiazepine hypnotics: eszopiclone, zaleplon, zolpidem (IR or ER); **or**
      - other alternatives: Belsomra, Dayvigo, diphenhydramine, doxepin, melatonin, Quvivq, Rozerem, trazodone.

flurazepam and quazepam

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to all of the following hypnotic benzodiazepines: estazolam, temazepam 7.5, 15, or 30 mg, triazolam; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - medical necessity for > one unit/day.

Loreev XR

- Documentation of all of the following is required
  - appropriate diagnosis; **and**
  - medical records documenting stability with lorazepam tablets in three evenly divided daily doses; **and**
  - one of the following:
    - medical records documenting inadequate response or adverse reaction to two intermediate/long- or long-acting benzodiazepines; **or**
    - contraindication to all other long-acting benzodiazepines; **and**

- requested quantity is ≤ one unit/day.

meprobamate
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all benzodiazepines (Please note, up to two one-month provisional approvals may be allowed for members who are stabilized on the requested medication to avoid risk of withdrawal).
- For recertification requests, documentation of all of the following is required:
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to three or contraindication to all of the following: buspirone, SSRI, SNRI, TCA; **and**
  - clinical rationale for continued therapy with meprobamate.

temazepam 22.5 mg
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - adverse reaction or inadequate response to all of the following hypnotic benzodiazepines:
    - estazolam; **and**
    - temazepam 7.5 mg, 15 mg, or 30 mg; **and**
    - triazolam; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - all of the following
      - inadequate response to 30 mg/day; **and**
      - medical records documenting titration of medication up to current dose; **and**
      - clinical rationale for dosing higher than the FDA approved limits.

triazolam 0.25 mg > one unit/day
- Documentation of all of the following is required:
  - diagnosis of insomnia; **and**
  - inadequate response to 0.25 mg/day.

Brand-name products (Ativan, Klonopin, Xanax)
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an adverse reaction or inadequate response to a generic equivalent of the requested product; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one other non-hypnotic benzodiazepine; **and**
  - requested dose cannot be consolidated within the quantity limit.

Benzodiazepine Polypharmacy ***(overlapping pharmacy claims for two or more benzodiazepines [excludes clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations] for at least 60 days within a 90-day period)*** **for members ≥ 18 years of age**
- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required for a sleep diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - prescriber is a neurologist, sleep medicine specialist, or psychiatrist, or consultation notes from specialist are provided; **and**

- clear treatment plan (i.e., medication name(s), dose, frequency); **and**
- severity of sleep diagnosis outlined; **and**
- intended treatment duration and prescriber follow-up plan noted; **and**
- one of the following:
  - cross-titration/taper of benzodiazepine therapy (Please note, six-month provisional approval may be allowed for members who are cross-titrating or tapering from one agent to another); **or**
  - both of the following:
    - inadequate response, adverse reaction, or contraindication to all alternative hypnotics indicated for diagnosis: eszopiclone, zaleplon, zolpidem (IR or ER), an orexin receptor antagonist (Belsomra, Dayvigo, Quviviq), Rozerem, doxepin; **and**
    - the benzodiazepine regimen includes one short acting benzodiazepine agent and one long-acting benzodiazepine agent (Please note, up to two one-month provisional approvals may be allowed for members whose regimens include two short-acting or two long-acting benzodiazepine agents and all other criteria are met).

- Documentation of the following is required for a psychiatric diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - clear treatment plan (i.e., diagnosis intended to treat, medication name(s), dose, frequency); **and**
    - severity of psychiatric condition outlined; **and**
    - intended treatment duration and prescriber follow-up plan noted; **and**
    - one of the following:
      - cross-titration/taper of benzodiazepine therapy (Please note, six-month provisional approval may be allowed for members who are cross-titrating or tapering from one agent to another); **or**
      - both of the following:
        - inadequate response or adverse reaction to three (trials must include at least one SSRI and one SNRI, unless classes are contraindicated) or contraindication to all of the following: buspirone (for the diagnosis of GAD only), mirtazapine, SNRI, SSRI, TCA, Trintellix, vilazodone; **and**
        - the benzodiazepine regimen includes one short acting benzodiazepine agent and one long-acting benzodiazepine agent (Please note, up to two one-month provisional approvals may be allowed for members whose regimens include two short-acting or two long-acting benzodiazepine agents and all other criteria are met).

Please note, up to two one-month provisional approvals may be allowed for members who are stabilized on the requested medication(s) to avoid risk of destabilization.

- Documentation of the following is required for a musculoskeletal diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - clear treatment plan (i.e., diagnosis intended to treat, medication name(s), dose, frequency); **and**
    - severity of musculoskeletal condition outlined; **and**
    - intended treatment duration and prescriber follow-up plan noted; **and**
    - one of the following:
      - cross-titration/taper of benzodiazepine therapy (Please note, six-month provisional approval may be allowed for members

who are cross-titrating or tapering from one agent to another); **or**
- both of the following:
  - inadequate response or adverse reaction to three or contraindication to all of the following skeletal muscle relaxants: chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol, orphenadrine; **and**
  - the benzodiazepine regimen includes one short-acting benzodiazepine agent and one long-acting benzodiazepine agent (Please note, up to two one-month provisional approvals may be allowed for members whose regimens include two short-acting or two long-acting benzodiazepine agents and all other criteria are met).

Please note, up to two one-month provisional approvals may be allowed for members who are stabilized on the requested medication(s) to avoid risk of destabilization.

- Documentation of the following is required for a seizure diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - clear treatment plan (i.e., diagnosis intended to treat, medication name(s), dose, frequency); **and**
    - intended treatment duration and prescriber follow-up plan noted; **and**
    - one of the following:
      - stability on the requested regimen; **or**
      - cross-titration/taper of benzodiazepine therapy (Please note, six-month provisional approval may be allowed for members who are cross-titrating or tapering from one agent to another); **or**
      - both of the following:
        - inadequate response or adverse reaction to three anticonvulsants; **and**
        - the benzodiazepine regimen includes one short-acting benzodiazepine agent and one long-acting benzodiazepine agent.

Please note, up to two one-month provisional approvals may be allowed for members who are stabilized on the requested medication(s) to avoid risk of destabilization.

- Documentation of the following is required for both a seizure and psychiatric diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - clear treatment plan (i.e., diagnosis intended to treat, medication name(s), dose, frequency); **and**
    - intended treatment duration and prescriber follow-up plan noted; **and**
    - one of the following:
      - stability on the requested regimen; **or**
      - cross-titration/taper of benzodiazepine therapy (Please note, six-month provisional approval may be allowed for members who are cross-titrating or tapering from one agent to another); **or**
      - all of the following:
        - inadequate response or adverse reaction to three anticonvulsants; **and**
        - inadequate response or adverse reaction to three (trials must include at least one SSRI and one SNRI, unless classes are contraindicated) or contraindication to all of the following: buspirone (for the diagnosis of GAD only), mirtazapine, SNRI, SSRI, TCA, Trintellix, vilazodone; **and**
        - the benzodiazepine regimen includes one short-acting benzodiazepine agent and one long-acting benzodiazepine agent.

Please note, up to two one-month provisional approvals may be allowed for members who are stabilized on the requested

medication(s) to avoid risk of destabilization.

Concomitant Opioid and Benzodiazepine Polypharmacy ***(pharmacy claims for ≥ 15 days supply for one or more opioid(s) [new to therapy] and one or more benzodiazepine(s) [clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations are not included] for ≥ 15 days supply within the past 45-day period.)***

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of all of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - appropriate diagnosis for the benzodiazepine; **and**
  - appropriate diagnosis for the opioid; **and**
  - one of the following:
    - member's treatment is currently managed by palliative care; **or**
    - member is currently in hospice or is transitioning to hospice; **or**
    - member is currently being treated for sickle cell disease or cancer pain; **or**
    - if the benzodiazepine is being used for a psychiatric diagnosis, an inadequate response (defined as ≥ 4 weeks of therapy), or adverse reaction to three antidepressants, or contraindication to all antidepressants; **or**
    - if the benzodiazepine is being used for a musculoskeletal diagnosis, an inadequate response, or adverse reaction to three skeletal muscle relaxants (e.g., cyclobenzaprine, chlorzoxazone, metaxalone, methocarbamol, orphenadrine), or a contraindication to all skeletal muscle relaxants; **or**
    - if the benzodiazepine is being used for a sleep disorder, an inadequate response, or adverse reaction to three non-benzodiazepine sleep medications, or a contraindication to all non-benzodiazepine sleep medications; **or**
    - if the benzodiazepine is being used for a seizure disorder, member is stable on a non-benzodiazepine anticonvulsant; **or**
    - treatment plan to taper off or taper down from benzodiazepine therapy; **or**
    - treatment plan to taper off opioid therapy; **or**
    - clinical rationale for the concomitant use of opioids and benzodiazepines; **and**
  - member will be co-prescribed naloxone.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy (*pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, viloxazine, and xanomeline/trospium] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period*) for members < 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist (including psychiatric nurse practitioners) neurologist,

pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
        - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
        - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
        - other significant barrier for therapy discontinuation.
- For regimens including ≥ two mood stabilizers, documentation of the following is required:
    - one of the following:
        - member had a recent psychiatric hospitalization (within the last three months); **or**
        - member has a history of severe risk of harm to self or others; **or**
    - all of the following:
        - appropriate diagnoses; **and**
        - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
        - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist (including psychiatric nurse practitioners) neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
        - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
            - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
            - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
            - other significant barrier for therapy discontinuation; **and**
        - one of the following:
            - member has a seizure diagnosis only; **or**
            - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
                - cross-titration/taper of mood stabilizer therapy; **or**
                - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
            - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
            - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and**
            - one off the following:
                - cross-titration/taper of mood stabilizer therapy; **or**
                - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Benzodiazepine Polypharmacy ***(overlapping pharmacy claims for two or more benzodiazepines [hypnotic benzodiazepine agents, clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations are not included] for at least 60 days within a 90-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
    - one of the following:
        - member had a recent psychiatric hospitalization (within the last three months); **or**
        - member has a history of severe risk of harm to self or others; **or**
        - member has a seizure diagnosis only; **or**
    - all of the following:
        - appropriate diagnosis; **and**

- treatment plan including names of current benzodiazepines and corresponding diagnoses; **and**
- one of the following:
  - cross-titration/taper of benzodiazepine therapy; **or**
  - clinical rationale for use of ≥ two benzodiazepines of different chemical entities.

buspirone for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

Benzodiazepine *(hypnotic benzodiazepine agents are not included)* for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - member has a seizure diagnosis only; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding indications; **and**
    - prescriber is a specialist (e.g. psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

SmartPA: Claims for mood stabilizers or benzodiazepines will usually process at the pharmacy without a PA request if the member is < six years of age, has a history of MassHealth medical claims for seizure, and does not have a history of MassHealth medical claims for psychiatric diagnoses and/or other diagnoses in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain).†

Hypnotic agents in members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required for members with a diagnosis of insomnia with other behavioral health comorbidities, excluding ADHD/ASD:

- treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
- prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
- at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
- if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnosis of insomnia without behavioral health comorbidities or insomnia with comorbid ASD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation; **and**
  - inadequate response (defined by ≥ 10 days of therapy), adverse reaction, or contraindication to melatonin.

- Documentation of the following is required for members with a diagnosis of insomnia with comorbid ADHD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation; **and**
  - inadequate response (defined by ≥ 10 days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - inadequate response (defined by ≥ 10 days of therapy), adverse reaction, or contraindication to clonidine.

†Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 70 - Progesterone Agents

Drug Category: Endocrine/Metabolic Agents

Medication Class/Individual Agents: Progesterone agents

I. Prior-Authorization Requirements

Progesterone Agents				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
hydroxyprogesterone caproate injection		PA		**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** • On April 6, 2023 the Food and Drug Administration (FDA) announced a final decision to withdraw the approval of Makena (hydroxyprogesterone caproate, HPC, 17-OHPC) and effective immediately Makena and its generics are no longer approved.[1] • The American Academy of Obstetricians and Gynecologists has updated the Clinical Guidance for the Use of Progesterone Supplementation for the Prevention of Recurrent Preterm Birth noting that hydroxyprogesterone caproate is not recommended for the primary prevention of preterm birth in patients with a history of spontaneous preterm birth.[2] • Preterm birth is a significant public health issue in the United States. According to the March of Dimes, preterm birth or the birth of a baby at less than 37 weeks of gestation affects one in ten babies born in the United States. Although the causes of spontaneous preterm birth are often unknown, a leading risk factor is history of prior preterm birth, pregnancy of multiples, and abnormalities associated with the uterus or cervix.[3] • Hydroxyprogesterone caproate injection is ONLY indicated in non-pregnant women for the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV), in the management of amenorrhea (primary or
progesterone gel	Crinone	PA		
progesterone vaginal insert	Endometrin	PA		

	Clinical Notes
	secondary) and abnormal uterine bleeding, as a test for endogenous estrogen production and for the production of secretory endometrium and desquamation.[4] [1]FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena [press release on the Internet]. Rockville (MD): Food and Drug Administration (US); 2023 April 6 [cited 2023 Apr 6]. Available from: https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena. [2]American College of Obstetricians and Gynecologists. Updated Clinical Guidance for the Use of Progesterone Supplementation for the Prevention of Recurrent Preterm Birth. 2023 [Practice Advisory on the internet] [cited 2023 Apr 12]. Available from: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/04/updated-guidance-use-of-progesterone-supplementation-for-prevention-of-recurrent-preterm-birth. [3]Preterm labor and premature birth [webpage on the Internet]. March of Dimes; 2016 Mar 1 [cited 2021 Oct 16]. Available from: http://www.marchofdimes.org/complications/preterm-labor-and-premature-birth.aspx [4]Hydroxyprogesterone caproate [package insert on the Internet]. Morgantown (WV): Mylan Institutional LLC; 2021 Nov [cited 2023 April 13]. Available from: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0919b927-c57c-40ae-88a8-39e9efe4f677

II. Therapeutic Uses

FDA-approved, for example:

- Advanced adenocarcinoma of the uterine corpus
- Management of amenorrhea (primary and secondary)
- Production of secretory endometrium and desquamation
- Progestin challenge for the diagnosis of secondary amenorrhea
- Test for endogenous estrogen production

Non-FDA-approved, for example:

- Maintenance of pregnancy/placental support through gestational week 12 after positive pregnancy test
- Prevention of miscarriage with history of recurrent miscarriages through gestational week 12
- Prevention of spontaneous preterm birth

- Short cervix

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Crinone

- Documentation of all the following is required for requests for Crinone 4% or 8% gel for progestin challenge for the diagnosis of secondary amenorrhea:
  - appropriate diagnosis; **and**
  - inadequate response or adverse drug reaction to one or contraindication to all of the following: medroxyprogesterone, norethindrone, progesterone capsule; **and**
  - requested dose is ≤ six doses; **and**
  - for the 8% gel, inadequate response or adverse reaction to the 4% gel.
- Documentation of all the following is required for requests for Crinone 8% gel for all other diagnoses:
  - indication of one of the following:
    - prevention of spontaneous preterm birth with one of the following:
      - both of the following:
        - history of spontaneous singleton delivery and/or premature rupture of membranes; **and**
        - gestational age ≥ 18 weeks to < 23 weeks; **and**
      - both of the following: diagnosis of short cervix and gestational age ≥ 18 weeks to < 23 weeks; **or**
    - maintenance of pregnancy/placental support through gestational week 12 after positive pregnancy test; **or**
    - prevention of miscarriage with history of recurrent miscarriages through gestational week 12; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: compounded progesterone suppository, progesterone injection, oral progesterone capsule, Endometrin (progesterone vaginal insert); **and**
  - appropriate dosing and treatment duration.

Endometrin

- Documentation of all the following is required for the diagnosis of prevention of spontaneous preterm birth:
  - appropriate diagnosis; and
  - gestational age ≥ 18 weeks to < 23 weeks; and
  - one of the following:
    - member has a history of spontaneous singleton delivery and/or premature rupture of membranes; or
    - short cervix.

hydroxyprogesterone caproate injection

- Documentation of all the following is required:
  - indication of one of the following:
    - treatment of advanced adenocarcinoma of the uterine corpus (stage III or IV); **or**
    - management of amenorrhea (primary and secondary); **or**
    - member requires a test for endogenous estrogen production; **or**
    - production of secretory endometrium and desquamation; **and**
  - appropriate dosing.

Please note: The MassHealth agency does not pay for any drug when used to promote fertility as described in 130 CMR 406.413(B) "Limitations on Coverage of Drugs – Drug Exclusions" (see link below).
https://www.mass.gov/regulations/130-CMR-406000-pharmacy-services

MassHealth Evaluation Criteria
Table 71 - Pediatric Behavioral Health

Drug Category: Behavioral Health

Medication Class/Individual Agents: various

I. Prior-Authorization Requirements

Pediatric Behavioral Health – Second-Generation (Atypical) Antipsychotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aripiprazole extended-release injection	Abilify Asimtufii	PA	
aripiprazole extended-release injection	Abilify Maintena	PA	
aripiprazole film	Opipza	PA	
aripiprazole lauroxil 1,064 mg	Aristada PD	PA - < 10 years and PA > 1 injection/56 days	
aripiprazole lauroxil 441 mg, 662 mg, 882 mg	Aristada PD	PA - < 10 years and PA > 1 injection/28 days	
aripiprazole lauroxil 675 mg	Aristada Initio PD	PA - < 10 years and PA > 1 injection/28 days	
aripiprazole orally disintegrating tablet		PA	A90
aripiprazole solution		PA - < 10 years or ≥ 13 years and PA ≥ 10 mL/day	A90
aripiprazole tablet	Abilify	PA - < 10 years and PA > 2 units/day	# , A90
aripiprazole tablet with sensor	Abilify Mycite	PA	
asenapine sublingual tablet	Saphris	PA	A90
asenapine transdermal	Secuado	PA	
brexpiprazole	Rexulti	PA	
cariprazine	Vraylar PD	PA	
clozapine orally disintegrating tablet		PA	A90
clozapine suspension	Versacloz	PA	A90
clozapine tablet	Clozaril	PA - < 10 years	# , A90
iloperidone	Fanapt	PA	

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Please note: For a comprehensive list of all behavioral health medications included in the Pediatric Behavioral Health Medication Initiative, please see Appendix I below. The member will need to meet all criteria for the requested agent as specified in the respective medication class guideline, if applicable.

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- The American Academy of Child and Adolescent Psychiatry Practice Parameter on the use of Psychotropic Medications in Children and Adolescents encourages a complete medical and psychiatric evaluation before initiation of pharmacotherapy, a psychosocial and psychopharmacological treatment and monitoring strategy, and member and family education about the treatment plan.[1]
- A treatment and monitoring plan is essential to properly assess therapy response and adverse effects upon initiation, dose optimization, and discontinuation. Appropriate follow-up allows for opportunities to educate the member and family/caregiver and to address treatment plan concerns.[1]
- Evidence-based and age-appropriate psychosocial treatments should be tried prior to psychopharmacologic

Pediatric Behavioral Health – Second-Generation (Atypical) Antipsychotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
lumateperone	Caplyta	PA	
lurasidone 20 mg, 40 mg, 60 mg, 120 mg	Latuda	PA - < 10 years and PA > 1 unit/day	# , A90
lurasidone 80 mg	Latuda	PA - < 10 years and PA > 2 units/day	# , A90
olanzapine 15 mg orally disintegrating tablet	Zyprexa Zydis	PA - < 10 years and PA > 2 units/day	# , A90
olanzapine 15 mg, 20 mg tablet	Zyprexa	PA - < 10 years and PA > 2 units/day	# , A90
olanzapine 2.5 mg, 5 mg, 7.5 mg, 10 mg tablets	Zyprexa	PA - < 10 years and PA > 3 units/day	# , A90
olanzapine 210 mg, 300 mg extended-release injection	Zyprexa Relprevv	PA - < 10 years and PA > 2 injections/28 days	
olanzapine 405 mg extended-release injection	Zyprexa Relprevv	PA - < 10 years and PA > 1 injection/28 days	
olanzapine 5 mg, 10 mg, 20 mg orally disintegrating tablet	Zyprexa Zydis	PA - < 10 years and PA > 1 unit/day	# , A90
paliperidone 1.5 mg, 3 mg, 9 mg tablet	Invega	PA - < 10 years and PA > 1 unit/day	# , A90
paliperidone 6 mg tablet	Invega	PA - < 10 years and PA > 2 units/day	# , A90
paliperidone extended-release 1-month injection	Invega Sustenna PD	PA - < 10 years, PA > 2 injections/28 days within the first 28 days of therapy and PA > 1 injection/28 days after 28 days of therapy	
paliperidone extended-release 1-month injection -Erzofri	Erzofri	PA	
paliperidone extended-release 3-month injection	Invega Trinza PD	PA - < 10 years and PA > 1 injection/84 days	
paliperidone extended-release 6-month injection	Invega Hafyera PD	PA - < 10 years and PA > 1 injection/168 days	
quetiapine	Seroquel	PA - < 10 years and PA > 3	# , A90

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treatments in pediatric members as clinically appropriate.[2] Pharmacological treatments should be reserved for members who have not responded to psychological treatment and if benefits outweigh the risks associated with treatment.[3]

- Psychotherapy in combination with pharmacotherapy may lead to more favorable outcomes compared to either treatment alone.[4,5] Member and family/caregiver education about the importance of both interventions is essential.[6]
- With initial treatment non-response, dose optimization or switching to an alternative agent should be considered prior to polypharmacy when clinically appropriate.[7] Prescribers should have clear rationale for use of medication combinations to treat a condition, multiple comorbidities, and/or adverse effects resulting from therapy.[1] At this time there is limited evidence supporting the use of medication polypharmacy from the same medication class, especially in the pediatric and adolescent population.[1]
- Refractory members and those considered as being a risk to self or others should be referred to a specialist provider.[7]

References:

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[3] Anderson IM, Ferrier IN, Baldwin RC, Cowen PJ, Howard L, Lewis G, et al. Evidence-based guidelines for treating depressive disorders with antidepressants: a revision of the 2000 British Association for the Psychopharmacology guidelines. J Psychopharmacology. 2008;22(4):343-96.

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[5] March J, Silva S, Petrycki S, CurryJ, Wells K, Fairbank J, et al. Fluoxetine, cognitive-behavioral therapy and their

Pediatric Behavioral Health – Second-Generation (Atypical) Antipsychotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
		units/day	
quetiapine extended-release	Seroquel XR	PA - < 10 years and PA > 2 units/day	# , A90
risperidone 0.25 mg, 0.5 mg, 1 mg, 2 mg orally disintegrating tablet		PA - < 10 years and PA > 2 units/day	A90
risperidone 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg tablets	Risperdal	PA - < 10 years and PA > 3 units/day	# , A90
risperidone 12.5 mg, 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection-Risperdal Consta	Risperdal Consta	PA - < 10 years and PA > 2 injections/28 days	BP
risperidone 150 mg, 200 mg, 250 mg extended-release subcutaneous injection	Uzedy PD	PA - < 10 years and PA > 1 injection/56 days	
risperidone 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection-Rykindo	Rykindo	PA	
risperidone 3 mg, 4 mg orally disintegrating tablet		PA	A90
risperidone 4 mg tablet	Risperdal	PA - < 10 years and PA > 4 units/day	# , A90
risperidone 50 mg, 75 mg, 100 mg, 125 mg extended-release subcutaneous injection	Uzedy PD	PA - < 10 years and PA > 1 injection/28 days	
risperidone 90 mg, 120 mg extended-release subcutaneous injection	Perseris PD	PA - < 10 years and > 1 injection/28 days	
risperidone solution	Risperdal	PA - < 10 years and PA > 16 mL/day	# , A90
ziprasidone capsule	Geodon	PA - < 10 years and PA > 2 units/day	# , A90

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combination for adolescents with depression: treatment for adolescents with depression (TADS) randomized controlled -trial. JAMA.2004;292(7):807-20.

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[7] Balwin DS, Anderson IM, Nutt DJ, Allqulander C, Bandelow B, den Boer JA, et al. Evidence-based pharmacological treatment of anxiety disorders, post-traumatic stress disorder and obsessive-compulsive disorder: a revision of the 2005 guidelines from the British Association for Psychopharmacology. J Psychopharmacology. 2014;28(5):403-39.

Pediatric Behavioral Health – Cerebral Stimulants and Miscellaneous Agents - Short- and Intermediate-Acting Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amphetamine salts	Adderall	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#
amphetamine sulfate		PA	
amphetamine sulfate orally disintegrating tablet	Evekeo ODT	PA	
dexmethylphenidate	Focalin	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#
dextroamphetamine 2.5 mg, 7.5 mg, 15 mg, 20 mg, 30 mg tablet		PA	
dextroamphetamine 5 mg, 10 mg tablet		PA - < 3 years or ≥ 21 years and PA > 3 units/day	
dextroamphetamine 5 mg, 10 mg, 15 mg capsule	Dexedrine Spansule	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#
dextroamphetamine solution		PA - < 3 years or ≥ 21 years and PA > 40 mL/day	
methamphetamine	Desoxyn	PA	
methylphenidate chewable tablet		PA - < 3 years or ≥ 21 years and PA > 3 units/day	
methylphenidate oral solution	Methylin oral solution	PA - < 3 years or ≥ 21 years and PA > 30 mL/day	#
methylphenidate sustained-release tablet		PA - < 3 years or ≥ 21 years and PA > 3 units/day	
methylphenidate-Ritalin	Ritalin	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#

Pediatric Behavioral Health – Cerebral Stimulants and Miscellaneous Agents - Long-Acting Amphetamine Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amphetamine extended-release 1.25 mg/mL oral suspension		PA	
amphetamine extended-release 2.5 mg/mL oral suspension	Dyanavel XR	PA	

Pediatric Behavioral Health – Cerebral Stimulants and Miscellaneous Agents - Long-Acting Amphetamine Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amphetamine extended-release chewable tablet	Dyanavel XR	PA	
amphetamine extended-release orally disintegrating tablet	Adzenys XR-ODT	PA	BP
amphetamine salts extended-release-Adderall XR	Adderall XR PD	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
amphetamine salts extended-release-Mydayis	Mydayis	PA	
lisdexamfetamine capsule	Vyvanse	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
lisdexamfetamine chewable tablet	Vyvanse	PA	BP

Pediatric Behavioral Health – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
armodafinil	Nuvigil	PA - < 6 years and PA > 1 unit/day	#
donepezil 10 mg tablet	Aricept	PA - < 6 years and PA > 2 units/day	# , A90
donepezil 5 mg, 23 mg tablet	Aricept	PA - < 6 years and PA > 1 unit/day	# , A90
donepezil orally disintegrating tablet		PA - < 6 years and PA > 1 unit/day	A90
donepezil patch	Adlarity	PA	
memantine / donepezil extended-release	Namzaric	PA	BP, A90
memantine extended-release	Namenda XR	PA - < 6 years and PA > 1 unit/day	# , A90
memantine solution		PA	A90
memantine tablet		PA - < 6 years and PA > 2 units/day	A90
memantine titration pack	Namenda	PA - < 6 years and PA > 49 units/28 days	A90
modafinil 100 mg	Provigil	PA - < 6 years and PA > 1.5 units/day	#
modafinil 200 mg	Provigil	PA - < 6 years and PA > 2 units/day	#
naltrexone tablet		PA - < 6 years	A90
prazosin		PA - < 6 years	A90

Pediatric Behavioral Health – Hypnotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
daridorexant	Quviviq	PA	
doxepin tablet		PA	A90
estazolam		PA - < 6 years and PA > 1 unit/day	
eszopiclone		PA - < 6 years and PA > 1 unit/day	
flurazepam		PA	
lemborexant	Dayvigo	PA	
suvorexant	Belsomra	PA	
temazepam 22.5 mg	Restoril	PA	
temazepam 7.5 mg, 15 mg, 30 mg	Restoril	PA - < 6 years and PA > 1 unit/day	#
triazolam	Halcion	PA - < 6 years and PA > 1 unit/day	#
zaleplon		PA - < 6 years and PA > 1 unit/day	
zolpidem 1.75 mg, 3.5 mg sublingual tablet		PA	
zolpidem 10 mg tablet	Ambien	PA - < 6 years and PA > 1 unit/day	#
zolpidem 5 mg tablet	Ambien	PA - < 6 years and PA > 1.5 units/day	#
zolpidem 5 mg, 10 mg sublingual tablet	Edluar	PA	
zolpidem 7.5 mg capsule		PA	
zolpidem extended -release tablet	Ambien CR	PA - < 6 years and PA > 1 unit/day	#

Pediatric Behavioral Health – Antidepressants - Tricyclic Antidepressants (TCA)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amitriptyline tablet		PA - < 6 years	A90
amoxapine		PA	A90
clomipramine	Anafranil	PA	A90
desipramine	Norpramin	PA	A90
doxepin capsule, oral concentrate		PA - < 6 years	A90
imipramine hydrochloride		PA - < 6 years	A90
imipramine pamoate		PA	A90
nortriptyline	Pamelor	PA - < 6 years	# , A90
protriptyline		PA	A90

Pediatric Behavioral Health – Antidepressants - Tricyclic Antidepressants (TCA)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
trimipramine		PA	A90

Pediatric Behavioral Health – Antidepressants - Norepinephrine/Dopamine Reuptake Inhibitors (NDRI)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
bupropion hydrobromide extended-release	Aplenzin	PA	
bupropion hydrochloride extended-release 150 mg, 300 mg tablet	Wellbutrin XL	PA - < 6 years and PA > 1 unit/day	# , A90
bupropion hydrochloride extended-release 450 mg tablet	Forfivo XL	PA	A90
bupropion hydrochloride immediate-release		PA - < 6 years	A90
bupropion hydrochloride sustained-release-Wellbutrin SR	Wellbutrin SR	PA - < 6 years	# , A90
bupropion hydrochloride sustained-release-Zyban	Zyban	PA - < 6 years	# , A90

Pediatric Behavioral Health – Cerebral Stimulants and Miscellaneous Agents - Long-Acting Methylphenidate Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
dexmethylphenidate extended-release	Focalin XR	PA - < 3 years or ≥ 21 years and PA > 2 units/day	#
dextroamphetamine transdermal	Xelstrym	PA	
methylphenidate extended-release 72 mg tablet		PA	
methylphenidate extended-release chewable tablet	Quillichew ER	PA	
methylphenidate extended-release	Quillivant XR	PA	

Pediatric Behavioral Health – Cerebral Stimulants and Miscellaneous Agents - Long-Acting Methylphenidate Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
oral suspension			
methylphenidate extended-release orally disintegrating tablet	Cotempla XR-ODT	PA	
methylphenidate extended-release, CD		PA	
methylphenidate extended-release-Aptensio XR	Aptensio XR	PA	
methylphenidate extended-release-Concerta	Concerta	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
methylphenidate extended-release-Jornay PM	Jornay PM	PA	
methylphenidate extended-release-Relexxii	Relexxii	PA	
methylphenidate transdermal	Daytrana	PA - < 3 years or ≥ 21 years and PA > 1 unit/day	BP
methylphenidate-Ritalin LA	Ritalin LA	PA	
serdexmethylphenidate / dexmethylphenidate	Azstarys	PA	

Pediatric Behavioral Health – Mood Stabilizers			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
carbamazepine extended-release	Carbatrol	PA - < 6 years	# , A90
carbamazepine extended-release	Equetro	PA - < 6 years	
carbamazepine extended-release	Tegretol XR	PA - < 6 years	BP, A90
carbamazepine-Tegretol	Tegretol	PA - < 6 years	# , A90
divalproex delayed-release capsule	Depakote Sprinkle	PA - < 6 years	BP, A90
divalproex delayed-release tablet	Depakote	PA - < 6 years	# , A90
divalproex extended-release	Depakote ER	PA - < 6 years	# , A90
eslicarbazepine	Aptiom	PA	A90
gabapentin capsule, solution,	Neurontin	PA - < 6 years and PA > 3600 mg/day	#

Pediatric Behavioral Health – Mood Stabilizers			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
tablet			
gabapentin enacarbil	Horizant	PA - < 6 years and PA > 1200 mg/day	BP
gabapentin extended-release	Gralise	PA	
lamotrigine dispersible tablet	Lamictal	PA - < 6 years	# , A90
lamotrigine extended-release tablet	Lamictal XR	PA	A90
lamotrigine extended-release tablet starter kit	Lamictal XR	PA	
lamotrigine orally disintegrating tablet	Lamictal ODT	PA	A90
lamotrigine orally disintegrating tablet starter kit	Lamictal ODT	PA	
lamotrigine tablet	Lamictal	PA - < 6 years	# , A90
lamotrigine tablet starter kit	Lamictal	PA	
lithium	Lithobid	PA - < 6 years	# , A90
oxcarbazepine extended-release	Oxtellar XR	PA	BP, A90
oxcarbazepine suspension	Trileptal	PA - < 6 years	BP, A90
oxcarbazepine tablet	Trileptal	PA - < 6 years	# , A90
pregabalin	Lyrica	PA - < 6 years and PA > 600 mg/day	#
pregabalin extended-release	Lyrica CR	PA	BP
topiramate extended-release capsule-Qudexy XR	Qudexy XR	PA - < 6 years	BP, A90
topiramate extended-release capsule-Trokendi XR	Trokendi XR	PA	BP, A90
topiramate solution	Eprontia	PA	
topiramate sprinkle capsule	Topamax	PA - < 6 years	# , A90
topiramate tablet	Topamax	PA - < 6 years	# , A90
valproic acid	Depakene	PA - < 6 years	# , A90

Pediatric Behavioral Health – Antianxiety Agents - Benzodiazepines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alprazolam extended-release	Xanax XR	PA - < 6 years and PA > 2 units/day	#
alprazolam orally disintegrating tablet		PA	
alprazolam solution		PA - < 6 years and ≥ 13 years	
alprazolam tablet	Xanax	PA - < 6 years	#
chlordiazepoxide		PA - < 6 years	
clonazepam 0.125 mg, 0.25 mg, 0.5 mg, 1 mg orally disintegrating tablet		PA - < 6 years and PA > 3 units/day	
clonazepam 2 mg orally disintegrating tablet		PA - < 6 years and PA > 2 units/day	
clonazepam tablet	Klonopin	PA - < 6 years	#
clorazepate		PA	
diazepam 25 mg/5 mL solution		PA	
diazepam 5 mg/5 mL solution, tablet	Valium	PA - < 6 years	#
lorazepam extended-release	Loreev XR	PA	
lorazepam solution		PA - < 6 years and ≥ 13 years	
lorazepam tablet	Ativan	PA - < 6 years	#
midazolam syrup		PA - < 6 years	
oxazepam		PA	
quazepam	Doral	PA	

Pediatric Behavioral Health – Antidepressants - NMDA Receptor Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dextromethorphan / bupropion	Auvelity	PA	
esketamine	Spravato	PA	

Pediatric Behavioral Health – Antidepressants - Selective Serotonin Reuptake Inhibitors (SSRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
citalopram capsule		PA	A90
citalopram solution, tablet	Celexa	PA - < 6 years	# , A90
escitalopram	Lexapro	PA - < 6 years	# , A90
fluoxetine 10 mg, 20 mg tablet		PA - < 6 years	A90
fluoxetine 10 mg, 20 mg, 40 mg capsule, solution	Prozac	PA - < 6 years	# , A90
fluoxetine 60 mg tablet		PA	A90
fluoxetine 90 mg delayed-release capsule		PA	A90
fluvoxamine extended-release		PA	A90
fluvoxamine immediate-release		PA - < 6 years	A90
paroxetine controlled-release	Paxil CR	PA	A90
paroxetine hydrochloride	Paxil	PA - < 6 years	# , A90
sertraline capsule		PA	A90
sertraline oral concentrate, tablet	Zoloft	PA - < 6 years	# , A90

Pediatric Behavioral Health – Antipsychotics - Muscarinic Agonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
xanomeline / trospium	Cobenfy	PA	

Pediatric Behavioral Health – Antidepressants - Serotonin/Norepinephrine Reuptake Inhibitors (SNRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
desvenlafaxine extended-release		PA	A90
desvenlafaxine succinate extended-release 100 mg	Pristiq	PA - < 6 years and PA > 4 units/day	# , A90
desvenlafaxine	Pristiq	PA - < 6 years and	# , A90

Pediatric Behavioral Health – Antidepressants - Serotonin/Norepinephrine Reuptake Inhibitors (SNRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
succinate extended-release 25 mg, 50 mg		PA > 1 unit/day	
duloxetine 20 mg, 30 mg, 60 mg capsule	Cymbalta	PA - < 6 years	# , A90
duloxetine 40 mg capsule		PA	A90
duloxetine sprinkle capsule	Drizalma	PA	
levomilnacipran	Fetzima	PA	
venlafaxine besylate extended -release tablet		PA	A90
venlafaxine extended-release capsule	Effexor XR	PA - < 6 years	# , A90
venlafaxine hydrochloride extended-release tablet		PA	A90
venlafaxine immediate-release		PA - < 6 years	A90

Pediatric Behavioral Health – Antidepressants - Monoamine Oxidase Inhibitors (MAOI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
isocarboxazid	Marplan	PA	
phenelzine	Nardil	PA - < 6 years	# , A90
selegiline transdermal patch	Emsam	PA	
tranylcypromine		PA - < 6 years	A90

Pediatric Behavioral Health – First-Generation (Typical) Antipsychotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amitriptyline / perphenazine		PA	A90
chlorpromazine		PA - < 10 years	A90
fluphenazine		PA - < 10 years	A90
haloperidol	Haldol	PA - < 10 years	# , A90
loxapine capsule	Loxitane	PA - < 10 years	# , A90

Pediatric Behavioral Health – First-Generation (Typical) Antipsychotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
molindone		PA - < 10 years	A90
perphenazine		PA - < 10 years	A90
pimozide	Orap	PA - < 10 years	# , A90
thioridazine		PA - < 10 years	A90
thiothixene	Navane	PA - < 10 years	# , A90
trifluoperazine		PA - < 10 years	A90

Pediatric Behavioral Health – Cerebral Stimulants and Miscellaneous Agents - Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
atomoxetine	Strattera	PA - < 6 years	# , A90
clonidine extended -release 0.1 mg tablet		PA - < 3 years and PA > 4 units/day	A90
guanfacine extended-release	Intuniv	PA - < 3 years	# , A90
viloxazine	Qelbree	PA	

Pediatric Behavioral Health – Second-Generation (Atypical) Antipsychotic and Opioid Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
olanzapine / samidorphan	Lybalvi	PA	

Pediatric Behavioral Health – Alpha Agonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
clonidine extended -release 0.17 mg tablet	Nexiclon	PA	A90
clonidine extended -release suspension	Onyda XR	PA	
clonidine patch		PA	A90
clonidine tablet		PA - < 3 years	A90
guanfacine		PA - < 3 years	A90

Pediatric Behavioral Health – Antidepressants - Noradrenergic and Specific Serotonergic Antidepressants (NaSSA)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
mirtazapine	Remeron	PA - < 6 years	# , A90
mirtazapine orally disintegrating tablet	Remeron Sol Tab	PA	A90

Pediatric Behavioral Health – Second-Generation (Atypical) Antipsychotic-Selective Serotonin Reuptake Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
olanzapine / fluoxetine	Symbyax	PA	A90

Pediatric Behavioral Health – Antidepressants - Serotonin Modulators

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
nefazodone		PA - < 6 years	A90
trazodone 300 mg tablet		PA	A90
trazodone 50 mg, 100 mg, 150 mg		PA - < 6 years	A90
vilazodone	Viibryd	PA	A90
vortioxetine	Trintellix	PA	

Pediatric Behavioral Health – Antidepressants – Gamma-Aminobutyric (GABA)-A Receptor Positive Modulator

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
zuranolone	Zurzuvae PD	PA	

Pediatric Behavioral Health – Antianxiety Agents - Not Otherwise Classified

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
amitriptyline / chlordiazepoxide		PA	
buspirone		PA - < 6 years	A90
meprobamate		PA	

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Anxiety
- Attention Deficit Hyperactivity Disorder (ADHD)
- Bipolar disorder
- Depression
- Hyperactivity associated with autism spectrum disorder (ASD)
- Psychotic disorders
- Schizophrenia
- Tourette Disorder

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28-days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Please note: The member will need to meet all criteria for the requested agent as specified in the respective medication class table, if applicable.

Behavioral Health Medication Polypharmacy *(pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, viloxazine, and xanomeline/trospium] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period)* for members < 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
    - one of the following:
      - member has a seizure diagnosis only; **or**
      - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**

- member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
- member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and**
- one of the following:
  - cross-titration/taper of mood stabilizer therapy; **or**
  - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Antidepressant Polypharmacy ***(overlapping pharmacy claims for two or more antidepressants for at least 60 days within a 90-day period, except esketamine)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate psychiatric diagnosis; **and**
    - treatment plan including names of current antidepressants and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - one of the following:
      - cross-titration/taper of antidepressant therapy; **or**
      - inadequate response (defined as four weeks of therapy) or adverse reaction to two monotherapy trials as clinically appropriate; **or**
      - antidepressant polypharmacy regimen of ≤ two antidepressants includes one of the following: bupropion, mirtazapine, trazodone, or zuranolone; **or**
      - one antidepressant in the regimen is indicated for a comorbid condition in which antidepressants may be clinically appropriate; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

SmartPA: Claims will usually process at the pharmacy without a PA request if the member is < 18 years of age and has a history of paid MassHealth pharmacy claims for two antidepressants (except esketamine) for at least 60 days of therapy out of the last 90 days and one or both agents are bupropion, trazodone, mirtazapine, or zuranolone.†

Antipsychotic Polypharmacy ***(overlapping pharmacy claims for two or more antipsychotics [includes first-generation and/or second-generation antipsychotics, except short-acting injectable formulations] for at least 60 days within a 90-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**

- all of the following:
  - treatment plan including name, dose, and frequency of all current behavioral health medications, associated target symptom(s), and behavioral health diagnoses; **and**
  - a comprehensive behavioral health plan (i.e. non-pharmacologic interventions) is in place; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - stage of treatment is acute, maintenance, or discontinuation; **and**
  - one of the following:
    - for acute stage (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects), one of the following:
      - cross-titration/taper of antipsychotic therapy; **or**
      - inadequate response or adverse reaction to two monotherapy trials as clinically appropriate; **or**
    - for maintenance stage (response to antipsychotic treatment with goal of remission or recovery), all of the following:
      - regimen is effective, therapy benefits outweigh risks, and appropriate monitoring is in place; **and**
      - if member has been on the antipsychotic regimen for the past 12 months, clinical rationale for extended therapy including at least one of the following: previous efforts to reduce/simplify the antipsychotic regimen in the past 24 months resulted in symptom exacerbation; or family/caregiver does not support the antipsychotic regimen change at this time due to risk of exacerbation; or other significant barrier for antipsychotic therapy discontinuation; **or**
    - for discontinuation stage (clinically indicated that the antipsychotic regimen can likely be successfully tapered), cross-titration/taper of antipsychotic therapy.

SmartPA: Claims for risperidone and aripiprazole will usually process at the pharmacy without a PA request if the member is ≥ six and < ten years of age and has a history of MassHealth medical claims for diagnosis of autism spectrum disorder.†

Benzodiazepine Polypharmacy ***(overlapping pharmacy claims for two or more benzodiazepines [hypnotic benzodiazepine agents, clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations are not included] for at least 60 days within a 90-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - member has a seizure diagnosis only; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - treatment plan including names of current benzodiazepines and corresponding diagnoses; **and**
    - one of the following:
      - cross-titration/taper of benzodiazepine therapy; **or**
      - clinical rationale for use of ≥ two benzodiazepines of different chemical entities.

Cerebral Stimulant Polypharmacy ***(overlapping pharmacy claims for two or more cerebral stimulants [immediate-release and extended -release formulations of the same chemical entity are counted as one] for at least 60 days within a 90-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**

- member has a history of severe risk of harm to self or others; **or**
- all of the following:
  - appropriate diagnosis; **and**
  - treatment plan including names of current cerebral stimulants and corresponding diagnoses; **and**
  - inadequate response (defined as > seven days of therapy), adverse reaction, or contraindication to monotherapy trial with a methylphenidate product; **and**
  - inadequate response (defined as > seven days of therapy), adverse reaction, or contraindication to monotherapy trial with an amphetamine product; **and**
  - clinical rationale for cerebral stimulant polypharmacy.

Mood Stabilizer Polypharmacy ***(overlapping pharmacy claims for three or more mood stabilizers [agents considered to be used only for seizure diagnoses are not included] for at least 60 days within a 90-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required for members with seizure diagnosis only:
  - appropriate diagnosis (seizure) without comorbid condition.

- Documentation of the following is required for members with psychiatric diagnoses, with or without seizure diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate psychiatric diagnoses; **and**
    - treatment plan including names of current mood stabilizers and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - one of the following:
      - cross-titration/taper of mood stabilizer therapy; **or**
      - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain); **and**
    - treatment plan including names of current mood stabilizers and corresponding diagnoses; **and**
    - other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed.

- Documentation of the following is required for members with a psychiatric diagnosis and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis:
  - one of the following:

- member had a recent psychiatric hospitalization (within the last three months); **or**
- member has a history of severe risk of harm to self or others; **or**

- all of the following:
  - psychiatric diagnosis and diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain); **and**
  - treatment plan including names of current mood stabilizers and corresponding diagnoses; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **and**
  - one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **and**
  - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

Antidepressant, armodafinil, buspirone, donepezil, memantine, meprobamate, modafinil, naltrexone, prazosin, or xanomeline/trospium for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

Antipsychotic for members < ten years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - for requests for aripiprazole or risperidone for members ≥ six years of age and < ten years of age, a diagnosis of ASD; **or**
  - all of the following:
    - complete medication treatment plan including name, dose, and frequency of all current behavioral health medications, associated target symptom(s), and behavioral health diagnoses; **and**
    - a comprehensive behavioral health treatment plan (i.e., non-pharmacological interventions) is in place; **and**

- prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
- one of the following:
  - member is in acute stage of treatment (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects); **or**
  - all of the following:
    - member is in maintenance stage of treatment (response to antipsychotic treatment with goal of remission or recovery); **and**
    - regimen is effective, therapy benefits outweigh risks, and appropriate monitoring is in place; **and**
    - if member has been on the antipsychotic regimen for the past 12 months, clinical rationale for extended therapy including at least one of the following: previous efforts to reduce/simplify the antipsychotic regimen in the past 12 months resulted in symptom exacerbation; or family/caregiver does not support the antipsychotic regimen change at this time due to risk of exacerbation; or other significant barrier for antipsychotic therapy discontinuation; **or**
  - all of the following:
    - member is in discontinuation stage of treatment (clinically indicated that the antipsychotic regimen can likely be successfully tapered); **and**
    - cross-titration/taper of antipsychotic therapy.

Atomoxetine and viloxazine for members < six years of age

- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - if member is < three years of age, prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided.

Benzodiazepine *(hypnotic benzodiazepine agents are not included)* or Mood Stabilizer *(agents considered to be used only for seizure diagnoses are not included)* for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - member has a seizure diagnosis only; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding indications; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

SmartPA: Claims for mood stabilizers or benzodiazepines will usually process at the pharmacy without a PA request if the member is

< six years of age, has a history of MassHealth medical claims for seizure, and does not have a history of MassHealth medical claims for psychiatric diagnoses and/or other diagnoses in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain).†

Alpha$_2$ Agonist for members < three years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - member has a cardiovascular diagnosis only; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - treatment plan including names of current alpha$_2$ agonist(s) and corresponding diagnoses; **and**
    - clinical rationale for use of alpha$_2$ agonist in member < three years of age.

Cerebral Stimulant for members < three years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - treatment plan including names of current cerebral stimulant(s) and corresponding diagnoses; **and**
    - clinical rationale for use of cerebral stimulant in member < three years of age; **and**
    - for requests for an amphetamine product, inadequate response (defined as > seven days of therapy), adverse reaction, or contraindication to a methylphenidate product.

Hypnotic agents for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required for members with a diagnosis of insomnia with other behavioral health comorbidities, excluding ADHD/ASD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnosis of insomnia without behavioral health comorbidities or insomnia with comorbid ASD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - inadequate response (defined by ≥ ten days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnosis of insomnia with comorbid ADHD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - inadequate response (defined by ≥ ten days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - inadequate response (defined by ≥ ten days of therapy), adverse reaction, or contraindication to clonidine; **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

The following behavioral health medications are included in the Pediatric Behavioral Health Medication Initiative:

Appendix I:

Pediatric Behavioral Health Medication Initiative Medication List[1]

Antidepressants		**Mood Stabilizers**	
amitriptyline	levomilnacipran	carbamazepine	lithium
amoxapine	mirtazapine	divalproex	oxcarbazepine
bupropion	nefazodone	gabapentin	pregabalin
citalopram	nortriptyline	lamotrigine	topiramate
clomipramine	paroxetine		valproic acid
desipramine	phenelzine	**Antianxiety Agents**	
desvenlafaxine	protriptyline	alprazolam	diazepam[3]
dextromethorphan/ bupropion	selegiline[2]	buspirone	lorazepam
doxepin	sertraline	chlordiazepoxide	meprobamate
duloxetine	tranylcypromine	chlordiazepoxide/ amitriptyline	midazolam[3]
escitalopram	trazodone	clonazepam	oxazepam
esketamine	trimipramine	clorazepate	

fluoxetine	venlafaxine	**Hypnotics**	
fluvoxamine	vilazodone	daridorexant	quazepam
imipramine	vortioxetine	doxepin[4]	suvorexant
isocarboxazid	zuranolone	estazolam	temazepam
Antipsychotics		eszopiclone	triazolam
aripiprazole	olanzapine/fluoxetine	flurazepam	zaleplon
asenapine	olanzapine/samidorphan	lemborexant	zolpidem
brexipiprazole	paliperidone	**Alpha$_2$ Agonists**	
cariprazine	perphenazine	clonidine	guanfacine
chlorpromazine	perphenazine/amitriptyline	**Stimulants**	
clozapine	pimozide	amphetamine	lisdexamfetamine
fluphenazine	quetiapine	dextroamphetamine	methamphetamine
haloperidol	risperidone	dexmethylphenidate	methylphenidate
iloperidone	thioridazine	dextroamphetamine/ amphetamine	serdexmethylphenidate/ dexmethylphenidate
loxapine	thiothixene	**Miscellaneous**	
lumateperone	trifluoperazine	armodafinil	modafinil
lurasidone	xanomeline/trospium	atomoxetine	naltrexone[5]
molindone	ziprasidone	donepezil	prazosin
olanzapine		memantine	viloxazine

[1]Short-acting intramuscular injectable and intravenous formulations are excluded from the Pediatric Behavioral Health Medication Initiative requirements.

[2]Emsam (selegiline) is the only selegiline formulation included in the Pediatric Behavioral Health Medication Initiative.

[3]Nasal and rectal diazepam and nasal midazolam formulations are excluded from the Pediatric Behavioral Health Medication Initiative requirements.

[4]Doxepin tablet is classified as a hypnotic agent and the Pediatric Behavioral Health Medication Initiative requirements for antidepressants do not apply. Pediatric Behavioral Health Medication Initiative requirements for hypnotics apply.

[5]Vivitrol (naltrexone injection) is excluded from the Pediatric Behavioral Health Medication Initiative requirements.

†Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 72 - Agents Not Otherwise Classified

Drug Category: Various

Medication Class/Individual Agents: Various

I. Prior-Authorization Requirements

Agents Not Otherwise Classified – COVID-19 Related Medications

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

baricitinib COVID EUA - November 19, 2020 for members 2 to 17 years of age	Olumiant		MB	**Lagevrio**
				• Documentation of all of the following is required:
				  • indication for the treatment of COVID-19; **and**
				  • member is ≥ 18 years of age; **and**
				  • medical necessity for use of requested agent instead of Paxlovid; **and**
				  • appropriate dosing; **and**
				  • requested quantity is ≤ 40 units/treatment.
				
				Paxlovid > 20 units/claim
				• Documentation of all of the following is required:
				  • indication for the treatment of COVID-19; **and**
				  • member is ≥ 12 years of age; **and**
				  • medical necessity for exceeding standard dosing or duration recommendations.
				
				Pemgarda
				• Documentation of all of the following is required:
				  • indication for pre-exposure prophylaxis for COVID-19; **and**
				  • member is ≥ 12 years of age; **and**
				  • member weighs ≥ 40 kg; **and**
				  • one of the following:
				  • member has moderate-to-severe immune compromise due to a medical condition; **or**
				  • member has moderate-to-severe immune compromise due to the receipt of immunosuppressive medications or treatments; **and**
				• appropriate dosing.

baricitinib for members ≥ 18 years of age COVID	Olumiant		MB	
molnupiravir COVID EUA – December 23, 2021	Lagevrio	PA		
nirmatrelvir / ritonavir 150 mg-100 mg	Paxlovid [PD]	PA - < 12 years and PA > 20 units/claim		
nirmatrelvir / ritonavir 300-100 mg	Paxlovid [PD]	PA - < 12 years and PA > 30 units/claim		
nirmatrelvir / ritonavir 300/150 -100 mg	Paxlovid [PD]			
pemivibart COVID EUA – March 22, 2024	Pemgarda	PA	MB	
remdesivir	Veklury		MB	
tocilizumab vial COVID	Actemra		MB	
vilobelimab COVID EUA - April 4, 2023	Gohibic		MB	

Agents Not Otherwise Classified – Adrenocorticotropic Hormone

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

corticotropin	Acthar	PA		**Acthar vial and Cortrophin**
				• Documentation of the following is required for a diagnosis of infantile spasms:
				  • appropriate diagnosis; **and**
				  • member is < two years of age; **and**
				  • prescriber is a neurologist or consult notes from a neurologist are provided; **and**
				  • for initial therapy, one of the following:
				  • requested dose and duration is 20 units daily for two weeks followed by a taper over one week (specific taper must be documented); **or**
				  • requested dose and duration is 75 units/m^2 twice daily for two weeks [body surface area (BSA) must be documented] followed by a gradual taper over a two-week period (specific and appropriate taper must be documented); **and**
				  • for Cortrophin, medical necessity for use instead of Acthar vial.
				• For recertification for a diagnosis of infantile spasms, documentation of the following is required:
				  • one of the following:
				  • inadequate response to 20 units daily for the initial two weeks, and request is for continuation of therapy at 40 units daily for four weeks followed by a taper over one week (specific taper must be documented); **or**
				  • history of relapse after previous treatment with corticotropin and medical necessity for retreatment; **and**
				  • for Cortrophin, medical necessity for use instead of Acthar vial.
				
				• Documentation of all of the following is required for a diagnosis of an acute exacerbation of multiple sclerosis:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is a neurologist or consult notes from a neurologist are provided; **and**
				  • for Cortrophin, medical necessity for use instead of Acthar vial; **and**
				  • one of the following:
				  • requested dose and duration is 80 units daily for five days; **or**
				  • requested dose and duration is 80 to 120 units daily

corticotropin	Cortrophin	PA		

	Clinical Notes
	for two to three weeks; **and** • medical records documenting inadequate response or adverse reaction to one or contraindication to both of the following: high-dose intravenous methylprednisolone, high-dose oral corticosteroids. • For recertification for the same exacerbation, documentation of the following is required: • medical necessity for use beyond initial therapy; **and** • requested dose and duration is ≤ 120 units daily for three weeks; **and** • for Cortrophin, medical necessity for use instead of Acthar vial. • Documentation of all of the following is required for use to induce remission of proteinuria associated with idiopathic nephrotic syndrome: • appropriate diagnosis; **and** • etiology of proteinuria in nephrotic syndrome has been confirmed with renal biopsy; **and** • prescriber is a nephrologist or consult notes from a nephrologist are provided; **and** • for Cortrophin, medical necessity for use instead of Acthar vial; **and** • pretreatment proteinuria > 50 mg/kg per day or a spot urine sample with a total protein/creatinine ratio > 3 mg; **and** • pretreatment serum albumin < 3 g/dL (30 g/L); **and** • inadequate response, adverse reaction, or contraindication to all of the following: corticosteroids, calcineurin inhibitors (e.g., cyclosporine, tacrolimus), cyclophosphamide, mycophenolate, rituximab; **and** • requested dose is 40 or 80 units twice weekly for 12 to 24 weeks. • For recertification for use to induce remission of proteinuria associated with idiopathic nephrotic syndrome, documentation of the following is required: • prescriber is a nephrologist or consult notes from a nephrologist are provided; **and** • current proteinuria or spot urine total protein/creatinine ratio; **and** • positive response to therapy as shown by improvements in proteinuria or spot urine total protein/creatinine ratio; **and** • total treatment duration is ≤ 24 weeks; **and** • for Cortrophin, medical necessity for use instead of

	Clinical Notes

	Acthar vial.
	
	Acthar prefilled pen
	• Documentation of all of the following is required for a diagnosis of an acute exacerbation of multiple sclerosis:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is a neurologist or consult notes from a neurologist are provided; **and**
	  • one of the following:
	  • requested dose and duration is 80 units daily for five days; **or**
	  • requested dose and duration is 80 units daily for two to three weeks; **and**
	  • medical records documenting inadequate response or adverse reaction to one or contraindication to both of the following: high-dose intravenous methylprednisolone, high-dose oral corticosteroids; **and**
	  • request is for self-administration; **and**
	  • medical necessity for use instead of Acthar vial.
	• For recertification for the same exacerbation, documentation of all of the following is required:
	  • medical necessity for use beyond initial therapy; **and**
	  • requested dose and duration is ≤ 120 units daily for three weeks.
	
	• Documentation of all of the following is required for use to induce remission of proteinuria associated with idiopathic nephrotic syndrome:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • etiology of proteinuria in nephrotic syndrome has been confirmed with renal biopsy; **and**
	  • prescriber is a nephrologist or consult notes from a nephrologist are provided; **and**
	  • pretreatment proteinuria > 50 mg/kg per day or a spot urine sample with a total protein/creatinine ratio > 3 mg; **and**
	  • pretreatment serum albumin < 3 g/dL (30 g/L); **and**
	  • inadequate response, adverse reaction, or contraindication to all of the following: corticosteroids, calcineurin inhibitors (e.g., cyclosporine, tacrolimus), cyclophosphamide, mycophenolate, rituximab; **and**

	Clinical Notes
	• requested dose is 40 or 80 units twice weekly for 12 to 24 weeks; **and** • request is for self-administration; **and** • medical necessity for use instead of Acthar vial. • For recertification for use to induce remission of proteinuria associated with idiopathic nephrotic syndrome, documentation of all of the following is required: • prescriber is a nephrologist or consult notes from a nephrologist are provided; **and** • current proteinuria or spot urine total protein/creatinine ratio; **and** • positive response to therapy as shown by improvements in proteinuria or spot urine total protein/creatinine ratio; **and** • total treatment duration is ≤ 24 weeks.

Agents Not Otherwise Classified – Epinephrine Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
epinephrine 0.15 mg auto-injection -Epipen Jr	Epipen Jr		#	Auvi-Q • Documentation of all of the following is required: • diagnosis is for the emergency treatment of allergic reactions, including anaphylaxis to stinging insects, biting insects, allergen immunotherapy, foods, drugs, diagnostic testing substances, and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis; **and** • for Auvi-Q 0.15 mg and 0.3 mg auto-injector, medical necessity for use of the requested agent instead of alternative agents available without PA; **and** • for Auvi-Q 0.1 mg dose auto-injector, one of the following: • member's current weight is <13 kg; **or** • both of the following: • member's current weight is 13 kg to <15 kg; **and** • medical necessity for use of Auvi-Q 0.1 mg auto-injector. • For recertification, documentation that the member meets the criteria above is required. Neffy • Documentation of all of the following is required: • diagnosis is for the emergency treatment of type I allergic reactions, including anaphylaxis; **and**
epinephrine 0.3 mg auto-injection-Epipen	Epipen		#	
epinephrine auto-injection				
epinephrine auto-injection-Auvi-Q	Auvi-Q	PA		
epinephrine injection	Adrenalin		#	
epinephrine nasal spray	Neffy	PA		

	Clinical Notes

	• one of the following:
	  • member has needle phobia; **or**
	  • medical necessity for use of the requested agent instead of alternative agents available without PA; **and**
	• member's current weight is ≥ 30 kg.
	• For recertification, documentation of continued medical necessity for use of the requested agent instead of alternative agents available without PA is required.

Agents Not Otherwise Classified – Transthyretin Amyloidosis Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

eplontersen	Wainua	PA		**Amvuttra and Onpattro**
				• Documentation of all of the following is required for hereditary transthyretin-mediated (hATTR) amyloidosis:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • for Onpattro, member's current weight; **and**
				  • baseline polyneuropathy disability (PND) score of I, II, IIIa, or IIIb; **and**
				  • appropriate dosing.
				Wainua
				• Documentation of all of the following is required for hATTR amyloidosis:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is a rheumatologist or neurologist or consult notes from a rheumatologist or neurologist are provided; **and**
				  • results from genetic testing showing mutations in the TTR gene; **and**
				  • inadequate response, adverse reaction, or contraindication to both Amvuttra and Onpattro; **and**
				  • baseline PND score of I, II, IIIa, or IIIb; **and**
				  • appropriate dosing.
				MassHealth Drug Utilization Review will be reaching out to prescribers after Amvuttra or Onpattro PA approval to verify clinical effectiveness and for long-term monitoring of sustained response.

patisiran	Onpattro PD	PA	MB	
vutrisiran	Amvuttra PD	PA	MB	

Agents Not Otherwise Classified – Monoclonal Antibodies

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

anifrolumab-fnia	Saphnelo	PA	MB	**Benlysta**
				• Documentation of all of the following is required for a diagnosis of lupus nephritis:
				  • appropriate diagnosis; **and**
				  • member is ≥ five years of age; **and**
				  • member is receiving low-dose oral corticosteroids in combination with one of the following immunosuppressant agents: azathioprine, mycophenolic acid analog; **and**
				  • member will not be receiving cyclophosphamide or biologics as maintenance immunosuppressive therapy; **and**
				  • appropriate dosing.
				• Documentation of all of the following is required for a diagnosis of systemic lupus erythematosus:
				  • appropriate diagnosis; **and**
				  • member is ≥ five years of age; **and**
				  • inadequate response, adverse reaction, or contraindication to hydroxychloroquine; **and**
				  • inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, cyclophosphamide, cyclosporine, leflunomide, methotrexate, mycophenolate; **and**
				  • appropriate dosing.
				Saphnelo
				• Documentation of all of the following is required for a diagnosis of systemic lupus erythematosus:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • inadequate response, adverse reaction, or contraindication to hydroxychloroquine; **and**
				  • inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, cyclophosphamide, cyclosporine, leflunomide, methotrexate, mycophenolate; **and**
				  • inadequate response, adverse reaction, or contraindication to Benlysta; **and**
				  • appropriate dosing.

belimumab auto-injection, prefilled syringe	Benlysta	PA		
belimumab vial	Benlysta	PA	MB	

Agents Not Otherwise Classified – Hormone Replacement Therapy

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
estradiol / progesterone	Bijuva	PA		**Bijuva** • Documentation of all of the following is required:

	Clinical Notes
	• diagnosis of moderate to severe vasomotor symptoms due to menopause; **and** • medical necessity for the combination product instead of the commercially available separate agents.

Agents Not Otherwise Classified – COVID-19 Test Kit Products

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
COVID-19 antigen self-test	Binaxnow	PA - > 2 tests/28 days		**All requests for COVID-19 antigen self-test kits at quantities above established quantity limits** • Documentation of the following is required: • indication of testing for COVID-19; **and** • medical necessity for increased testing.
COVID-19 antigen self-test	Carestart	PA - > 2 tests/28 days		
COVID-19 antigen self-test	CVS COVID-19 At-Home Test	PA - > 2 tests/28 days		
COVID-19 antigen self-test	Flowflex	PA - > 2 tests/28 days		
COVID-19 antigen self-test	Genabio	PA - > 2 tests/28 days		
COVID-19 antigen self-test	Ihealth	PA - > 2 tests/28 days		
COVID-19 antigen self-test	Inteliswab	PA - > 2 tests/28 days		
COVID-19 antigen self-test	On-Go	PA - > 2 tests/28 days		
COVID-19 antigen self-test	Quickvue	PA - > 2 tests/28 days		

Agents Not Otherwise Classified – Protein C Deficiency Agent

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
protein C concentrate	Ceprotin	PA	MB	**Ceprotin** • Documentation of all of the following is required: • diagnosis of inherited protein C deficiency; **and** • prescriber is a hematologist or consult notes from a hematologist are provided; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: Eliquis, dabigatran, Savaysa, warfarin, Xarelto; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: enoxaparin, fondaparinux, Fragmin.

Agents Not Otherwise Classified – Corticotropin-Releasing Factor (CRF) Type 1 Receptor Antagonist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
crinecerfont	Crenessity	PA		**Crenessity** • Documentation of all of the following is required for a

	Clinical Notes

	diagnosis of classic congenital adrenal hyperplasia (CAH):
	• appropriate diagnosis; **and**
	• member is ≥ four years of age; **and**
	• prescriber is an endocrinologist or consult notes from an endocrinology office are provided; **and**
	• member's BSA; **and**
	• appropriate dosing; **and**
	• for pediatric members, member's current weight; **and**
	• member currently requires a supraphysiologic dose of corticosteroids to control their disease, defined as one of the following:
	  • member is < 18 years of age and requires > 12 mg/m^2/day in hydrocortisone dose equivalents; **or**
	  • member is ≥ 18 years of age and requires > 13 mg/m^2/day in hydrocortisone dose equivalents; **and**
	• requested agent will be used as an adjunct to corticosteroids; **and**
	• for the oral solution formulation, medical necessity for the requested formulation as noted by one of the following:
	  • member is < 13 years of age; **or**
	  • member utilizes tube feeding (G-tube/J-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow.
	• For recertification, all of the following is required:
	• positive response to therapy as noted by a reduction in corticosteroid dose requirements; **and**
	• member continues to be treated with corticosteroids; **and**
	• for the oral solution formulation, continued medical necessity for the use of the requested formulation as noted by one of the following:
	  • member is < 13 years of age; **or**
	  • member utilizes tube feeding (G-tube/J-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow.

Agents Not Otherwise Classified – Oral, Injectable, and Miscellaneous Glycopyrrolate Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
glycopyrrolate 1 mg tablet	Robinul		# , A90	**Dartisla ODT**

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

glycopyrrolate 1.5 mg tablet		PA	A90	• Documentation of all of the following is required for a diagnosis of adjunctive therapy in treatment of peptic ulcer:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to glycopyrrolate 1 mg or 2 mg tablet; **and**
				  • medical necessity for use of orally disintegrating formulation as noted by one of the following:
				  • member utilizes tube feeding (J-tube, G-tube); **or**
				  • member has a swallowing disorder or condition affecting ability to swallow; **or**
				  • member is < 13 years of age; **and**
				  • requested quantity is ≤ three units/day.
				• Documentation of all of the following is required for a diagnosis of neurologic condition associated with drooling:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to glycopyrrolate 1 mg or 2 mg tablet; **and**
				  • appropriate dosing; **and**
				  • medical necessity for use of orally disintegrating formulation as noted by one of the following:
				  • member utilizes tube feeding (J-tube, G-tube); **or**
				  • member has a swallowing disorder or condition affecting ability to swallow; **or**
				  • member is < 13 years of age; **and**
				  • inadequate response, adverse reaction, or contraindication to scopolamine patches.
				• For recertification, documentation of the following is required:
				  • positive response to therapy; **and**
				  • if initial request was approved based on medical necessity for the requested formulation, continued medical necessity for requested formulation.
				
				glycopyrrolate injection
				• Documentation of all of the following is required for a diagnosis of adjunctive therapy in treatment of peptic ulcer:
				  • appropriate diagnosis; **and**
				  • member's current weight; **and**
				  • inadequate response, adverse reaction, or

glycopyrrolate 2 mg tablet	Robinul Forte		# , A90	
glycopyrrolate injection	Glyrx-PF	PA	MB	
glycopyrrolate injection		PA	MB	
glycopyrrolate oral solution	Cuvposa	PA	A90	
glycopyrrolate orally disintegrating tablet	Dartisla ODT	PA		

	Clinical Notes

	contraindication to Glyrx-PF (glycopyrrolate injection); **and**
	• medical necessity for use of an injection formulation as noted by one of the following:
	  • member utilizes tube feeding (J-tube, G-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • member is < 13 years of age.
	• Documentation of all of the following is required for a diagnosis of neurologic condition associated with drooling:
	  • appropriate diagnosis; **and**
	  • member's current weight; **and**
	  • medical necessity for use of an injection formulation as noted by one of the following:
	  • member utilizes tube feeding (J-tube, G-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • member is < 13 years of age; **and**
	  • inadequate response, adverse reaction, or contraindication to all of the following: glycopyrrolate oral solution, Glyrx-PF (glycopyrrolate injection, solution), scopolamine patches.
	• For recertification, documentation of the following is required:
	  • positive response to therapy; **and**
	  • updated member weight within the last year; **and**
	  • if initial request was approved based on medical necessity for the requested formulation, continued medical necessity for requested formulation.
	
	glycopyrrolate oral solution
	• Documentation of all of the following is required:
	  • diagnosis of neurologic condition associated with drooling; **and**
	  • member's current weight; **and**
	  • medical necessity for use of a solution formulation as noted by one of the following:
	  • member utilizes tube feeding (J-tube, G-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • member is < 13 years of age; **and**
	  • requested quantity is ≤ 45 mL/day; **and**
	  • for members ≥ 17 years of age, inadequate response or

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	adverse reaction to one or contraindication to both of the following: scopolamine patches, trihexyphenidyl solution.
	• For recertification, documentation of the following is required:
	  • positive response to therapy; **and**
	  • updated member weight within the last year; **and**
	  • if initial request was approved based on medical necessity for the requested formulation, continued medical necessity for requested formulation; **and**
	  • if the member was approved < 17 years of age and is now ≥ 17 years of age, inadequate response or adverse reaction to one or contraindication to both of the following: scopolamine patches, trihexyphenidyl solution.
	
	glycopyrrolate 1.5 mg tablet
	• Documentation of the following is required:
	  • diagnosis of adjunctive therapy in treatment of peptic ulcer; **and**
	  • member is ≥ 12 years of age; **and**
	  • inadequate response, adverse reaction, or contraindication to both of the following:
	  • glycopyrrolate 1 mg or 2 mg tablet; **and**
	  • glycopyrrolate oral solution.
	
	Glyrx-PF
	• Documentation of all of the following is required for a diagnosis of adjunctive therapy in treatment of peptic ulcer:
	  • appropriate diagnosis; **and**
	  • member's current weight; **and**
	  • medical necessity for use of an injection formulation as noted by one of the following:
	  • member utilizes tube feeding (J-tube, G-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • member is < 13 years of age.
	• Documentation of all of the following is required for a diagnosis of neurologic condition associated with drooling:
	  • appropriate diagnosis; **and**
	  • member's current weight; **and**
	  • medical necessity for use of an injection formulation as

	Clinical Notes
	noted by one of the following: • member utilizes tube feeding (J-tube, G-tube); **or** • member has a swallowing disorder or condition affecting ability to swallow; **or** • member is < 13 years of age; **and** • inadequate response, adverse reaction, or contraindication to both of the following: glycopyrrolate oral solution, scopolamine patches. • For recertification, documentation of the following is required: • positive response to therapy; **and** • updated member weight within the last year; **and** • if initial request was approved based on medical necessity for the requested formulation, continued medical necessity for requested formulation.

Agents Not Otherwise Classified – Cystinosis Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
cysteamine 0.37% ophthalmic solution	Cystadrops	PA		**Cystaran, Cystadrops** • Documentation of all of the following is required for a diagnosis of corneal cystine crystal accumulation due to cystinosis: • appropriate diagnosis; **and** • appropriate dosing; **and** • prescriber is a nephrologist or ophthalmologist or consult notes from a nephrologist or ophthalmologist are provided. **Procysbi** • Documentation of all of the following is required for a diagnosis of nephropathic cystinosis: • appropriate diagnosis; **and** • appropriate dosing; **and** • prescriber is a nephrologist or consult notes from a nephrologist are provided; **and** • medical records documenting an inadequate response or adverse reaction to cysteamine immediate-release capsule; **and** • for Procysbi granules, medical necessity for the requested formulation as noted by one of the following: • member utilizes tube feeding (J-tube, G-tube); **or** • member has a swallowing disorder or condition
cysteamine 0.44% ophthalmic solution	Cystaran	PA		
cysteamine delayed-release capsule	Procysbi	PA		
cysteamine delayed-release granule	Procysbi	PA		
cysteamine immediate-release capsule	Cystagon			

	Clinical Notes
	affecting ability to swallow; **or** • member is < 13 years of age; **and**

Agents Not Otherwise Classified – Glycine-Proline-Glutamate Analog

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
trofinetide	Daybue	PA		**Daybue** • Documentation of all of the following is required for a diagnosis of classic or typical Rett syndrome: • appropriate diagnosis; **and** • member is ≥ two years of age; **and** • prescriber is a neurologist or consult notes from a neurologist are provided; **and** • results from genetic testing confirming a mutation in the MECP2 gene; **and** • RTT Clinical Severity Scale (RTT-CSS) rating of 10 to 36; **and** • Clinical Global Impression-Severity (CGI-S) score of ≥ four; **and** • appropriate dosing.

Agents Not Otherwise Classified – Complement Inhibitors and Miscellaneous Immunosuppressive Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
avacincaptad pegol	Izervay	PA	MB	**Empaveli** • Documentation of all of the following is required for a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH): • appropriate diagnosis; **and** • prescriber is a hematologist or consult notes from a specialist are provided; **and** • member is ≥ 18 years of age; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: Piasky, Soliris, Ultomiris; **and** • requested quantity is ≤ 160 mL/30 days. **Enjaymo** • Documentation of all of the following is required for the diagnosis of cold agglutinin disease (CAD): • appropriate diagnosis; **and** • prescriber is a hematologist or consult notes from a
avacopan	Tavneos	PA		
crovalimab-akkz	Piasky	PA	MB	
danicopan	Voydeya	PA		
eculizumab	Soliris	PA	MB	
efgartigimod alfa-fcab	Vyvgart	PA	MB	
efgartigimod alfa-fcab and hyaluronidase-qvfc	Vyvgart Hytrulo	PA	MB	
inebilizumab-cdon	Uplizna	PA	MB	
iptacopan	Fabhalta	PA		
pegcetacoplan 1,080 mg/20 mL vial	Empaveli	PA		
pegcetacoplan 150 mg/mL vial	Syfovre	PA	MB	
pozelimab-bbfg	Veopoz	PA	MB	
ravulizumab-cwvz	Ultomiris	PA	MB	
rozanolixizumab-noli	Rystiggo	PA	MB	
satralizumab-mwge	Enspryng	PA		

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

sutimlimab-jome	Enjaymo	PA	MB	specialist are provided; **and**
				• member is ≥ 18 years of age; **and**
				• Hemoglobin (Hb) ≤ 10 g/dL (dated within the last 60 days); **and**
				• one of the following:
				  • inadequate response, adverse reaction, or contraindication to a rituximab-containing regimen; **or**
				  • requested agent is being used as a bridge therapy to initiate a rituximab-containing regimen; **and**
				• appropriate dosing.
				
				Enspryng and Uplizna
				• Documentation of all of the following is required for the diagnosis of neuromyelitis optica spectrum disorder (NMOSD):
				  • appropriate diagnosis; **and**
				  • prescriber is a neurologist or consult notes from a specialist are provided; **and**
				  • a positive serologic test for anti-aquaporin 4 (AQP4); **and**
				  • member is ≥ 18 years of age; **and**
				  • appropriate dosing; **and**
				  • for Uplizna, inadequate response, adverse reaction. or contraindication to Enspryng.
				
				Fabhalta
				• Documentation of all of the following is required for a diagnosis of immunoglobulin A nephropathy (IgAN):
				  • appropriate diagnosis; **and**
				  • prescriber is a nephrologist or consult notes from a specialist are provided; **and**
				  • member is ≥ 18 years of age; **and**
				  • one of the following:
				  • both of the following:
				  • inadequate response (defined as ≥ 90 days of therapy) to the maximally tolerated dose of an ACE inhibitor or ARB; **and**
				  • medical records documenting intolerance to an ACE inhibitor or ARB at a dose above the maximally tolerated dose; **or**
				  • inadequate response (defined as ≥ 90 days of therapy) to the maximum FDA-approved dose of an ACE inhibitor or ARB; **and**

zilucoplan	Zilbrysq	PA		

	Clinical Notes
	• medical records documenting one of the following despite treatment with a maximally tolerated dose of an ACE inhibitor or ARB for ≥ 90 days: urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g, proteinuria >1.0 g/day; **and** • inadequate response, adverse reaction, or contraindication to both of the following: Filspari, Tarpeyo; **and** • requested quantity is ≤ two units/day. • Documentation of all of the following is required for a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH): • appropriate diagnosis; **and** • prescriber is a hematologist or consult notes from a specialist are provided; **and** • member is ≥ 18 years of age; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: Empaveli, Piasky, Soliris, Ultomiris; **and** • requested quantity is ≤ two units/day. **Izervay and Syfovre** • Documentation of all of the following is required for a diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD): • appropriate diagnosis; **and** • prescriber is an ophthalmologist; **and** • member is ≥ 50 years of age; **and** • absence of choroidal neovascularization (CNV or wet AMD) in the treatment eye; **and** • normal luminance best corrected visual acuity (BCVA) ≥ 24 letters (20/230 Snellen equivalence); **and** • total GA lesion area ≥ 2.5 and ≤ 17.5 mm2, with at least 1 lesion ≥ 1.25 mm2 if GA is multifocal; **and** • presence of any pattern of hyperautoflorescence in the junctional zone of GA; **and** • one of the following: • for Izervay, requested dosing is 2 mg (0.1 mL) every 28 days; **or** • for Syfovre, requested dosing is 15 mg (0.1 mL) once every 25 days to 60 days. • For recertification, documentation of all of the following is required for a diagnosis of GA secondary to AMD:

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	• positive response to therapy; **and**
	• member has not developed nAMD (wet AMD); **and**
	• for Izervay, total treatment duration ≤ 1 year; **and**
	• for Syfovre, if requested dosing is ≥ every 60 days, prescriber has assessed using less frequent dosing.
	
	Piasky
	• Documentation of all of the following is required for a diagnosis of PNH:
	  • appropriate diagnosis; **and**
	  • prescriber is a hematologist or consult notes from a specialist are provided; **and**
	  • member is ≥ 13 years of age; **and**
	  • inadequate response, adverse reaction, or contraindication to Ultomiris; **and**
	  • appropriate dosing.
	
	Rystiggo
	• Documentation of all of the following is required for a diagnosis of generalized myasthenia gravis:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • member is AchR or MuSK antibody positive; **and**
	  • prescriber is a neurologist or consult notes from specialist are provided; **and**
	  • inadequate response, adverse reaction, or contraindication to pyridostigmine; **and**
	  • one of the following:
	  • both of the following:
	  • member has severe disease requiring faster onset medication; **and**
	  • inadequate response, adverse reaction, or contraindication to IVIG or plasmapheresis with glucocorticoids; **or**
	  • inadequate response or adverse reaction to two or contraindication to all of the following: azathioprine, cyclosporine, glucocorticoids, mycophenolate, tacrolimus; **and**
	  • one of the following:
	  • inadequate response, adverse reaction, or contraindication to Vyvgart or Vyvgart Hytrulo; **or**
	  • member is MuSK antibody positive; **and**
	  • appropriate dosing.

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	Soliris
	• Documentation of all of the following is required for a diagnosis of atypical hemolytic-uremic syndrome (aHUS):
	  • appropriate diagnosis; **and**
	  • prescriber is a hematologist or nephrologist or consult notes from specialist are provided; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to Ultomiris.
	• Documentation of all of the following is required for a diagnosis of CD55-deficient protein-losing enteropathy (PLE), or complement hyperactivation, angiopathic thrombosis, and protein-losing enteropathy (CHAPLE) disease:
	  • appropriate diagnosis; **and**
	  • member is ≥ two months of age; **and**
	  • prescriber is a specialist in rare genetic or hematologic diseases or consult notes from specialist are provided; **and**
	  • results from genetic testing confirming a CD55 loss-of-function mutation; **and**
	  • appropriate dosing.
	• For recertification, medical records documenting all of the following are required for a diagnosis of CD55-deficient PLE, or CHAPLE disease:
	  • one of the following:
	  • increase in current serum albumin concentration from baseline serum albumin concentration; **or**
	  • serum albumin concentration stabilized above lower threshold for normal range (≥3.5 g/dL); **and**
	  • one of the following:
	  • increase in current serum IgG concentration from baseline serum IgG concentration; **or**
	  • serum IgG concentration stabilized above lower threshold for age-adjusted normal range; **and**
	  • improvement or no worsening of clinical symptoms (e.g., abdominal pain, bowel movements, facial and peripheral edema).
	• Documentation of all of the following is required for a diagnosis of generalized myasthenia gravis:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • member is AchR antibody positive; **and**
	  • prescriber is a neurologist or consult notes from a

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	specialist are provided; **and**
	• inadequate response, adverse reaction or contraindication to pyridostigmine; **and**
	• one of the following:
	  • both of the following:
	  • member has severe disease requiring faster onset medication; **and**
	  • inadequate response, adverse reaction, or contraindication to IVIG or plasmapheresis with glucocorticoids; **or**
	  • inadequate response or adverse reaction to two or contraindication to all of the following: azathioprine, cyclosporine, glucocorticoids, mycophenolate, tacrolimus; **and**
	• inadequate response or adverse reaction to one or contraindication to all of the following:
	  • Rystiggo; **or**
	  • Vyvgart or Vyvgart Hytrulo; **and**
	• inadequate response, adverse reaction, or contraindication to both of the following: Ultomiris and Zilbrysq; **and**
	• appropriate dosing.
	• For recertification for a diagnosis of generalized myasthenia gravis, documentation of positive response to therapy is required.
	• Documentation of all of the following is required for a diagnosis of NMOSD:
	• appropriate diagnosis; **and**
	• prescriber is a neurologist or consult notes from a specialist are provided; **and**
	• a positive serologic test for anti-aquaporin-4 (AQP4); **and**
	• member is ≥ 18 years of age; **and**
	• appropriate dosing; **and**
	• inadequate response, adverse reaction, or contraindication to Ultomiris.
	• Documentation of all of the following is required for a diagnosis of PNH:
	• appropriate diagnosis; **and**
	• prescriber is a hematologist or consult notes from a specialist are provided; **and**
	• member is ≥ 18 years of age; **and**
	• inadequate response, adverse reaction, or contraindication to Ultomiris; **and**
	• appropriate dosing.

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	Tavneos
	• Documentation of all of the following is required for a diagnosis of granulomatosis with polyangiitis or microscopic polyangiitis:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is a rheumatologist or nephrologist or consult notes from a specialist are provided; **and**
	  • requested quantity is ≤ six capsules/day; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used as adjunctive therapy with both of the following:
	  • a systemic glucocorticoid; **and**
	  • one of the following: azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil, or rituximab.
	• For recertification, documentation of positive response to therapy is required.
	
	Ultomiris
	• Documentation of all of the following is required for a diagnosis of aHUS:
	  • appropriate diagnosis; **and**
	  • prescriber is a specialist (e.g., hematologist or nephrologist) or consult notes are provided; **and**
	  • appropriate dosing.
	• Documentation of all of the following is required for a diagnosis of generalized myasthenia gravis:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • member is AchR antibody positive; **and**
	  • prescriber is a neurologist or consult notes from a specialist are provided; **and**
	  • inadequate response, adverse reaction or contraindication to pyridostigmine; **and**
	  • one of the following:
	  • both of the following:
	  • member has severe disease requiring faster onset medication; **and**
	  • inadequate response, adverse reaction, or contraindication to IVIG or plasmapheresis with glucocorticoids; **or**
	  • inadequate response or adverse reaction to two or

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	contraindication to all of the following: azathioprine, cyclosporine, glucocorticoids, mycophenolate, tacrolimus; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: • Rystiggo; **or** • Vyvgart or Vyvgart Hytrulo; **and** • appropriate dosing. • For recertification for a diagnosis of generalized myasthenia gravis, documentation of positive response to therapy is required. • Documentation of all of the following is required for a diagnosis of NMOSD: • appropriate diagnosis; **and** • prescriber is a neurologist or consult notes from a specialist are provided; **and** • a positive serologic test for anti-aquaporin-4 (AQP4); **and** • member is ≥ 18 years of age; **and** • appropriate dosing; **and** • Documentation of all of the following is required for a diagnosis of PNH: • appropriate diagnosis; **and** • prescriber is a hematologist or consult notes from a specialist are provided; **and** • appropriate dosing. **Veopoz** • Documentation of all of the following is required for a diagnosis of CD55-deficient PLE, or CHAPLE disease: • appropriate diagnosis; **and** • member is ≥ one year of age; **and** • prescriber is a specialist in rare genetic or hematologic diseases or consult notes from specialist are provided; **and** • results from genetic testing confirming a CD55 loss-of-function mutation; **and** • inadequate response, adverse reaction, or contraindication to Soliris; **and** • appropriate dosing. • For recertification, medical records documenting all of the following are required for a diagnosis of CD55-deficient PLE, or CHAPLE disease: • one of the following:

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	• increase in current serum albumin concentration from baseline serum albumin concentration; **or** • serum albumin concentration stabilized above lower threshold for normal range (≥3.5 g/dL); **and** • one of the following: • increase in current serum IgG concentration from baseline serum IgG concentration; **or** • serum IgG concentration stabilized above lower threshold for age-adjusted normal range; **and** • improvement or no worsening of clinical symptoms (e.g., abdominal pain, bowel movements, facial and peripheral edema). **Voydeya** • Documentation of all of the following is required for a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH): • appropriate diagnosis; **and** • prescriber is a hematologist or consult notes from a specialist are provided; **and** • member is ≥ 18 years of age; **and** • appropriate dosing (150 to 200 mg three times daily); **and** • member has clinically significant extravascular hemolysis; **and** • inadequate response (defined as ≥ 6 months of therapy) to one of the following: Soliris, Ultomiris; **and** • requested medication will be used in combination with one of the following: Soliris, Ultomiris. **Vyvgart and Zilbrysq** • Documentation of all of the following is required for a diagnosis of generalized myasthenia gravis: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • member is AchR antibody positive; **and** • prescriber is a neurologist or consult notes from a specialist are provided; **and** • inadequate response, adverse reaction or contraindication to pyridostigmine; **and** • one of the following: • both of the following: • member has severe disease requiring faster onset medication; **and**

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	• inadequate response, adverse reaction, or contraindication to IVIG or plasmapheresis with glucocorticoids; **or** • inadequate response or adverse reaction to two or contraindication to all of the following: azathioprine, cyclosporine, glucocorticoids, mycophenolate, tacrolimus; **and** • appropriate dosing; **and** • for Zilbrysq, inadequate response or adverse reaction to one or contraindication to all of the following: • Rystiggo; **or** • Vyvgart or Vyvgart Hytrulo. • For recertification of Zilbrysq for a diagnosis of generalized myasthenia gravis, documentation of positive response to therapy is required. **Vyvgart Hytrulo** • Documentation of all of the following is required for a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP): • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is a neurologist or consult notes from a neurologist are provided; **and** • appropriate dosing; **and** • two of the following: • inadequate response, adverse reaction, or contraindication to immune globulin; **or** • inadequate response, adverse reaction, or contraindication to plasma exchange; **or** • one of the following: • inadequate response or adverse reaction to glucocorticoids (e.g., budesonide, methylprednisolone, prednisone); **or** • both of the following: • inadequate response or adverse reaction to immunosuppressants (e.g., azathioprine, cyclosporine, cyclophosphamide, mycophenolate mofetil, rituximab); **and** • contraindication to glucocorticoids. • Documentation of all of the following is required for a diagnosis of generalized myasthenia gravis: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and**

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	• member is AchR antibody positive; **and**
	• prescriber is a neurologist or consult notes from a specialist are provided; **and**
	• inadequate response, adverse reaction, or contraindication to pyridostigmine; **and**
	• one of the following:
	  • both of the following:
	  • member has severe disease requiring faster onset medication; **and**
	  • inadequate response, adverse reaction, or contraindication to IVIG or plasmapheresis with glucocorticoids; **or**
	  • inadequate response or adverse reaction to two or contraindication to all of the following: azathioprine, cyclosporine, glucocorticoids, mycophenolate, tacrolimus; **and**
	• appropriate dosing.

Agents Not Otherwise Classified – Thyroid Preparations

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

levothyroxine capsule-Tirosint	Tirosint	PA	M90	**Brand name Euthyrox**
				• Documentation of all of the following is required:
				  • diagnosis of one of the following:
				  • hypothyroidism; **or**
				  • pituitary TSH suppression as an adjunct to surgery and radioiodine therapy in the management of thyroid cancer; **and**
				  • medical necessity for use of the requested agent as noted by historical difficulty in achieving consistent therapeutic levels on other formulations; **and**
				  • medical records documenting an inadequate response or adverse reaction to the therapeutically generic equivalent.
				Tirosint
				• Documentation of all of the following is required:
				  • diagnosis of one of the following:
				  • hypothyroidism; **or**
				  • pituitary TSH suppression as an adjunct to surgery and radioiodine therapy in the management of thyroid cancer; **and**
				  • medical necessity for use of levothyroxine capsule as noted by one of the following:
				  • more precise thyroxine dosing is required due to

levothyroxine-Euthyrox	Euthyrox		# , M90	

	Clinical Notes
	malabsorption issues or historical difficulty in achieving consistent therapeutic levels; **or** • 13 mcg dose is required to achieve therapeutic response; **or** • member has a gluten allergy/lactose intolerance or has a history of sensitivities/allergies to dyes.

Agents Not Otherwise Classified – Amyotrophic Lateral Sclerosis (ALS) Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
edaravone	Radicava	PA		**edaravone, Radicava, Radicava ORS** • Documentation of all of the following is required: • medical records supporting the diagnosis of definite, probable, or probable-laboratory supported ALS per El Escorial criteria; **and** • prescriber is a neurologist, neuromuscular specialist, or other specialist in the treatment of ALS, or consult notes from a specialist are provided; **and** • pre-treatment ALSFRS-R questionnaire score (within the past 12 weeks); **and** • pre-treatment ALSFRS-R questionnaire score of ≥ two on each individual item; **and** • pre-treatment FVC ≥ 80%; **and** • member is not dependent on invasive mechanical ventilation by intubation or tracheostomy; **and** • appropriate dosing; **and** • one of the following: • requested agent will be used in combination with riluzole; **or** • adverse reaction or contraindication to riluzole. • For recertification, documentation of all of the following is required: • a current (within the last 12 weeks) copy of the ALSFRS-R questionnaire including scores on each individual domain; **and** • member is not dependent on invasive mechanical ventilation by intubation or tracheostomy. **Exservan, Tiglutik** • Documentation of all of the following is required for a diagnosis of amyotrophic lateral sclerosis (ALS): • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • one of the following:
edaravone	Radicava ORS	PA		
edaravone		PA		
riluzole film	Exservan	PA		
riluzole suspension	Tiglutik	PA		
riluzole tablet	Rilutek		# , A90	
tofersen	Qalsody	PA	MB	

	Clinical Notes
	• member has severe dysphagia and is currently utilizing only dosage formulations that can easily be swallowed; **or** • member utilizes tube feeding (J-tube, G-tube) and is unable to use crushed tablets; **or** • medical necessity for use instead of riluzole tablets; **and** • appropriate dosing. • For recertification, documentation of all of the following is required: • one of the following: • member has severe dysphagia and is currently utilizing only dosage formulations that can easily be swallowed; **or** • member utilizes tube feeding (J-tube, G-tube) and is unable to use crushed tablets; **or** • continued medical necessity for use instead of riluzole tablets; **and** • appropriate dosing. Qalsody • Documentation of all of the following is required for a diagnosis of ALS: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is a neurologist, neuromuscular specialist, or other specialist in the treatment of ALS, or consult notes from a specialist are provided; **and** • genetic test confirming SOD1 mutation; **and** • pre-treatment ALSFRS-R questionnaire score (within the past 12 weeks); **and** • appropriate dosing; **and** • member is not dependent on invasive mechanical ventilation by intubation or tracheostomy; **and** • one of the following: • requested agent will be used in combination with riluzole; **or** • adverse reaction or contraindication to riluzole. • For recertification, documentation of all of the following is required: • a current (within the last 12 weeks) copy of the ALSFRS-R questionnaire including scores on each individual domain; **and** • member is not dependent on invasive mechanical

	Clinical Notes
	ventilation by intubation or tracheostomy.

Agents Not Otherwise Classified – Wound Care

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
anacaulase-bcdb	Nexobrid	PA	MB	Filsuvez • Documentation of all of the following is required: • diagnosis of dystrophic or junctional epidermolysis bullosa (DEB or JEB); **and** • member is ≥ six months of age; **and** • prescriber is a specialist (e.g., dermatologist, geneticist, histopathologist) or consult notes from a specialist are provided; **and** • copy of a genetic test confirming diagnosis of DEB or JEB (e.g., mutation of COL7A1 gene or PLOD3 gene for DEB or mutation of LAMA3, LAMB3, LAMC2, COL17A1, ITGA3, ITGA6, or ITGB4 genes for JEB); **and** • documentation of ≥ one partial thickness wound that is clean in appearance and does not appear infected; **and** • for the diagnosis of DEB, requested agent will not be used in combination with Vyjuvek. • For recertification, documentation of all of the following is required: • requested agent is not being applied on target wounds that have completely healed; **and** • positive response to therapy as indicated by one of the following: • decrease in wound size; **or** • decrease in pain or itch severity for target wound sites associated with dressing changes. Nexobrid • Documentation of all of the following is required: • diagnosis of deep partial thickness and/or full thickness thermal burns; **and** • prescriber is a specialist (e.g., dermatologist, burn specialist) or consult notes from a specialist are provided; **and** • one of the following: • requested quantity is one unit; **or** • both of the following: • requested quantity is two units; **and** • BSA of wound area is > 15 % and ≤ 20 %.
becaplermin	Regranex	PA		
beremagene geperpavec-svdt	Vyjuvek	PA		
birch triterpenes	Filsuvez	PA		
collagenase	Santyl	PA		

	Clinical Notes

	Regranex
	• Documentation of all of the following is required:
	  • diagnosis of diabetic neuropathic ulcers in the lower extremities; **and**
	  • number and size of the ulcers intended for treatment; **and**
	  • requested duration of treatment; **and**
	  • ulcer extends to subcutaneous tissue or beyond; **and**
	  • lower extremities have adequate blood supply; **and**
	  • ulcer is clear of infection; **and**
	  • member has ≥ two months of good wound care (sharp debridement, saline dressing, and pressure relief) without adequate ulcer healing.
	
	Santyl
	• Documentation of all of the following is required:
	  • diagnosis of chronic dermal ulcers or severely burned areas; **and**
	  • number and size of the ulcers and/or size of lesion intended for treatment; **and**
	  • requested duration of treatment; **and**
	  • one of the following:
	  • member is not a candidate for surgical intervention alone; **or**
	  • member is not a candidate for autolytic debridement; **or**
	  • the requested agent is being used in combination with surgery.
	Vyjuvek
	• Documentation of all of the following is required:
	  • diagnosis of DEB; **and**
	  • copy of a genetic test confirming diagnosis of dystrophic epidermolysis bullosa (e.g., mutation of COL7A1 gene); **and**
	  • member is ≥ six months of age; **and**
	  • prescriber is a specialist (i.e., dermatologist, geneticist, histopathologist, etc.) or consult notes from a specialist are provided; **and**
	  • member has ≥ one cutaneous wound that is clean in appearance with adequate granulation tissue, has excellent vascularization, and does not appear infected; **and**
	  • appropriate dosing.
	• For recertification, documentation of all of the following

	Clinical Notes
	is required: • one of the following: • complete wound healing of ≥ one wound after six months of treatment; **or** • clinical rationale for continued treatment despite lack of efficacy; **and** • member has ≥ one cutaneous wound that is clean in appearance with adequate granulation tissue, has excellent vascularization, and does not appear infected.

Agents Not Otherwise Classified – Neuromuscular Potassium Channel Blockers

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amifampridine	Firdapse	PA		**Firdapse** • Documentation of all of the following is required: • diagnosis of symptomatic Lambert-Eaton myasthenic syndrome (LEMS); **and** • member is ≥ six years of age; **and** • prescriber is a neurologist or consult notes from a neurologist are provided; **and** • one of the following laboratory results confirming the diagnosis: • neurophysiology study tests; **or** • positive anti-P/Q type voltage-gated calcium channel antibody test; **and** • appropriate dosing.

Agents Not Otherwise Classified – Interferon Gamma Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
emapalumab-lzsg	Gamifant	PA		**Gamifant** • Documentation of all of the following is required for a diagnosis of primary hemophagocytic lymphohistiocytosis (HLH): • appropriate diagnosis; **and** • prescriber is a specialist (e.g., hematologist or oncologist) or consult notes from a specialist are provided; **and** • one of the following: • molecular tests confirming diagnosis of primary HLH; **or**

	Clinical Notes
	• at least five of the following suggesting primary HLH: fever, splenomegaly, cytopenia (defined by two of the following: hemoglobin < 9 g/dL, platelets < 100 x 10^9/L, neutrophils < 1 x 10^9/L), hypertriglyceridemia (defined by fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL) and/or hypofibrinogenemia (≤ 1.5 g/L), hemophagocytosis in bone marrow, spleen, or lymph nodes, low or absent NK-cell activity based on laboratory reference, ferritin ≥ 500 mcg/L, soluble CD25 ≥ 2400 U/mL; **and** • member has active disease; **and** • member does not have active infections caused by specific pathogens favored by interferon gamma neutralization (e.g., mycobacteria, Histoplasma Capsulatum, Shigella, salmonella, campylobacter, leishmanial infections); **and** • inadequate response or adverse reaction to one or contraindication to all conventional HLH therapy (chemotherapy, systemic corticosteroids, immunosuppressive therapy); **and** • requested agent will be administered in combination with dexamethasone, or clinical rationale for not using dexamethasone; **and** • anticipated hematopoietic stem cell transplantation (HSCT) date is provided, or member is not a candidate for HSCT; **and** • appropriate dosing. • For recertification, documentation of the following is required: • positive response to therapy as evidenced by one of the following: • complete response (normalization of all HLH abnormalities); **or** • partial response (normalization of ≥ 3 HLH abnormalities); **or** • HLH improvement (≥ 3 HLH abnormalities improved by at least 50% from baseline); **and** • requested agent will be administered in combination with dexamethasone, or clinical rationale for not using dexamethasone; **and** • anticipated HSCT date is provided, or member is not a candidate for HSCT.

Agents Not Otherwise Classified – Small Interfering RNA Therapies

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

givosiran	Givlaari PD	PA	MB	**Givlaari**
				• Documentation of all of the following is required for acute hepatic porphyria (AHP):
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • member's current weight; **and**
				  • appropriate dosing.
				
				Oxlumo
				• Documentation of all of the following is required for primary hyperoxaluria type 1 (PH1):
				  • appropriate diagnosis; **and**
				  • prescriber is a specialist (e.g., nephrologist) or consult notes from a specialist are provided; **and**
				  • results from genetic testing showing mutations in the AGXT gene; **and**
				  • member's current weight; **and**
				  • appropriate dosing.
				• For recertification, documentation of all of the following is required:
				  • positive response to therapy; **and**
				  • updated member weight; **and**
				  • appropriate dosing.
				
				Rivfloza
				• Documentation of all of the following is required for PH1:
				  • appropriate diagnosis; **and**
				  • member is ≥ nine years of age; **and**
				  • prescriber is a specialist (e.g., nephrologist) or consult notes from a specialist are provided; **and**
				  • results from genetic testing showing mutations in the AGXT gene; **and**
				  • member has eGFR > 30 mL/min/1.73 m^2; **and**
				  • member's current weight; **and**
				  • inadequate response, adverse reaction, or contraindication to Oxlumo; **and**
				  • appropriate dosing.
				• For recertification, documentation of all of the following is required:
				  • positive response to therapy; **and**
				  • updated member weight; **and**
				  • appropriate dosing.

lumasiran	Oxlumo PD	PA	MB	
nedosiran	Rivfloza	PA		

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

gabapentin capsule, solution, tablet	Neurontin	PA - < 6 years and PA > 3600 mg/day	#	**gabapentin containing products > 3,600 mg/day and pregabalin containing products > 600 mg/day**
				• For all requests, individual drug PA criteria must be met first where applicable.
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • clinical rationale for exceeding the maximum daily dose limit.
				
				gabapentin extended-release
				• Documentation of all of the following is required for a diagnosis of postherpetic neuralgia:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • inadequate response, adverse reaction, or contraindication to a tricyclic antidepressant; **and**
				  • inadequate response (defined as ≥ 14 days of therapy at a dose of ≥ 1,200 mg/day) or adverse reaction to gabapentin immediate-release; **and**
				  • inadequate response or adverse reaction to Horizant.
				• Documentation of all of the following is required for a diagnosis of fibromyalgia:
				  • appropriate diagnosis; **and**
				  • inadequate response (defined as ≥ 14 days of therapy at a dose of ≥ 1,200 mg/day) or adverse reaction to gabapentin immediate-release; **and**
				  • inadequate response (defined as ≥ 4 weeks of therapy) or adverse reaction to one or contraindication to all of the following: cyclobenzaprine, SSRI/SNRI, tricyclic antidepressant; **and**
				  • inadequate response or adverse reaction to Horizant.
				• Documentation of all of the following is required for a diagnosis of diabetic peripheral neuropathy:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • inadequate response (defined as ≥ 14 days of therapy at a dose of ≥ 1,200 mg/day), or adverse reaction to gabapentin immediate-release; **and**
				  • inadequate response, adverse reaction, or contraindication to a tricyclic antidepressant; **and**
				  • inadequate response or adverse reaction to Horizant.
				
				Horizant > 1200 mg/day

gabapentin enacarbil	Horizant	PA - < 6 years and PA > 1200 mg/day	BP	
gabapentin extended-release	Gralise	PA		
pregabalin	Lyrica	PA - < 6 years and PA > 600 mg/day	#	
pregabalin extended-release	Lyrica CR	PA	BP	

	Clinical Notes

	• Documentation of all of the following is required:
	  • diagnosis of one of the following:
	  • restless leg syndrome; **or**
	  • neuropathic pain condition; **and**
	  • clinical rationale for exceeding the maximum daily dose limit.
	
	pregabalin extended-release
	• Documentation of all of the following is required:
	  • diagnosis of one of the following:
	  • diabetic peripheral neuropathy; **or**
	  • postherpetic neuralgia; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: duloxetine, lidocaine patch, a tricyclic antidepressant, venlafaxine; **and**
	  • inadequate response (defined as ≥ 14 days of therapy at a dose of ≥ 1,200 mg/day), adverse reaction or contraindication to gabapentin immediate-release; **and**
	  • inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to pregabalin immediate-release; **and**
	  • one of the following:
	  • for diabetic peripheral neuropathy, requested quantity is ≤ one unit/day; **or**
	  • for postherpetic neuralgia, requested quantity is ≤ two units/day.
	
	Concomitant gabapentin and pregabalin polypharmacy (a history of at least one paid MassHealth pharmacy claim for the other agent within the last 30 days) for all formulations
	• For all requests, individual drug PA criteria must be met first where applicable.
	• Documentation of the following is required:
	  • appropriate diagnosis for gabapentin; **and**
	  • appropriate diagnosis for pregabalin; **and**
	  • complete treatment plan; **and**
	  • clinical rationale for the concomitant use of gabapentin and pregabalin; **and**
	  • one of the following:
	  • inadequate response to the maximum daily dose of each agent as monotherapy; **or**
	  • inadequate response to the maximum tolerated dose of each agent as monotherapy and requested doses

	Clinical Notes
	are less than the doses at which the adverse drug reaction or side effect occurred; **and** • inadequate response or adverse reaction to two or contraindication to all other alternatives for the requested indication. In addition to individual drug PA criteria where applicable, the above behavioral health medications are subject to additional polypharmacy and age limit restrictions as per the Pediatric Behavioral Health Initiative. See Table 71 for additional information.

Agents Not Otherwise Classified – Oral Immunotherapy Agent

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
grass pollen allergen extract	Oralair	PA		**Grastek** • Documentation of all of the following is required: • diagnosis of allergic rhinitis with or without conjunctivitis; **and** • prescriber is a specialist in the treatment of allergic rhinoconjunctivitis (e.g., allergist, immunologist, otolaryngologist, rhinologist) or consult notes from a specialist are provided; **and** • member is ≥ five years of age; **and** • medical records of the skin test confirming pollen-specific immunoglobulin E (IgE) antibodies for the specific antigen (e.g., grass pollen); **and** • member is not currently a candidate for subcutaneous immunotherapy; **and** • inadequate response (defined as at least 14 days of therapy), adverse reaction, or contraindication to one agent from all of the following classes of symptomatic therapy: intranasal antihistamine, intranasal corticosteroid, second generation oral antihistamine; **and** • requested quantity is ≤ one unit/day. **Odactra** • Documentation of all of the following is required: • diagnosis of allergic rhinitis with or without conjunctivitis; **and** • prescriber is a specialist in the treatment of allergic rhinoconjunctivitis (e.g., allergist, immunologist,
house dust mite allergen extract	Odactra	PA		
peanut allergen powder-dnfp	Palforzia	PA		
short ragweed pollen allergen extract	Ragwitek	PA		
timothy grass pollen allergen extract	Grastek	PA		

	Clinical Notes
	otolaryngologist, rhinologist) or consult notes from a specialist are provided; **and** • member is ≥ 12 years of age; **and** • medical records of the skin test confirming immunoglobulin E (IgE) antibodies for the specific antigen (e.g., house dust mite); **and** • member is not currently a candidate for subcutaneous immunotherapy; **and** • inadequate response (defined as at least 14 days of therapy), adverse reaction, or contraindication to one agent from all of the following classes of symptomatic therapy: intranasal antihistamine, intranasal corticosteroid, second generation oral antihistamine; **and** • requested quantity is ≤ one unit/day. **Oralair** • Documentation of all of the following is required: • diagnosis of allergic rhinitis with or without conjunctivitis; **and** • prescriber is a specialist in the treatment of allergic rhinoconjunctivitis (e.g., allergist, immunologist, otolaryngologist, rhinologist) or consult notes from a specialist are provided; **and** • member is ≥ five years of age; **and** • medical records of the skin test confirming pollen-specific immunoglobulin E (IgE) antibodies for the specific antigen (e.g., grass pollen); **and** • member is not currently a candidate for subcutaneous immunotherapy; **and** • inadequate response (defined as at least 14 days of therapy), adverse reaction, or contraindication to one agent from all of the following classes of symptomatic therapy: intranasal antihistamine, intranasal corticosteroid, second generation oral antihistamine; **and** • for Oralair 300 mg immediate-release tablet, requested quantity is ≤ one unit/day. **Palforzia** • Documentation of all of the following is required: • diagnosis of peanut allergy; **and** • prescriber is an allergist or immunologist, or consult

	Clinical Notes
	notes from an allergist or immunologist are provided; **and** • one of the following: • member is ≥ four to < 18 years of age; **or** • member started Palforzia at ≥ four to < 18 years of age; **and** • confirmation of diagnosis with one of the following: • serum peanut-specific immunoglobulin (IgE); **or** • skin test confirmation of immunoglobulin (IgE) antibodies for the specific antigen; **and** • appropriate dosing. • For recertification of Palforzia, documentation of tolerance to therapy during the initial dose escalation and up-dosing phases is required. **Ragwitek** • Documentation of all of the following is required: • diagnosis of allergic rhinitis with or without conjunctivitis; **and** • prescriber is a specialist in the treatment of allergic rhinoconjunctivitis (e.g., allergist, immunologist, otolaryngologist, rhinologist) or consult notes from a specialist are provided; **and** • member is ≥ five years of age; **and** • medical records of the skin test confirming pollen-specific immunoglobulin E (IgE) antibodies for the specific antigen (e.g., short ragweed pollen); **and** • member is not currently a candidate for subcutaneous immunotherapy; **and** • inadequate response (defined as at least 14 days of therapy), adverse reaction, or contraindication to one agent from all of the following classes of symptomatic therapy: intranasal antihistamine, intranasal corticosteroid, second generation oral antihistamine; **and** • requested quantity is ≤ one unit/day.

Agents Not Otherwise Classified – Melanocortin Receptor Agonists

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
afamelanotide	Scenesse	PA	MB	**Imcivree** • Documentation of the following is required for a diagnosis of obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1
setmelanotide	Imcivree	PA		

	Clinical Notes

	(PCSK1), or leptin receptor (LEPR) deficiency:
	• diagnosis of obesity is due to to a homozygous or presumed homozygous variant in at least one of the following genes (genetic test must be provided): POMC, PCSK1, LEPR; **and**
	• one of the following:
	  • for adult members, baseline height and weight supporting body mass index (BMI) ≥ 30 kg/m^2; **or**
	  • for pediatric members, baseline BMI supporting ≥ 95th percentile using growth chart assessment; **and**
	• genetic testing demonstrating that the variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS); **and**
	• prescriber is an endocrinologist; **and**
	• requested dose is ≤ three mg/day; **and**
	• member is ≥ six years of age.
	
	• Documentation of all of the following is required for a diagnosis of obesity due to Bardet-Biedl syndrome (BBS):
	  • appropriate diagnosis; **and**
	  • member is ≥ six years of age; **and**
	  • one of the following:
	  • for adult members, baseline height and weight supporting BMI of ≥ 30 kg/m2; **or**
	  • for pediatric members, baseline BMI supporting ≥ 95th percentile using growth chart assessment; **and**
	  • prescriber is an endocrinologist; **and**
	  • requested dose is ≤ three mg/day.
	
	• For recertification, documentation of the following is required:
	  • one of the following:
	  • for adult members, at least a 5% reduction in baseline body weight or maintenance in reduction of at least 5% in baseline body weight; **or**
	  • for pediatric members, at least a 5% reduction in baseline BMI or maintenance in reduction of at least 5% in baseline BMI in members with continued growth potential; **and**
	  • requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to the requested

	Clinical Notes

	agent.
	Scenesse
	• Documentation of the following is required for a diagnosis of erythropoietic protoporphyria:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is a dermatologist or consultation notes from a dermatologist are provided; **and**
	  • implant procedure will be performed at a specialized treatment center; **and**
	  • appropriate dosing.

Agents Not Otherwise Classified – Vasopressin Antagonist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

tolvaptan-Jynarque	Jynarque	PA		**Jynarque**
				• Documentation of all of the following is required:
				  • diagnosis of autosomal dominant polycystic kidney disease (ADPKD); **and**
				  • member is ≥ 18 and < 56 years of age; **and**
				  • prescriber is a nephrologist or consultation notes from a nephrologist are provided; **and**
				  • estimated glomerular filtration rate (eGFR) ≥ 25 mL/min (e.g., within the last 6 months).
				• For recertification, documentation of positive response to therapy and that eGFR continues to be ≥ 25 mL/min (e.g., within the last 6 months) is required.

Agents Not Otherwise Classified – Oral Carbonic Anhydrase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

acetazolamide			A90	**dichlorphenamide**
				• Documentation of all of the following is required for a diagnosis of primary hyperkalemic periodic paralysis:
				  • appropriate diagnosis; **and**
				  • prescriber is a specialist (e.g., genetic disease specialist, neurologist) or consult notes from a specialist are provided; **and**
				  • inadequate response, adverse reaction, or contraindication to both of the following: acetazolamide, hydrochlorothiazide.
				• Documentation of all of the following is required for a diagnosis of primary hypokalemic periodic paralysis:
				  • appropriate diagnosis; **and**

dichlorphenamide	Keveyis	PA		

	Clinical Notes

	• prescriber is a specialist (e.g., genetic disease specialist, neurologist) or consult notes from a specialist are provided; **and**
	• inadequate response, adverse reaction, or contraindication to both of the following:
	  • acetazolamide; **and**
	  • one of the following:
	  • spironolactone; **or**
	  • triamterene.

Agents Not Otherwise Classified – Metachromatic Leukodystrophy (MLD) Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

atidarsagene autotemcel	Lenmeldy	PA	CO	**Lenmeldy**
				• Documentation of all of the following is required:
				  • diagnosis of one of the following:
				  • presymptomatic late infantile metachromatic leukodystrophy (MLD); **or**
				  • presymptomatic early juvenile MLD; **or**
				  • early symptomatic early juvenile MLD; **and**
				  • prescriber is a specialist in the treatment of MLD (e.g., neurologist, geneticist); **and**
				  • deficient ARSA enzyme activity in leukocytes; **and**
				  • elevated sulfatides on 24-hour urine collection; **and**
				  • for presymptomatic late infantile MLD, all of the following:
				  • two null (0) mutant ARSA alleles; **and**
				  • member is ≤ 30 months of age; **and**
				  • absence of neurological signs and symptoms of MLD with the exception of abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia); **and**
				  • peripheral neuropathy as determined by electroneurographic study; **or**
				  • for presymptomatic early juvenile MLD, all of the following:
				  • one null (0) and 1 R mutant ARSA allele(s); **and**
				  • member is < seven years of age; **and**
				  • absence of neurological signs and symptoms of MLD or physical exam findings limited to abnormal reflexes and/or clonus with the exception of abnormal reflexes or abnormalities on brain

	Clinical Notes
	magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia); **and** • peripheral neuropathy as determined by electroneurographic study; **or** • for early symptomatic early juvenile MLD, all of the following: • one null (0) and 1 R mutant ARSA allele(s); **and** • disease onset > 30 months and < seven years of age; **and** • member is <18 years of age; **and** • Intelligence quotient ≥ 85 on age-appropriate neurodevelopmental testing; **and** • Gross Motor Function Classification in metachromatic leukodystrophy (GMFC-MLD) level 0 with ataxia OR GMFC-MLD level 1; **and** • appropriate dosing; **and** • infusion will take place in a qualified treatment facility; **and** • member has negative serology tests for all of the following: • human immunodeficiency virus (HIV)-1/2; **and** • human T-lymphotrophic virus (HTLV)-1/2; **and** • hepatitis B virus (HBV); **and** • hepatitis C virus (HCV); **and** • mycoplasma; **and** • member has NOT had previous gene therapy for MLD. **Please note: One-time cell and gene therapies are part of the ACPP and MCO unified pharmacy policy. PA requests for one-time cell and gene therapies for members with ACPP and MCO plans are reviewed by the MassHealth Drug Utilization Review (DUR) Program.**

Agents Not Otherwise Classified – Potassium Binding Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
patiromer	Veltassa	PA - > 1 unit/day		**Lokelma and Veltassa > one unit/day** • Documentation of all of the following is required: • diagnosis of hyperkalemia; **and**
sodium polystyrene sulfonate				

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
sodium zirconium cyclosilicate	Lokelma	PA - > 1 unit/day		• medical necessity for exceeding the quantity limit.

Agents Not Otherwise Classified – Inherited Retinal Disease Gene Therapy

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

voretigene neparvovec-rzyl	Luxturna	PA	CO	Luxturna
				• Documentation of all of the following is required:
				  • diagnosis of biallelic RPE65 mutation-associated retinal dystrophy; **and**
				  • prescriber is a specialist (e.g., ophthalmologist or retinal specialist) or consult notes from a specialist are provided; **and**
				  • the treatment procedure will be performed at a specialized treatment center; **and**
				  • medical records documenting the results from genetic testing showing mutations in the RPE65 gene; **and**
				  • viable retinal cells (e.g., retinal thickness > 100 microns); **and**
				  • baseline full-field light sensitivity threshold (FST) scores; **and**
				  • member is ≥ one year of age on treatment date; **and**
				  • member has not undergone recent ocular surgery in the last six months; **and**
				  • member has discontinued retinoid compounds for at least 18 months; **and**
				  • appropriate dosing and treatment schedule; **and**
				  • member has not received any prior gene therapy for biallelic RPE65 mutation-associated retinal dystrophy.
				• **Please note: One-time cell and gene therapies are part of the ACPP and MCO unified pharmacy policy. PA requests for one-time cell and gene therapies for members with ACPP and MCO plans are reviewed by the MassHealth Drug Utilization Review (DUR) Program.**
				• MassHealth DUR will be reaching out to prescribers after PA approval to verify administration date and at ongoing intervals for long-term monitoring of response.

Agents Not Otherwise Classified – Acetylcholinesterase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
pyridostigmine bromide 30 mg tablet		PA	A90	pyridostigmine bromide 30 mg tablet • Documentation of the following is required:

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
pyridostigmine bromide 60 mg tablet, 180 mg extended-release tablet	Mestinon		BP, A90	• diagnosis of myasthenia gravis; **and** • medical necessity for the 30 mg tablet instead of the 60 mg tablet. • For recertification, documentation of continued medical necessity for the requested dosage formulation is required.
pyridostigmine bromide solution	Mestinon		BP, A90	

Agents Not Otherwise Classified – Progestin Antagonist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
mifepristone 200 mg	Mifeprex		#	

Agents Not Otherwise Classified – Leptin Analog

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
metreleptin	Myalept	PA		Myalept • Documentation of all of the following is required: • diagnosis of one of the following: • Congenital Generalized Lipodystrophy (CGL) or Berardinelli-Seip syndrome; **or** • Acquired Generalized Lipodystrophy (AGL) or Lawrence syndrome; **and** • member has at least one of the following metabolic abnormalities: • diabetes mellitus; **or** • fasting insulin levels > 30 microU/mL; **or** • fasting serum triglycerides > 200 mg/dL; **and** • member will be using as an adjunct to dietary restrictions; **and** • one of the following: • if the member has diabetes mellitus or fasting insulin levels > 30 microU/mL, medical records documenting an inadequate response to 90 days of therapy or adverse reaction to three different classes of antidiabetic therapies; **or** • if the member has fasting serum triglycerides > 200 mg/dL, medical records documenting an inadequate response to at least 90 days of therapy, adverse reaction or contraindication to both of the following: a fibrate, a high-potency statin (rosuvastatin 20 mg or 40 mg or atorvastatin 40 mg or 80 mg). • For recertification, medical records documenting positive response to therapy (e.g., improvements in HbA1c, fasting plasma glucose, and/or triglyceride levels by

	Clinical Notes
	month four of metreleptin therapy) are required.

Agents Not Otherwise Classified – Pseudobulbar Affect Agent

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
dextromethorphan / quinidine	Nuedexta	PA		Nuedexta • Documentation of all of the following is required: • diagnosis of pseudobulbar affect; **and** • requested quantity is ≤ two units/day.

Agents Not Otherwise Classified – Stem Cell Therapies

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
omidubicel-onlv	Omisirge	PA	CO	Omisirge • Documentation of all of the following is required: • diagnosis of hematologic malignancy; **and** • prescriber is a hematologist or oncologist; **and** • member is ≥ 12 years of age on treatment date; **and** • member is planned for umbilical cord blood transplantation following myeloablative conditioning; **and** • appropriate dosing of one-time treatment. • **Please note: One-time cell and gene therapies are part of the ACPP and MCO unified pharmacy policy. PA requests for one-time cell and gene therapies for members with ACPP and MCO plans are reviewed by the MassHealth Drug Utilization Review (DUR) Program.** • MassHealth DUR will be reaching out to prescribers after PA approval to verify administration date and at ongoing intervals for long-term monitoring of response.

Agents Not Otherwise Classified – Human Nerve Growth Factor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
cenegermin-bkbj	Oxervate	PA		Oxervate • Documentation of all of the following is required for a diagnosis of stage 2 or 3 neurotrophic keratitis (neurotrophic keratoconjunctivitis): • appropriate diagnosis; **and** • member is ≥ two years of age; **and** • prescriber is a specialist (e.g., ophthalmologist) or consult notes from a specialist are provided.

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

alitretinoin	Panretin	PA		**Panretin**
				• Documentation of all of the following is required for the diagnosis of AIDS-related Kaposi's sarcoma:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to all of the following: chemotherapy (e.g., pegylated liposomal doxorubicin, vinblastine or vincristine [with or without bleomycin], paclitaxel, oral etoposide, vinorelbine, gemcitabine, sirolimus), local radiation therapy, systemic antiretoviral therapy.
				• Documentation of all of the following is required for the diagnosis of Non-AIDS-related Kaposi's sarcoma:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to all of the following: two first line systemic therapies (e.g., pegylated liposomal doxorubicin, vinblastine or vincristine [with or without bleomycin], paclitaxel, oral etoposide, vinorelbine, gemcitabine, sirolimus), intralesional chemotherapy (e.g., vinblastine), local radiation therapy.

Agents Not Otherwise Classified – Antioxidant

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

coenzyme Q10		PA - ≥ 21 years		**coenzyme Q10 for members ≥ 21 years of age**
				• Documentation of all of the following is required for a diagnosis of mitochondrial disease:
				  • appropriate diagnosis; **and**
				  • one of the following:
				  • muscle biopsy positive for mitochondrial disease; **or**
				  • pathogenic mtDNA abnormality.
				SmartPA: Claims for coenzyme Q10 and coenzyme Q10 with vitamin E combination products will usually process at the pharmacy without a PA request if the member is ≥ 21 years of age and has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days of the requested agent.†
				
				Pedmark
				• Documentation of all of the following is required:
				  • diagnosis of localized, non-metastatic solid tumor; **and**

sodium thiosulfate	Pedmark	PA	MB	

	Clinical Notes
	• prescriber is an oncologist; **and** • member is ≥ one month and < 18 years of age; **and** • member is receiving cisplatin with an infusion duration ≤ six hours; **and** • appropriate dosing.

Agents Not Otherwise Classified – Presbyopia Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
phentolamine	Ryzumvi	PA	MB	**Qlosi and Vuity** • Documentation of the following is required: • diagnosis of presbyopia; **and** • prescriber is an optometrist or ophthalmologist or consult notes from an optometrist or ophthalmologist are provided; **and** • member is ≥ 40 years of age; **and** • member has a contraindication to the use of corrective lenses; **and** • for Qlosi, inadequate response, adverse reaction, or contraindication to Vuity; **and** • one of the following: • for Qlosi, requested quantity is ≤ two units/day; **or** • for Vuity, requested quantity is ≤ five mL/30 days. **Ryzumvi** • Documentation of the following is required: • indication to treat pharmacologically induced mydriasis produced by adrenergic agonists or parasympatholytics; **and** • prescriber is an optometrist or ophthalmologist or consult notes from an optometrist or ophthalmologist are provided; **and** • member is ≥ three years of age; **and** • one of the following: • member has a history of pharmacologically induced mydriasis not starting to wear off within eight hours; **or** • member has a history of pharmacologically induced mydriasis not wearing off completely by 24 hours; **or** • member has an underlying medical condition that results in diminished visual quality. • For recertification, documentation of need for a repeat treatment is required.
pilocarpine 0.4% ophthalmic solution	Qlosi	PA		
pilocarpine 1.25% ophthalmic solution	Vuity	PA		

Agents Not Otherwise Classified – Thyroid Hormone Receptor-Beta Agonist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

resmetirom	Rezdiffra	PA		**Rezdiffra**
				• Documentation of all of the following is required:
				  • diagnosis of nonalcoholic steatohepatitis (NASH) or metabolic dysfunction-associated steatohepatitis (MASH), with moderate to advanced liver fibrosis (consistent with stages F2 and F3 fibrosis); **and**
				  • results from liver biopsy or noninvasive testing supporting the diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is a gastroenterologist or hepatologist or consult notes from a gastroenterologist or hepatologist are provided; **and**
				  • member has been counseled to continue a reduced-calorie diet and increased physical activity; **and**
				  • member has been counseled to abstain from alcohol use; **and**
				  • member's current weight; **and**
				  • requested quantity is ≤ one unit/day

Agents Not Otherwise Classified – Urinary Tract Anti-Inflammatory Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
dimethyl sulfoxide solution	Rimso-50			

Agents Not Otherwise Classified – Friedreich's Ataxia Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

omaveloxolone	Skyclarys	PA		**Skyclarys**
				• Documentation of all of the following is required:
				  • diagnosis of Friedreich's Ataxia (FA); **and**
				  • member is ≥ 16 years of age; **and**
				  • prescriber is a neurologist or consult notes from a neurologist are provided; **and**
				  • genetic testing confirming the diagnosis of FA; **and**
				  • requested quantity is ≤ three units/day.
				• For recertification, documentation of both of the following is required:
				  • positive response to therapy; **and**
				  • requested quantity is ≤ three units/day.

Agents Not Otherwise Classified – Cerebral Adrenoleukodystrophy [CALD] Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

elivaldogene autotemcel	Skysona	PA	CO	**Skysona**
				• Documentation of all of the following is required:
				  • diagnosis of cerebral adrenoleukodystrophy (CALD); **and**
				  • member is ≥ four years and < 18 years of age at the time of treatment; **and**
				  • elevated very long chain fatty acids (VLCFAs); **and**
				  • genetic testing showing mutation in the ABCD1; **and**
				  • prescriber is a specialist in the treatment of CALD (e.g., neurologist); **and**
				  • member has all of the following:
				  • Neurologic Function Score (NFS) score ≤1; **and**
				  • Loes score between 0.5 and 9 (inclusive); **and**
				  • gadolinium enhancement on brain magnetic resonance imaging (MRI); **and**
				  • infusion will take place in a qualified treatment facility; **and**
				  • member has a negative serology test for HIV; **and**
				  • member has not had previous allogeneic transplant or gene therapy for CALD.
				• **Please note: One-time cell and gene therapies are part of the ACPP and MCO unified pharmacy policy. PA requests for one-time cell and gene therapies for members with ACPP and MCO plans are reviewed by the MassHealth Drug Utilization Review (DUR) Program.**
				• MassHealth DUR will be reaching out to prescribers after PA approval to verify administration date and at ongoing intervals for long-term monitoring of response.

Agents Not Otherwise Classified – Retinoic Acid Receptor Agonist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

palovarotene	Sohonos	PA		**Sohonos**
				• Documentation of all of the following is required:
				  • diagnosis of Fibrodysplasia Ossificans Progressiva (FOP) with ACVR1 R206H mutation; **and**
				  • results from genetic testing to confirm diagnosis; **and**
				  • one of the following:
				  • for members assigned female at birth/biologic female, member is ≥ eight years of age; **or**
				  • for members assigned male at birth/biologic male, member is ≥ ten years of age; **and**

	Clinical Notes

	• prescriber is a specialist in rare connective tissue disorders or consult notes from a specialist are provided; **and**
	• for members < 14 years of age, current weight; **and**
	• appropriate dosing; **and**
	• for members of reproductive potential, both of the following:
	  • attestation that the member is not pregnant; **and**
	  • appropriate contraception methods will be used at least one month before treatment, during treatment, and one month after the last dose.

Agents Not Otherwise Classified – Sclerosing Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

tetradecyl sulfate injection	Sotradecol	PA	MB	Sotradecol
				• Documentation of all of the following is required:
				  • diagnosis of varicose veins; **and**
				  • symptoms due to varicose veins are non-cosmetic.
				• For recertification, documentation that significant symptoms persist following previously approved invasive treatment is required.

Agents Not Otherwise Classified – Thyroid Eye Disease Agent

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

teprotumumab-trbw	Tepezza	PA		Tepezza
				• Documentation of all of the following is required:
				  • diagnosis of thyroid eye disease; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is an endocrinologist or ophthalmologist, or consult notes from an endocrinologist or ophthalmologist are provided; **and**
				  • inadequate response, adverse reaction, or contraindication to glucocorticoids; **and**
				  • appropriate dosing.

Agents Not Otherwise Classified – Nonhormonal Agents for Menopausal Symptoms

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
fezolinetant	Veozah	PA		paroxetine mesylate capsule

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

paroxetine mesylate capsule		PA	A90	• Documentation of all of the following is required for a diagnosis of moderate to severe vasomotor symptoms associated with menopause (hot flashes) in female sex assigned at birth/biologic female members:
				  • appropriate diagnosis; **and**
				  • medical records documenting an inadequate response or adverse reaction to paroxetine hydrochloride; **and**
				  • medical records documenting an inadequate response or adverse reaction to three or contraindication to all of the following: clonidine, desvenlafaxine or venlafaxine, gabapentin, menopausal hormone therapy, oxybutynin, an SSRI other than paroxetine.
				
				Veozah
				• Documentation of all of the following is required for a diagnosis of moderate to severe vasomotor symptoms associated with menopause (hot flashes) in female sex assigned at birth/biologic female members:
				  • appropriate diagnosis; **and**
				  • inadequate response or adverse reaction to one or contraindication to all menopausal hormonal agents; **and**
				  • inadequate response or adverse reaction to two or contraindication to all of the following: clonidine, gabapentin, oxybutynin, SNRI, SSRI; **and**
				  • requested quantity is ≤ one unit/day.

Agents Not Otherwise Classified – C-Type Natriuretic Peptide

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

vosoritide	Voxzogo	PA		**Voxzogo**
				• Documentation of the following is required:
				  • medical records documenting diagnosis of achondroplasia based on symptoms and radiographic findings or genetic testing; **and**
				  • prescriber is an endocrinologist or geneticist or consult notes from an endocrinologist or geneticist are provided; **and**
				  • appropriate dosing; **and**
				  • requested quantity is ≤ one vial/day; **and**
				  • member has open epiphyses.
				• For recertification, documentation of the following is required:

	Clinical Notes
	• member continues to have open epiphyses; **and** • growth velocity is at least 2.5 cm/year.

Agents Not Otherwise Classified – Transthyretin Stabilizer

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

tafamidis	Vyndamax	PA		**Vyndamax, Vyndaqel**
				• Documentation of all of the following is required for cardiomyopathy of wild-type transthyretin-mediated or hereditary transthyretin-mediated amyloidosis:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is a cardiologist or consult notes from a cardiologist are provided; **and**
				  • one of the following:
				  • results from genetic testing showing mutations in the TTR gene; **or**
				  • presence of amyloid deposits in biopsy tissue with confirmed TTR; **or**
				  • TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry; **and**
				  • one of the following:
				  • for Vyndamax, requested quantity is ≤ one unit/day; **or**
				  • for Vyndaqel, requested quantity is ≤ four units/day.

tafamidis	Vyndaqel	PA		

Agents Not Otherwise Classified – Purified Collagenase

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

collagenase clostridium histolyticum	Xiaflex	PA		**Xiaflex**
				• Documentation of all of the following is required for a diagnosis of Dupuytren's contracture:
				  • appropriate diagnosis; **and**
				  • number of cords being treated.
				• Documentation of all of the following is required for a diagnosis of Peyronie's disease:
				  • appropriate diagnosis; **and**
				  • prescriber is a urologist or consult notes from a urologist are provided; **and**
				  • member is ≥ 18 years of age; **and**
				  • appropriate dosing; **and**
				  • member is not a candidate for surgery at this time; **and**
				  • one of the following:

	Clinical Notes

	• both of the following:
	  • member has active disease; **and**
	  • inadequate response, adverse reaction, or contraindication to pentoxifylline; **or**
	• both of the following:
	  • member has stable disease; **and**
	  • member's penile curvature is > 30 degrees.
	SmartPA: Claims for Xiaflex will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for Dupuytren's contracture and the current claim plus all history is ≤ one vial.†

Agents Not Otherwise Classified – Phosphate Binders and Phosphate Absorption Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

tenapanor 20 mg, 30 mg tablet	Xphozah	PA		**Xphozah**
				• Documentation of all of the following is required:
				  • diagnosis of hyperphosphatemia in chronic kidney disease on dialysis for ≥ three months; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is a nephrologist or consult notes from a nephrologist are provided; **and**
				  • inadequate response or adverse reaction to two or contraindication to all of the following: Auryxia, calcium acetate, lanthanum, sevelamer hydrochloride or sevelamer carbonate, Velphoro; **and**
				  • appropriate dosing; **and**
				  • requested quantity is ≤ two units/day.

Agents Not Otherwise Classified – Farnesyltransferase Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

lonafarnib	Zokinvy	PA		**Zokinvy**
				• Documentation of all of the following is required:
				  • one of the following:
				  • diagnosis of processing deficient Progeroid Laminopathy with one of the following:
				  • heterozygous LMNA mutation with progerin-like protein accumulation; **or**
				  • homozygous or compound heterozygous ZMPSTE24 mutations; **or**
				  • diagnosis of Hutchinson-Gilford progeria syndrome; **and**

	Clinical Notes
	• results from genetic testing or molecular analysis to confirm diagnosis; **and** • prescriber is a specialist in genetic diseases or consult notes from a specialist are provided; **and** • member is ≥ one year of age; **and** • member's BSA is ≥ 0.39 m^2; **and** • appropriate dosing; **and** • requested dose cannot be consolidated; **and** • requested quantity is ≤ four units/day.

Agents Not Otherwise Classified – Decongestant

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

pseudoephedrine		PA - > 240 mg/day	*	**pseudoephedrine > 240 mg/day**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • member is ≥ 12 years of age; **and**
				  • medical necessity for exceeding the dose limit.
				• For recertification, documentation of positive response to therapy is required.

Agents Not Otherwise Classified – Medical Foods

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

levomethylfolate tablet		PA - > 1 unit/day		**Deplin FC and levomethylfolate/algal oil capsule**
				• Documentation of all of the following is required:
				  • diagnosis of one of the following:
				  • depression; **or**
				  • schizophrenia; **or**
				  • other clinically appropriate diagnosis; **and**
				  • medical necessity for use instead of levomethylfolate tablets; **and**
				  • one of the following:
				  • requested quantity is ≤ one unit/day; **or**
				  • medical necessity for exceeding the quantity limits.
				
				levomethylfolate tablet > one unit/day
				• Documentation of all of the following is required:
				  • diagnosis of one of the following:
				  • depression; **or**
				  • schizophrenia; **or**
				  • other clinically appropriate diagnosis; **and**
				  • medical necessity for exceeding the quantity limit.

Agents Not Otherwise Classified – Melatonin Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
melatonin			*, A90	

Agents Not Otherwise Classified – Potassium Iodide

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

potassium iodide		PA - > 1 mL/day		**potassium iodide > one mL/day**
				• Documentation of the following is required for the indication for the use of thyroid protection prior to MIBG scan or prior to thyroidectomy surgery:
				  • appropriate indication; **and**
				  • requested dose and frequency; **and**
				  • requested duration of therapy.
				• Documentation of the following is required for all other indications:
				  • appropriate indication; **and**
				  • requested dose and frequency; **and**
				  • requested duration of therapy.

Agents Not Otherwise Classified – Psoralen Agent

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

methoxsalen capsule		PA	A90	**methoxsalen capsule**
				• Documentation of the following is required:
				  • diagnosis of moderate to severe plaque psoriasis; **and**
				  • prescriber is a dermatologist or consult notes from a dermatologist are provided; **and**
				  • appropriate dosing; **and**
				  • one of the following:
				  • inadequate response or adverse reaction to one or contraindication to all conventional therapies: topical agent, UVB phototherapy, systemic agent; **or**
				  • inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for plaque psoriasis.

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

CO	Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements. All requests for one-time cell and gene therapies (as listed on the Acute Hospital Carve-Out Drug List), including for members enrolled in an Accountable Care Partnership Plan (ACPP) or Managed Care Organization (MCO), will be reviewed by the MassHealth Drug Utilization Review (DUR) Program.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Various

Non-FDA-approved, for example:

- Various

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member’s condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member’s current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate

and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Please see clinical criteria for agents requiring PA in the table above under the Clinical Notes section.
† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 73 - Iron Agents and Chelators

Drug Category: Iron supplementation and management

Medication Class/Individual Agents: Nutrients and antidotes

I. Prior-Authorization Requirements

Iron Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ferric carboxymaltose injection	Injectafer	PA	MB
ferric citrate	Auryxia	PA	BP, A90
ferric derisomaltose	Monoferric	PA	
ferric maltol	Accrufer	PA	
ferrous fumarate			*, M90
ferrous gluconate			*, M90
ferrous sulfate			*, M90
ferumoxytol	Feraheme	PA	
iron polysaccharide complex			*, M90
iron sucrose	Venofer		MB
low molecular weight iron dextran	Infed		
sodium ferric gluconate complex	Ferrlecit		#

Iron Chelators			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
deferasirox 125 mg, 250 mg, 500 mg	Exjade		BP, A90
deferasirox 90 mg, 180 mg, 360 mg	Jadenu		# , A90
deferiprone	Ferriprox	PA	A90
deferoxamine	Desferal		#

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Intravenous iron replacement therapies[1]

- Injectable iron replacement products are iron-carbohydrate complexes consisting of a core made of an iron-oxyhydroxy gel surrounded by a shell of carbohydrate that stabilizes the gel, slows the release of iron, and maintains the resulting particles in colloidal suspension.
- Current injectable iron replacement formulations differ from each other by chemical structure, adverse event profile, cost and dosing schedule.

Parenteral Iron Chelators:

- Deferoxamine
  - Food and Drug Administration (FDA)-approved for the treatment of acute iron intoxication and chronic iron overload due to transfusion-dependent anemias.
  - Available in vials for intramuscular, subcutaneous, and intravenous administration.
  - Generally requires one administration with additional doses as needed based on clinical response for the treatment of acute iron intoxication and infusion on at least 5 days per week for at least 8 hours per day for

	Clinical Notes

	the treatment of chronic iron overload.
	
	Oral Iron Chelators:
	• Deferasirox
	  • Once-daily formulation that was FDA-approved for the treatment of chronic iron overload due to blood transfusions in patients two years of age and older.
	  • Administered once daily.
	• Deferiprone
	  • Approved by the FDA for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate, sickle cell disease, or other anemias.
	  • Administered two to three times daily based on formulation.
	
	[1] Auerbach M, Ballard H. Clinical Use of Intravenous Iron: Administration, Efficacy, and Safety. Hematology. 2010 Dec; 1: 338-347.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- hyperphosphatemia in chronic kidney disease on dialysis (Auryxia)
- iron deficiency (Accrufer)
- iron deficiency anemia (Auryxia, ferumoxytol, Injectafer, Monoferric)
- iron deficiency in adults with heart failure categorized as NYHA class II/III (Injectafer)

- transfusional iron overload due to thalassemia syndromes, sickle cell disease, or other anemias (deferiprone)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Accrufer

- Documentation of all of the following is required:
  - diagnosis of iron deficiency; **and**
  - inadequate response or adverse reaction to two of the following oral iron products: ferrous fumarate, ferrous gluconate, ferrous sulfate or polysaccharide iron complex; **and**
  - member has attempted strategies to improve tolerability of other iron products if gastrointestinal adverse events occurred.

deferiprone

- Documentation of all of the following is required:
  - one of the following:
    - diagnosis of transfusional iron overload due to thalassemia syndromes; **or**
    - diagnosis of transfusional iron overload due to sickle cell disease or other anemia; **and**
  - member is under the care of an appropriate specialist (hematologist, oncologist); **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: deferoxamine, deferasirox; **and**
  - for the tablet formulation, the member is ≥ eight years of age; **and**
  - for the oral solution formulation, one of the following:
    - member is ≥ three years to < 13 years of age; **or**
    - medical necessity for the use of an oral solution formulation.

Injectafer

- Documentation of all of the following is required for a diagnosis of iron deficiency anemia:
  - diagnosis of iron deficiency anemia; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Infed (low molecular weight iron

dextran), sodium ferric gluconate complex, Venofer (iron sucrose).

- Documentation of all of the following is required for a diagnosis of iron deficiency in adults with heart failure categorized as NYHA class II/III:
  - diagnosis of iron deficiency in adults with heart failure categorized as NYHA class II/III; **and**
  - member is ≥18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Infed (low molecular weight iron dextran), sodium ferric gluconate complex, Venofer (iron sucrose); **and**
  - appropriate dosing.

ferric citrate

- Documentation of all of the following is required for a diagnosis of iron deficiency anemia:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction two of the following oral iron products: ferrous fumarate, ferrous gluconate, ferrous sulfate or polysaccharide iron complex; **and**
  - member has attempted strategies to improve tolerability of other iron products if gastrointestinal adverse events occurred,
- Documentation of all of the following is required for a diagnosis of hyperphosphatemia in chronic kidney disease on dialysis:
  - appropriate diagnosis; **and**
  - member is ≥18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: calcium acetate, lanthanum, sevelamer hydrochloride or sevelamer carbonate, Velphoro; **and**
  - appropriate dosing.

SmartPA: Claims for ferric citrate will usually process at the pharmacy without a PA request if the member has a history of medical claims for hyperphosphatemia, is greater than or equal to 18 years of age, and has a history of paid claims for at least two lower-cost phosphate binders [calcium acetate, sevelamer hydrochloride or sevelamer carbonate, lanthanum, Velphoro (sucroferric oxyhydroxide)] in all claims history. †

ferumoxytol and Monoferric

- Documentation of all of the following is required:
  - diagnosis of iron deficiency anemia; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Infed (low molecular weight iron dextran), sodium ferric gluconate complex, Venofer (iron sucrose).

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 74 - Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors

Drug Category: VMAT2 Inhibitors

Medication Class/Individual Agents: VMAT2 Inhibitors

I. Prior-Authorization Requirements

Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.
deutetrabenazine	Austedo	PA		
deutetrabenazine extended-release	Austedo XR	PA		
tetrabenazine	Xenazine	PA	M90	
valbenazine	Ingrezza	PA		

M90 Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- chorea associated with Huntington’s disease
- tardive dyskinesia

Non-FDA-approved, for example:

- tardive dyskinesia (tetrabenazine)
- Tourette syndrome/tics (Austedo, Austedo XR, Ingrezza, tetrabenazine)
- unspecified hyperkinetic movement disorder (Austedo, Austedo XR, Ingrezza, tetrabenazine)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.

- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Austedo and Austedo XR

- Documentation of all of the following is required for a diagnosis of Huntington's disease:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to tetrabenazine; **and**
  - one of the following:
    - requested dose is ≤ 36 mg/day; **or**
    - requested dose is > 36 mg/day and ≤ 48 mg/day, and member has been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer; **and**
  - one of the following:
    - for Austedo, requested quantity is ≤ four units/day; **or**
    - for Austedo XR, requested quantity is ≤ one unit/day.
- Documentation of all of the following is required for a diagnosis of tardive dyskinesia:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - persistent, disabling, or intrusive tardive dyskinesia; **and**
  - one of the following:
    - requested dose is ≤ 36 mg/day; **or**
    - requested dose is > 36 mg/day and ≤ 48 mg/day, and member has been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer; **and**
  - one of the following:
    - for Austedo, requested quantity is ≤ four units/day; **or**
    - for Austedo XR, requested quantity is ≤ one unit/day.
- Documentation of all of the following is required for a diagnosis of Tourette syndrome/tics:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: baclofen, botulinum toxin, clonidine or guanfacine, first or second generation antipsychotic, topiramate or levetiracetam; **and**
  - inadequate response or adverse reaction to tetrabenazine; **and**
  - one of the following:
    - requested dose is < 36 mg/day; **or**
    - requested dose is > 36 mg/day and < 48 mg/day and member has been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer; **and**
  - one of the following:
    - for Austedo, requested quantity is ≤ four units/day; **or**

    - for Austedo XR, requested quantity is ≤ one unit/day.
- Documentation of all of the following is required for a diagnosis of unspecified hyperkinetic movement disorder:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - inadequate response or adverse reaction to two or contraindication to all of the following: baclofen, benzodiazepine, botulinum toxin, clonidine, levodopa/carbidopa, trihexyphenidyl; **and**
    - inadequate response or adverse reaction to tetrabenazine; **and**
    - one of the following:
        - requested dose is < 36 mg/day; **or**
        - requested dose is > 36 mg/day and < 48 mg/day and member has been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer; **and**
    - one of the following:
        - for Austedo, requested quantity is ≤ four units/day; **or**
        - for Austedo XR, requested quantity is ≤ one unit/day.

Ingrezza

- Documentation of all of the following is required for a diagnosis of Huntington's Disease:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - inadequate response or adverse reaction to tetrabenazine; **and**
    - requested quantity is ≤ one unit/day.
- Documentation of all of the following is required for a diagnosis of tardive dyskinesia:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - persistent, disabling, or intrusive tardive dyskinesia; **and**
    - requested quantity is ≤ one unit/day.
- Documentation of all of the following is required for a diagnosis of unspecified Tourette syndrome/tics:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - inadequate response or adverse reaction to two or contraindication to all of the following: baclofen, botulinum toxin, clonidine or guanfacine, first or second generation antipsychotic, topiramate or levetiracetam, **and**
    - inadequate response or adverse reaction to tetrabenazine; **and**
    - requested quantity is ≤ one unit/day.
- Documentation of all of the following is required for a diagnosis of unspecified hyperkinetic movement disorder:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - inadequate response or adverse reaction to two or contraindication to all of the following: baclofen, benzodiazepine, botulinum toxin, clonidine, levodopa/carbidopa, trihexyphenidyl, **and**
    - inadequate response or adverse reaction to tetrabenazine; **and**
    - requested quantity is ≤ one unit/day.

tetrabenazine

- Documentation of all of the following is required for a diagnosis of Huntington’s disease:
    - appropriate diagnosis; **and**
    - one of the following:
        - requested dose is ≤ 50 mg/day; **or**
        - requested dose is > 50 mg/day and ≤ 100 mg/day, and member has been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer.

    - member is ≥ 18 years of age.
- Documentation of all of the following is required for a diagnosis of tardive dyskinesia:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - persistent, disabling, or intrusive tardive dyskinesia; **and**
    - requested dose is ≤ 200 mg/day.
- Documentation of all of the following is required for a diagnosis of Tourette syndrome/tics:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - inadequate response or adverse reaction to two or contraindication to all of the following: baclofen, botulinum toxin, clonidine or guanfacine, first or second generation antipsychotic, topiramate or levetiracetam; **and**
    - requested dose is ≤ 75 mg/day.
- Documentation of all of the following is required for a diagnosis of unspecified hyperkinetic movement disorder:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - inadequate response or adverse reaction to two or contraindication to all of the following: baclofen, benzodiazepine, botulinum toxin, clonidine, levodopa/carbidopa, trihexyphenidyl; **and**
    - requested dose is ≤ 200 mg/day.

SmartPA: Claims for tetrabenazine at a dose of ≤ 100 mg/day will usually process at the pharmacy without a PA request if the member is ≥ 18 years of age, has a history of MassHealth medical claims for Huntington's disease with chorea, and has a history of paid MassHealth pharmacy claims for tetrabenazine for at least 90 out of the last 120 days.†

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 75 - T-Cell Immunotherapies

Drug Category: Immunotherapies

Medication Class/Individual Agents: T-Cell Immunotherapies

I. Prior-Authorization Requirements

T-Cell Immunotherapies - Chimeric Antigen Receptor (CAR)-T Immunotherapies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
axicabtagene ciloleucel	Yescarta	PA	CO
brexucabtagene autoleucel	Tecartus	PA	CO
ciltacabtagene autoleucel	Carvykti	PA	CO
idecabtagene vicleucel	Abecma	PA	CO
lisocabtagene maraleucel	Breyanzi	PA	CO
tisagenlecleucel	Kymriah	PA	CO

T-Cell Immunotherapies - Autologous T-cell Immunotherapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
afamitresgene autoleucel	Tecelra	PA	CO
lifileucel	Amtagvi	PA	CO
obecabtagene autoleucel	Aucatzyl	PA	CO

T-Cell Immunotherapies - Bispecific Antibodies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
elranatamab-bcmm	Elrexfio	PA	MB
epcoritamab-bysp	Epkinly	PA	MB
glofitamab-gxbm	Columvi	PA	MB
mosunetuzumab-axgb	Lunsumio	PA	MB
talquetamab-tgvs	Talvey	PA	MB
tarlatamab-dlle	Imdelltra	PA	MB
teclistamab-cqyv	Tecvayli	PA	MB

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Please note: One-time cell and gene therapies are part of the ACPP and MCO unified pharmacy policy. PA requests for one-time cell and gene therapies for members with ACPP and MCO plans are reviewed by the MassHealth Drug Utilization Review (DUR) Program.

Autologous T-cell Immunotherapies are treatments that use a patient's own T cells to attack cancer cells. The T cells are genetically modified ex vivo to activate the patient's immune response and then reinfused back into the patient. Recognition of a specific tumor/cell surface antigen activates T cell response independently of major histocompatibility complex.

Some examples of these include Chimeric Antigen Receptor (CAR)-T cell therapy and Tumor-infiltrating lymphocyte (TIL) therapy and miscellaneous therapy, such as autologous T cells transduced with melanoma-associated antigen A4 (MAGE-A4).

	Clinical Notes
	Currently available CAR-T cell therapies include those directed against CD19-positive B-cell malignancies (axicabtagene ciloleucel, brexucabtagene autoleucel, lisocabtagene maraleucel, obecabtagene autoleucel, tisagenlecleucel) and B cell maturation antigen (BCMA) (ciltacabtagene autoleucel, idecabtagene vicleucel). Given the risk of serious adverse reactions, such as cytokine release syndrome (CRS) and neurological toxicities, these agents are only available through a restricted program under a Risk Evaluation and Mitigation (REMS) and administered by certified treatment centers. Lifileucel is currently the only TIL therapy on the market. It is approved for the treatment of adults with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. To manufacture this therapy, a portion of the patient's tumor tissue is removed during a surgical procedure prior to treatment. The patient's TIL cells are separated from the tumor tissue, activated and multiplied into billions of cells at a manufacturing center and then returned to the patient as a single dose for intravenous infusion following lymphodepletion. This agent must be administered in an inpatient hospital setting where specialists skilled in cardiopulmonary or intensive care medicine are available. Afamitresgene autoleucel is the first gene therapy to treat adults with metastatic synovial sarcoma and is also the first FDA-approved T cell receptor gene therapy. This product is manufactured by modifying the patient's own T cells to express a T cell receptor that targets MAGE-A4, an antigen expressed by cancer cells in synovial sarcoma. It is administered as a single intravenous dose. Due to the boxed warning for CRS, it must be given in an authorized treatment center. For additional information regarding these T-cell immunotherapies, please see the Acute Hospital Carve-Out Drugs List found at www.mass.gov/druglist

	Clinical Notes
	. Another form of T-cell immunotherapies is the Bispecific T Cell Engagers (BiTE). These are monoclonal antibodies that act as linkers between T cells and specific target antigens. They contain two distinct variable regions, one of which engages T cells, typically at the CD3 receptor, and a second which engages the target antigen, effectively activating the T cell against that target. Because BiTE agents are ready for use "off the shelf" without patient specific processing, they can be deployed in a wider range of health care settings.

CO Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements. All requests for one-time cell and gene therapies (as listed on the Acute Hospital Carve-Out Drug List), including for members enrolled in an Accountable Care Partnership Plan (ACPP) or Managed Care Organization (MCO), will be reviewed by the MassHealth Drug Utilization Review (DUR) Program.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse (Kymriah)
- Extensive stage small cell lung cancer (ES-SCLC) (Imdelltra)
- B-cell precursor ALL (Aucatzyl, Tecartus)
- relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (Breyanzi)
- Relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy (Epkinly, Kymriah, Lunsumio, Yescarta)
- Relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from FL, after two or more lines of systemic therapy (Columvi)
- Relapsed or refractory LBCL after two or more lines of systemic therapy, including DLBCL, NOS, high grade B-cell lymphoma, and DLBCL arising from FL (Kymriah)
- Relapsed or refractory LBCL after two or more lines of systemic therapy, including DLBCL, NOS, primary mediastinal LBCL, high grade B-cell lymphoma, and DLBCL arising from FL (Yescarta)
- Relapsed or refractory mantle cell lymphoma (Breyanzi)
- LBCL refractory to first line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy (Yescarta)
- LBCL refractory to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy, or refractory to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age (Breyanzi)
- Relapsed or refractory LBCL after two or more lines of systemic therapy, including DLBCL, NOS (including DLBCL arising from indolent lymphoma), and high grade B-cell lymphoma (Epkinly)

- Relapsed or refractory LBCL or FL after two or more lines of systemic therapy, including DLBCL, NOS (including DLBCL arising from indolent lymphoma), high grade B-cell lymphoma, primary mediastinal LBCL, and FL grade 3B (Breyanzi)
- Relapsed or refractory mantle cell lymphoma (Tecartus)
- Relapsed or refractory multiple myeloma after at least one prior line of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody (Carvykti)
- Relapsed or refractory multiple myeloma after two or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody (Abecma)
- Relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody (Elrexfio, Talvey, Tecvayli)
- Unresectable or metastatic melanoma (Amtagvi)
- Unresectable or metastatic synovial sarcoma (Tecelra)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member’s condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member’s current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Abecma

- Documentation of the following is required:
  - diagnosis of relapsed or refractory multiple myeloma; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to two or more lines of systemic therapies or contraindication to all other lines of systemic therapies; **and**
  - member’s disease is refractory to at least one proteasome inhibitor or has a contraindication to all proteasome inhibitors; **and**
  - member’s disease is refractory to at least one immunomodulatory agent or has a contraindication to all immunomodulatory agents; **and**
  - member’s disease is refractory to at least one anti-CD38 monoclonal antibody or has a contraindication to all anti-CD38 monoclonal antibodies; **and**

- administration will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.

Amtagvi

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is an oncologist; **and**
  - inadequate response or adverse reaction to one or contraindication to all appropriate PD-1 blocking antibodies; **and**
  - for BRAF V600 mutation positive, inadequate response or adverse reaction to one or contraindication to all BRAF inhibitors; **and**
  - appropriate dosing and treatment dates; **and**
  - infusion will take place in a qualified treatment facility.

Aucatzyl

- Documentation of the following is required for B-cell precursor ALL:
  - appropriate diagnosis; **and**
  - prescriber is hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - one of the following:
    - member has primary refractory ALL; **or**
    - member experienced a first relapse following a remission lasting ≤ 12 months; **or**
    - member has relapsed or refractory ALL after second-line or higher therapy; **or**
    - member has relapsed or refractory ALL at least 100 days after allogeneic stem cell transplant; **and**
  - infusion will take place in a qualified treatment facility; **and**
  - if the member has Philadelphia chromosome positive ALL, inadequate response, adverse reaction, or contraindication to one tyrosine kinase inhibitor.

Breyanzi

- Documentation of the following is required for large B-cell lymphoma refractory to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy, or refractory to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to one line of systemic therapy; **and**
  - one of the following:
    - member has refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; **or**
    - member has refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and is not eligible for HSCT (e.g., due to comorbidities or age); **and**
  - infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.
- Documentation of the following is required for a diagnosis of relapsed or refractory large B-cell lymphoma or follicular lymphoma after two or more lines of systemic therapy, including DLBCL, NOS (including DLBCL arising from indolent lymphoma), high grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and FL grade 3B:
  - appropriate diagnosis; **and**

- prescriber is a hematologist or oncologist; **and**
- appropriate dosing (member's weight must be provided); **and**
- member is ≥ 18 years of age on treatment date; **and**
- inadequate response or adverse reaction to two lines of systemic therapies; **and**
- infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.

- Documentation of the following is required for a diagnosis of relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to one, or contraindication to all of the following: Brukinsa, Calquence, Imbruvica; **and**
  - inadequate response, adverse reaction, or contraindication to Venclexta; **and**
  - infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.
- Documentation of the following is required for a diagnosis of relapsed or refractory mantle cell lymphoma:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to one, or contraindication to all of the following: Brukinsa, Calquence, Imbruvica; **and**
  - inadequate response or adverse reaction to one other line of systemic therapy; **and**
  - infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.

Carvykti
- Documentation of the following is required:
  - diagnosis of relapsed or refractory multiple myeloma; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to one prior line of systemic therapy or contraindication to all other lines of systemic therapies; **and**
  - member’s disease is refractory to at least one proteasome inhibitor or has a contraindication to all proteasome inhibitors; **and**
  - member’s disease is refractory to at least one immunomodulatory agent or has a contraindication to all immunomodulatory agents; **and**
  - member’s disease is refractory to lenalidomide; **and**
  - administration will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.

Columvi
- Documentation of the following is required:
  - diagnosis of relapsed or refractory DLBCL, NOS or LBCL arising from FL; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing; **and**
  - member is ≥ 18 years of age; **and**
  - member has received at least two lines of systemic therapies, including at least one anti-CD20 monoclonal antibody.

Elrexfio, Talvey, and Tecvayli

- Documentation of the following is required:
  - diagnosis of relapsed or refractory multiple myeloma; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to four lines of systemic therapies or contraindication to all other lines of systemic therapies; **and**
  - member's disease is refractory to at least one proteasome inhibitor or has a contraindication to all proteasome inhibitors; **and**
  - member's disease is refractory to at least one immunomodulatory agent or has a contraindication to all immunomodulatory agents; **and**
  - member's disease is refractory to at least one anti-CD38 monoclonal antibody or has a contraindication to all anti-CD38 monoclonal antibodies; **and**
  - administration will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.

Epkinly

- Documentation of the following is required for the diagnosis of DLBCL:
  - diagnosis of one of the following:
    - relapsed or refractory DLBCL, NOS; **or**
    - relapsed or refractory DLBCL arising from indolent lymphoma; **or**
    - relapsed or refractory DLBCL arising from high-grade B-cell lymphoma; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing; **and**
  - member is ≥ 18 years of age; **and**
  - member has received at least two lines of systemic therapies, including at least one anti-CD20 monoclonal antibody; **and**
  - inadequate response, adverse reaction, or contraindication to Columvi.
- Documentation of the following is required for a diagnosis of relapsed or refractory FL:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; and appropriate dosing; **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to two lines of systemic therapies, including at least one anti-CD20 monoclonal antibody; **and**
  - inadequate response, adverse reaction, or contraindication to Lunsumio.

Imdelltra

- Documentation of the following is required:
  - diagnosis of extensive stage small cell lung cancer; **and**
  - prescriber is an oncologist; **and**
  - appropriate dosing; **and**
  - inadequate response, adverse reaction, or contraindication to one platinum-based chemotherapy.

Kymriah

- Documentation of the following is required for a diagnosis of relapsed or refractory FL after two or more lines of systemic therapy, or diagnosis of relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), high grade B-cell lymphoma and DLBCL arising from FL:
  - appropriate diagnosis; **and**

- prescriber is a hematologist or oncologist; **and**
- appropriate dosing (member's weight must be provided); **and**
- member is ≥ 18 years of age on treatment date; **and**
- inadequate response or adverse reaction to two lines of systemic therapies; **and**
- infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.

- Documentation of the following is required for a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is < 26 years of age on treatment date; **and**
  - infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided; **and**
  - one of the following:
    - all of the following:
      - member has Philadelphia chromosome positive ALL; **and**
      - member has refractory disease or ≥ two relapses; **and**
      - inadequate response or adverse reaction to two tyrosine kinase inhibitors or contraindication to all tyrosine kinase inhibitors; **or**
    - both of the following:
      - member has Philadelphia chromosome negative ALL; **and**
      - member has refractory disease or ≥ two relapses.

Lunsumio

- Documentation of the following is required for relapsed or refractory FL:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing; **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to two lines of systemic therapies including at least one anti-CD20 monoclonal antibody.

Tecartus

- Documentation of the following is required for relapsed or refractory MCL:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: anthracycline-containing chemotherapy, bendamustine-containing chemotherapy; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Brukinsa, Calquence, Imbruvica; **and**
  - infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.
- Documentation of the following is required for B-cell precursor ALL:
  - appropriate diagnosis; **and**
  - prescriber is hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**

- one of the following:
  - member has primary refractory ALL; **or**
  - member experienced a first relapse following a remission lasting ≤ 12 months; **or**
  - member has relapsed or refractory ALL after second-line or higher therapy; **or**
  - member has relapsed or refractory ALL at least 100 days after allogeneic stem cell transplant; **and**
- infusion will take place in a qualified treatment facility; **and**
- if the member has Philadelphia chromosome positive ALL, inadequate response, adverse reaction, or contraindication to one tyrosine kinase inhibitor.

Tecelra

- Documentation of the following is required for a diagnosis of unresectable or metastatic synovial sarcoma:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - prescriber is an oncologist; **and**
  - documentation of HLA-A 02:01P, HLA-A 02:02P, HLA-A 02:03P, or HLA-A 02:06P positive tumor; **and**
  - tumor expresses the MAGE-A4 antigen; **and**
  - inadequate response or adverse reaction to one or contraindication to all prior chemotherapy; **and**
  - appropriate dosing and treatment dates; **and**
  - infusion will take place in a qualified treatment facility.

Yescarta

- Documentation of the following is required for a diagnosis of relapsed or refractory FL after two or more lines of systemic therapy, or a diagnosis of relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL, NOS, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from FL:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to two lines of systemic therapies; **and**
  - infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.
- Documentation of the following is required for a diagnosis of large B-cell lymphoma refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to one line of systemic therapy; **and**
  - one of the following:
    - member has primary refractory disease; **or**
    - member relapsed within 12 months of a completed first line chemoimmunotherapy regimen; **and**
  - infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.

MassHealth Evaluation Criteria

Table 76 - Neuromuscular Agents – Duchenne Muscular Dystrophy and Spinal Muscular Atrophy

Drug Category: Genetic/Developmental Disorder

Medication Class/Individual Agents: Neuromuscular

I. Prior-Authorization Requirements

Neuromuscular Agents - Duchenne Muscular Dystrophy Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
casimersen	Amondys 45	PA	
delandistrogene moxeparvovec-rokl	Elevidys	PA	CO
eteplirsen	Exondys 51	PA	
givinostat	Duvyzat	PA	
golodirsen	Vyondys 53	PA	
viltolarsen	Viltepso	PA	

Neuromuscular Agents - Spinal Muscular Atrophy Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
nusinersen	Spinraza	PA	MB
onasemnogene abeparvovec-xioi	Zolgensma PD	PA	CO
risdiplam	Evrysdi	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Please note: One-time cell and gene therapies are part of the ACPP and MCO unified pharmacy policy. PA requests for one-time cell and gene therapies for members with ACPP and MCO plans are reviewed by the MassHealth Drug Utilization Review (DUR) Program.

Delandistrogene moxeparvovec-rokl

- Delandistrogene moxeparvovec-rokl is generally not covered for members with Duchene Muscular Dystrophy six years of age or greater or for members that are not ambulatory, as defined by a current six-minute walk test (6MWT – distance walked in six minutes in meters) ≥ 200 meters. This determination is based on clinical studies that do not demonstrate a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes compared to established therapy with corticosteroids, which remains the standard of care for these populations. Prescribers may request PA for this drug for members eligible for early and periodic screening, diagnosis, and treatment (130 CMR 450.144(A)) to determine medical necessity.

	Clinical Notes
	Nusinersen and risdiplam • Nusinersen and risdiplam target survival motor neuron-2 (SMN2). • Use of nusinersen in combination with risdiplam has not been evaluated. • Examples of baseline motor function tests to include: Hammersmith Functional Motor Scale [HFMSE], Hammersmith Infant Neurological Examination [HINE], Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders [CHOP INTEND], World Health Organization [WHO] Motor Milestones, etc. **Onasemnogene abeparvovec-xioi** • MassHealth Drug Utilization Review will be reaching out to prescribers after PA approval to verify administration date and at ongoing intervals for long-term monitoring of response.

CO Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements. All requests for one-time cell and gene therapies (as listed on the Acute Hospital Carve-Out Drug List), including for members enrolled in an Accountable Care Partnership Plan (ACPP) or Managed Care Organization (MCO), will be reviewed by the MassHealth Drug Utilization Review (DUR) Program.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Duchenne muscular dystrophy (Amondys 45, Duvyzat, Elevidys, Exondys 51, Viltepso, Vyondys 53)
- Spinal muscular atrophy (Evrysdi, Spinraza, Zolgensma)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.

- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Amondys 45

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - confirmed out-of-frame deletion in the DMD gene that is amenable to exon 45 skipping; **and**
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - member is ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - appropriate dosing (30 mg/kg intravenously every week); **and**
  - one of the following:
    - member has received a corticosteroid for at least six months prior and member will continue to use a corticosteroid in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**
  - member has at least a baseline measurement for each of the following timed function tests as shown in medical records (tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    - timed ten-meter walk/run (time in seconds); **and**
    - timed floor (supine) to stand (time in seconds); **and**
    - timed four-step descend (time in seconds); **and**
    - timed four-step climb (time in seconds); **and**
    - timed sit to stand (time in seconds); **and**
  - member has not previously received treatment with a gene therapy for DMD.

- For recertification requests, documentation of all of the following is required:
  - member remains ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - member has a stable or improving pattern of 6MWTs as shown in medical records with results of a pretreatment baseline and all interim results (all previous 6MWTs results must be included); **and**
  - dosing remains appropriate; **and**
  - one of the following:
    - member continues to utilize corticosteroids in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**
  - member has a stable or improving pattern of observed performance on at least two of the following five timed function tests as shown in medical records (all results for all tests must be included with the date of performance; tests must have been observed or

completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    - timed ten-meter walk/run (time in seconds); **and**
    - timed floor (supine) to stand (time in seconds); **and**
    - timed four-step descend (time in seconds); **and**
    - timed four-step climb (time in seconds); **and**
    - timed sit to stand (time in seconds); **and**
  - member has not previously received treatment with a gene therapy for DMD.

Duvyzat
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - copy of genetic test showing mutation in the DMD gene confirming the diagnosis; **and**
  - member is ≥ six years of age; **and**
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurologist office are provided; **and**
  - member is ambulatory as defined by a current six-minute walk test (6MWT – distance walked in six minutes in meters) ≥ 200 meters; **and**
  - baseline timed 4-step climb ≤ 8 seconds; **and**
  - baseline time to rise from floor < 10 seconds; **and**
  - member has at least a baseline measurement for each of the following timed function tests as shown in medical records:
    - timed 10-meter walk/run (time in seconds); **and**
    - timed floor (supine) to stand (time in seconds); **and**
    - timed 4-step descend (time in seconds); **and**
    - timed 4-step climb (time in seconds); **and**
    - timed sit to stand (time in seconds); **and**
  - one of the following:
    - member is on a stable dose of corticosteroid; **or**
    - attestation that the member will initiate corticosteroid and continue to utilize chronic corticosteroids in combination with Duvyzat; **or**
    - demonstrated contraindication to corticosteroids; **and**
  - requested agent will not be used in combination with other disease-modifying therapies for DMD; **and**
  - member has not previously received treatment with a gene therapy for DMD; **and**
  - appropriate dose.

- For recertification requests, documentation of all of the following is required:
  - member remains ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - member has timed 4-step climb ≤ 8 seconds; **and**
  - member has time to rise from floor < 10 seconds; **and**
  - member has a stable or improving pattern of 6MWTs as shown in medical records with results of a pretreatment baseline and all interim results (all previous 6MWTs results must be included); **and**
  - dosing remains appropriate; **and**
  - one of the following:
    - member continues to utilize corticosteroids in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**
  - member has a stable or improving pattern of observed performance on at least two of the following five timed function tests as shown in medical records (all results for all tests must be included with the date of performance; tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner);

- timed ten-meter walk/run (time in seconds); **and**
- timed floor (supine) to stand (time in seconds); **and**
- timed 4-step descend (time in seconds); **and**
- timed sit to stand (time in seconds); **and**

- requested agent will not be used in combination with other disease-modifying therapies for DMD (e.g., exon-skipping therapies); **and**
- member has not previously received treatment with a gene therapy for DMD.

Elevidys

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ four years of age and < six years of age at the time of administration; **and**
  - prescriber is a neuromuscular specialist; **and**
  - copy of genetic test with a confirmed mutation in the DMD gene; **and**
  - member does not have any deletion in exon 8 or exon 9 of the DMD gene; **and**
  - copy of baseline anti-AAVrh74 total binding antibody titers < 1:400; **and**
  - member has a baseline measurement for both of the following:
    - North Star Ambulatory Assessment, including scores and times on individual items (within the past three months); **and**
    - six-minute walk test (within the past three months); **and**
  - member is ambulatory as defined by a current six-minute walk test (6MWT – distance walked in six minutes in meters) ≥ 200 meters; **and**
  - one of the following:
    - member is on a stable dose of corticosteroid; **or**
    - attestation that the member will continue to utilize chronic corticosteroids after Elevidys infusion; **or**
    - demonstrated contraindication to corticosteroids; **and**
  - member has not previously received treatment with a gene therapy for DMD; **and**
  - infusion will take place in a qualified treatment facility; **and**
  - member is not currently utilizing antisense oligonucleotides; **and**
  - appropriate dosing.

Evrysdi

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - copy of genetic test confirming member has 4 copies of SMN2 and one of the following:
      - member is symptomatic; **or**
      - member is a pre-symptomatic infant diagnosed via newborn screening; **or**
    - copy of genetic test confirming member has 2 or 3 copies of SMN2; **and**
  - genetic test confirming diagnosis of SMA; **and**
  - prescriber is a neurologist or consult notes from a neurologist are provided; **and**
  - current motor function test; **and**
  - if the member has previously received Zolgensma, all of the following:
    - attestation that the member has had an inadequate response to Zolgensma; **and**
    - pre-treatment baseline motor function test (prior to treatment with any SMA agent); **and**
    - pre-Zolgensma baseline motor function test (if different than pre-treatment baseline); **and**
    - post-Zolgensma motor function tests; **and**
  - appropriate dosing for age and weight; **and**
  - one of the following:

    - for the solution formulation, requested quantity is ≤ 5 mg (6.67 mL) per day; **or**
    - for the tablet formulation, requested quantity is ≤ one unit per day; **and**
  - member does not have evidence of permanent ventilator dependence (defined as any of the following: member has an endotracheal tube, member has a tracheotomy tube, member had at least 14 days of continuous respiratory assistance for at least 16 hours per day); **and**
  - requested agent will not be used in combination with Spinraza.

- For recertification requests, documentation of both of the following is required:
  - one of the following:
    - current motor function test documenting positive response to therapy; **or**
    - medical necessity for continuing therapy; **and**
  - member does not have evidence of permanent ventilator dependence (defined as any of the following: member has an endotracheal tube, member has a tracheotomy tube, member had at least 14 days of continuous respiratory assistance for at least 16 hours per day).

Exondys 51

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - confirmed out-of-frame deletion in the DMD gene that is amenable to exon 51 skipping; **and**
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - member is ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - appropriate dosing (30 mg/kg intravenously every week); **and**
  - one of the following:
    - member has received a corticosteroid for at least six months prior and member will continue to use a corticosteroid in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**
  - member has at least a baseline measurement for each of the following timed function tests as shown in medical records (tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    - timed ten-meter walk/run (time in seconds); **and**
    - timed floor (supine) to stand (time in seconds); **and**
    - timed four-step descend (time in seconds); **and**
    - timed four-step climb (time in seconds); **and**
    - timed sit to stand (time in seconds; **and**
  - member has not previously received treatment with a gene therapy for DMD.

- For recertification requests, documentation of all of the following is required:
  - member remains ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - member has a stable or improving pattern of 6MWTs as shown in medical records with results of a pretreatment baseline and all interim results (all previous 6MWTs results must be included); **and**
  - dosing remains appropriate; **and**
  - one of the following:
    - member continues to utilize corticosteroids in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**

- member has a stable or improving pattern of observed performance on at least two of the following five timed function tests as shown in medical records (all results for all tests must be included with the date of performance; tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
  - timed ten-meter walk/run (time in seconds); **and**
  - timed floor (supine) to stand (time in seconds); **and**
  - timed four-step descend (time in seconds); **and**
  - timed four-step climb (time in seconds); **and**
  - timed sit to stand (time in seconds); **and**
- member has not previously received treatment with a gene therapy for DMD.

Spinraza

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - copy of genetic test confirming member has 4 copies of SMN2 and one of the following:
      - member is symptomatic; **or**
      - member is a pre-symptomatic infant diagnosed via newborn screening; **or**
    - copy of genetic test confirming member has 2 or 3 copies of SMN2; **and**
  - genetic test confirming diagnosis of SMA; **and**
  - prescriber is a neurologist or consult notes from a neurologist are provided; **and**
  - current motor function test; **and**
  - if the member has previously received Zolgensma, all of the following:
    - attestation that the member has had an inadequate response to Zolgensma; **and**
    - pre-treatment baseline motor function test (prior to treatment with any SMA agent); **and**
    - pre-Zolgensma baseline motor function test (if different than pre-treatment baseline); **and**
    - post-Zolgensma motor function tests; **and**
  - member does not have evidence of permanent ventilator dependence (defined as any of the following: member has an endotracheal tube, member has a tracheotomy tube, member had at least 14 days of continuous respiratory assistance for at least 16 hours per day); **and**
  - requested agent will not be used in combination with Evrysdi; **and**
  - appropriate dosing.

- For recertification requests, documentation of both of the following is required:
  - one of the following:
    - current motor function test documenting positive response to therapy; **or**
    - medical necessity for continuing therapy; **and**
  - member does not have evidence of permanent ventilator dependence (defined as any of the following: member has an endotracheal tube, member has a tracheotomy tube, member had at least 14 days of continuous respiratory assistance for at least 16 hours per day).

Viltepso

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - confirmed out-of-frame deletion in the DMD gene that is amenable to exon 53 skipping; **and**
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - member is ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**

- appropriate dosing (80 mg/kg intravenously every week); **and**
- one of the following:
  - member has received a corticosteroid for at least three months prior and member will continue to use a corticosteroid in combination with the requested agent; **or**
  - contraindication to corticosteroids; **and**
- member has at least a baseline measurement for each of the following timed function tests as shown in medical records (tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
  - timed ten-meter walk/run (time in seconds); **and**
  - timed floor (supine) to stand (time in seconds); **and**
  - timed four-step descend (time in seconds); **and**
  - timed four-step climb (time in seconds); **and**
  - timed sit to stand (time in seconds); **and**
- member has not previously received treatment with a gene therapy for DMD.

- For recertification requests, documentation of all of the following is required:
  - member remains ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - member has a stable or improving pattern of 6MWTs as shown in medical records with results of a pretreatment baseline and all interim results (all previous 6MWTs results must be included); **and**
  - dosing remains appropriate; **and**
  - one of the following:
    - member continues to utilize corticosteroids in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**
  - member has a stable or improving pattern of observed performance on at least two of the following five timed function tests as shown in medical records (all results for all tests must be included with the date of performance; tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    - timed ten-meter walk/run (time in seconds); **and**
    - timed floor (supine) to stand (time in seconds); **and**
    - timed four-step descend (time in seconds); **and**
    - timed four-step climb (time in seconds); **and**
    - timed sit to stand (time in seconds); **and**
  - member has not previously received treatment with a gene therapy for DMD.

Vyondys 53

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - confirmed out-of-frame deletion in the DMD gene that is amenable to exon 53 skipping; **and**
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - member is ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - appropriate dosing (30 mg/kg intravenously every week); **and**
  - one of the following:
    - member has received a corticosteroid for at least six months prior and member will continue to use a corticosteroid in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**

- member has at least a baseline measurement for each of the following timed function tests as shown in medical records (tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
  - timed ten-meter walk/run (time in seconds); **and**
  - timed floor (supine) to stand (time in seconds); **and**
  - timed four-step descend (time in seconds); **and**
  - timed four-step climb (time in seconds); **and**
  - timed sit to stand (time in seconds); **and**
- member has not previously received treatment with a gene therapy for DMD.

- For recertification requests, documentation of all of the following is required:
  - member remains ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - member has a stable or improving pattern of 6MWTs as shown in medical records with results of a pretreatment baseline and all interim results (all previous 6MWTs results must be included); **and**
  - dosing remains appropriate; **and**
  - one of the following:
    - member continues to utilize corticosteroids in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**
  - member has a stable or improving pattern of observed performance on at least two of the following five timed function tests as shown in medical records (all results for all tests must be included with the date of performance; tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    - timed ten-meter walk/run (time in seconds); **and**
    - timed floor (supine) to stand (time in seconds); **and**
    - timed four-step descend (time in seconds); **and**
    - timed four-step climb (time in seconds); **and**
    - timed sit to stand (time in seconds); **and**
  - member has not previously received treatment with a gene therapy for DMD.

Zolgensma

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neuromuscular specialist; **and**
  - member is < two years of age; **and**
  - genetic test confirming diagnosis of bi-allelic mutation in the SMN1 gene; **and**
  - genetic test confirming the member has two, three, or four copies of the SMN2 gene; **and**
  - baseline AAV9 antibody test confirming titers < 1:50; **and**
  - pre-treatment baseline Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) score; **and**
  - member does not have evidence of complete paralysis of limbs; **and**
  - member does not have evidence of permanent ventilator dependence (defined as any of the following: member has an endotracheal tube, member has a tracheotomy tube, member had at least 14 days of continuous respiratory assistance for at least 16 hours per day) at the time the requested agent is to be administered; **and**
  - member does not have active viral infection, including human immunodeficiency virus [HIV] or positive serology for hepatitis B or C, or Zika virus; **and**
  - member has not previously received treatment with a gene therapy for spinal muscular atrophy.

MassHealth Evaluation Criteria
Table 77 - Hyaluronan Injections

Drug Category: Hyaluronan Injections

Medication Class/Individual Agents: Hyaluronan Injections

I. Prior-Authorization Requirements

Hyaluronan Injections			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
hyaluronan, high molecular weight	Orthovisc	PA	MB
hyaluronate, crossed-linked	Gel-One	PA	MB
hyaluronate, modified	Hymovis	PA	MB
hyaluronate, stabilized	Durolane	PA	MB
hyaluronate-Euflexxa	Euflexxa	PA	MB
hyaluronate-Gelsyn	Gelsyn	PA	MB
hyaluronate-Genvisc	Genvisc	PA	MB
hyaluronate-Hyalgan	Hyalgan	PA	MB
hyaluronate-Monovisc	Monovisc	PA	MB
hyaluronate-Supartz	Supartz	PA	MB
hyaluronate-Synojoynt	Synojoynt	PA	MB
hyaluronate-Triluron	Triluron	PA	MB
hyaluronate-Trivisc	Trivisc	PA	MB
hyaluronate-Visco-3	Visco-3	PA	MB
hylan G-F20-Synvisc	Synvisc	PA	MB
hylan G-F20-Synvisc-One	Synvisc-One	PA	MB

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Hyaluronic acid (HA) is a constitutive component of matrix cartilage, which plays a key role in the maintenance of joint homeostasis. HA is also a biologically active component, secreted by chondrocytes, that protects the cartilage from degradation by interacting with matrix metalloproteinase (MMPs) and pain mediators.[1]

In patients with osteoarthritis (OA), the concentration and molecular weight of HA are reduced, diminishing elastoviscosity of the synovial fluid, joint lubrication and shock absorbency, and possible anti-inflammatory, analgesic, and chondroprotective effects.[2, 3]

The aim of HA treatment is to reduce pain and improve physical function by supplementing the viscosity and elasticity of synovial fluid which are reduced in OA.[2]

References:

1. Iannitti T, Lodi D, Palmieri B. Intra-articular injections for the treatment of osteoarthritis. Drugs R D 2011; 11(1):13-27.

2. Gigante A, Callegari L. The role of intra-articular hyaluronan in the treatment of osteoarthritis. Rheumatol Int 2011; 31:427-44.

	Clinical Notes
	3. Strauss EJ, Hart JA, Miller MD, Altman RD, Rosen JE. Hyaluronic acid viscosupplementation and osteoarthritis. Am J Sports Med 2009; 37(8):1636-44.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- treatment of pain associated with osteoarthritis (OA) or degenerative joint disease (DJD) of the knee

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, product name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

All Hyaluronan Injections

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 30 days of therapy), adverse reaction, or contraindication to acetaminophen; **and**
  - inadequate response or adverse reaction to one or contraindication to all intra-articular corticosteroid injections; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to all nonsteroidal anti-inflammatory drug (NSAIDs).

MassHealth Evaluation Criteria
Table 78 - Diabetes Medical Supplies and Emergency Treatments

Drug Category: Various

Medication Class/Individual Agents: Various

I. Prior-Authorization Requirements

Diabetes Emergency Treatments			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dasiglucagon	Zegalogue		
glucagon auto-injection, prefilled syringe, vial-Gvoke	Gvoke		
glucagon nasal powder	Baqsimi PD		
glucagon vial			
glucagon vial-Glucagen	Glucagen		

Diabetes Medical Supplies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
continuous glucose monitoring system	Dexcom G6	PA	PND
continuous glucose monitoring system	Dexcom G7	PA	PND
continuous glucose monitoring system	Freestyle Libre 14 day	PA	PND
continuous glucose monitoring system	Freestyle Libre 2	PA	PND
continuous glucose monitoring system	Freestyle Libre 3	PA	PND
insulin bolus delivery patch	Cequr Simplicity	PA	PND
insulin continuous subcutaneous infusion patch	V-Go	PA	PND
insulin continuous subcutaneous infusion pump	Omnipod 5	PA	PND

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

In addition to the products listed in Table 78: Diabetes Medical Supplies and Emergency Treatments, the following non-drug diabetes medical supplies are covered through the Pharmacy Online Processing System (POPS):

Medical Supplies

- Alcohol swabs
- Disposable syringe and needle units
- Lancets
- Urine glucose testing reagent strips used for the management of diabetes

Devices

- Insulin cartridge delivery devices and needles or other devices for injection of medication (for example, epinephrine auto-injectors)

Please see the following link to find out more information regarding the Non-Drug Product List: https://masshealthdruglist.ehs.state.ma.us/MHDL/pubdownloadpdfwelcome.do?docId=8&fileType=PDF.

Diabetes Medical Supplies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
insulin continuous subcutaneous infusion pump	Omnipod Classic	PA	PND
insulin continuous subcutaneous infusion pump	Omnipod Dash	PA	PND
insulin continuous subcutaneous infusion pump	Omnipod Go	PA	PND
test strips, blood glucose, all other non-preferred		PA	
test strips, blood glucose, preferred	Freestyle	PA - > 100 units/30 days	PND
test strips, blood glucose, preferred	Freestyle Insulinx	PA - > 100 units/30 days	PND
test strips, blood glucose, preferred	Freestyle Lite	PA - > 100 units/30 days	PND
test strips, blood glucose, preferred	Freestyle Neo	PA - > 100 units/30 days	PND
test strips, blood glucose, preferred	Precision Xtra	PA - > 100 units/30 days	PND

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

PND Preferred Non-Drug Product. This product is a preferred non-drug product for which MassHealth has entered into a rebate agreement with product manufacturer.

II. Therapeutic Uses

FDA-approved, for example:

- Diabetes mellitus

non-FDA-approved, for example:

- Hypoglycemia due to a diagnosis other than diabetes mellitus

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.

- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

All requests for blood glucose testing reagent strips at quantities above established quantity limits

- Documentation of one of the following is required:
  - for members utilizing a continuous glucose monitoring device, both of the following:
    - medical necessity for increased testing; **and**
    - treatment plan describing self-testing frequency.
  - for members not utilizing a continuous glucose monitoring device, one of the following:
    - medical necessity for increased testing; **or**
    - treatment plan describing self-testing frequency.

SmartPA: Claims for Freestyle, Freestyle Lite, Freestyle Insulinx, or Precision Xtra brand blood glucose testing reagent strips for > 100 strips/30 days but ≤ 200 strips/30 days will usually process at the pharmacy without a PA request if the member has a paid MassHealth pharmacy claim for injectable insulin or a prenatal vitamin within the last 90 days.†

Cequr Simplicity

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 21 years of age; **and**
  - one of the following:
    - member's current treatment plan involves testing blood glucose at least four times per day; **or**
    - use of continuous glucose monitoring; **and**
  - member is currently receiving at least three daily insulin injections or an insulin pump; **and**
  - one of the following:
    - member's A1c > 7.0% or does not meet documented target treatment; **or**
    - frequent hypoglycemia; **or**
    - fluctuations of more than 100 mg/dL in blood glucose before mealtime; **or**
    - dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; **or**
    - history of severe glycemic excursions; **and**
  - for Cequr Simplicity 4 day patch, one of the following:
    - both of the following:
      - requested quantity is ≤ one patch/four days; **and**
      - medical necessity for the Cequr Simplicity 4 day patch instead of the Cequr Simplicity 3 day patch; **and**
    - requested quantity is ≤ one patch/four days; **or**
  - for Cequr Simplicity 3 day patch, one of the following:
    - requested quantity is ≤ one patch/three days; **or**
    - both of the following:
      - requested quantity is ≥ one patch/one day; **and**

- medical necessity for > one patch/two days as noted by daily insulin requirement > 100 units; **or**
- both of the following:
  - requested quantity is one patch/two days; **and**
  - medical necessity for > one patch/three days as noted by one of the following:
    - daily insulin requirement is > 66 units; **or**
    - injection site irritation and inadequate response to at least one mitigation strategy; **or**
    - history of adhesion failure and inadequate response to at least one mitigation strategy; **or**
    - member has lipoatrophy or lipohypertrophy at the injection site; **or**
    - pooling of insulin at the injection site.

Dexcom G6, Dexcom G7, Freestyle Libre 2, Freestyle Libre 3, Freestyle Libre 14 Day

- Documentation of all of the following is required for a diagnosis of diabetes mellitus:
  - appropriate diagnosis; **and**
  - one of the following:
    - member has problematic hypoglycemia defined as one of the following;
      - at least two hypoglycemic events with blood glucose of < 54 mg/dL within the past 12 months; **or**
      - at least one hypoglycemic event with blood glucose of < 54 mg/dL that required third party assistance for treatment within the past 12 months; **or**
    - member's treatment regimen includes insulin; **and**
  - for Dexcom G6 or Dexcom G7, one of the following:
    - for receiver, requested quantity is ≤ one unit/365 days; **or**
    - for sensor, requested quantity is ≤ one unit/ten days; **or**
    - for Dexcom G6 transmitter, requested quantity is ≤ one unit/90 days; **and**
  - for Freestyle Libre 14 day, Libre 2, or Libre 3, one of the following:
    - for receiver, requested quantity is ≤ one unit/365 days; **or**
    - for Libre 14 day sensor, Libre 2 sensor, and Libre 3 sensor, requested quantity is ≤ one unit/14 days; **or**
    - for Libre 2 sensor plus and Libre 3 sensor plus, requested quantity is ≤ one unit/15 days.
- Documentation of all of the following is required for a diagnosis of hypoglycemia due to a diagnosis other than diabetes mellitus:
  - appropriate diagnosis; **and**
  - clinical rationale for use of continuous glucose monitoring instead of capillary blood glucose monitoring using test strips and a blood glucose meter; **and**
  - for Dexcom G6 or Dexcom G7, one of the following:
    - for receiver, requested quantity is ≤ one unit/365 days; **or**
    - for sensor, requested quantity is ≤ one unit/ten days; **or**
    - for Dexcom G6 transmitter, requested quantity is ≤ one unit/90 days; **and**
  - for Freestyle Libre 14 day, Libre 2, or Libre 3, one of the following:
    - for receiver, requested quantity is ≤ one unit/365 days; **or**
    - for Libre 14 day sensor, Libre 2 sensor, and Libre 3 sensor, requested quantity is ≤ one unit/14 days; **or**
    - for Libre 2 sensor plus and Libre 3 sensor plus, requested quantity is ≤ one unit/15 days.

SmartPA: Claims for Dexcom G6, Dexcom G7, Freestyle Libre 14 day, Freestyle Libre 2, and Freestyle Libre 3 within quantity limits will usually process and pay at the pharmacy without a PA request if the member has a history of a diagnosis of diabetes mellitus and a paid MassHealth pharmacy claim for injectable insulin within the last 90 days.†

Non-preferred blood glucose testing reagent strips

- Documentation of all of the following is required:
  - medical necessity for a non-preferred product; **and**
  - requested quantity is ≤ 100 strips/30 days.

SmartPA: Claims for Prodigy brand blood glucose testing reagent strips for ≤ 100 strips/30 days will usually process at the pharmacy

without a PA request if the member has a history of MassHealth medical claims for visual impairment. Claims for Prodigy brand blood glucose testing reagent strips for > 100 strips/30 days but ≤ 200 strips/30 days will also usually process at the pharmacy without a PA request if the member has a history of a paid MassHealth pharmacy claim for injectable insulin or a prenatal vitamin within the last 90 days in addition to a history of MassHealth medical claims for visual impairment.†

Omnipod 5, Omnipod Classic, Omnipod Dash, V-Go

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - for V-Go, both of the following:
    - member is ≥ 18 years of age; **and**
    - requested quantity is ≤ one unit/one day; **and**
  - one of the following:
    - member's current treatment plan involves testing blood glucose at least four times per day; **or**
    - use of continuous glucose monitoring; **and**
  - member is currently receiving at least three daily insulin injections or an insulin pump; **and**
  - one of the following:
    - member's A1c > 7.0% or does not meet documented target treatment; **or**
    - frequent hypoglycemia; **or**
    - fluctuations of more than 100 mg/dL in blood glucose before mealtime; **or**
    - dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; **or**
    - history of severe glycemic excursions; **and**
  - for Omnipod 5, Omnipod Classic, or Omnipod Dash, one of the following:
    - requested quantity is ≤ one pod/three days; **or**
    - both of the following:
      - requested quantity is ≤ one pod/one day; **and**
      - medical necessity for > one pod/two days as noted by daily insulin requirement > 100 units; **or**
    - both of the following:
      - requested quantity is one pod/two days; **and**
      - medical necessity for > one pod/three days as noted by one of the following:
        - member is < 19 years of age; **or**
        - daily insulin requirement is > 66 units; **or**
        - injection site irritation and inadequate response to at least one mitigation strategy; **or**
        - history of adhesion failure and inadequate response to at least one mitigation strategy; **or**
        - member has lipoatrophy or lipohypertrophy at the injection site; **or**
        - pooling of insulin at the injection site.

Omnipod Go

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - member's current treatment plan involves testing blood glucose at least four times per day; **or**
    - use of continuous glucose monitoring; **and**
  - member is currently receiving long-acting insulin or NPH insulin; **and**
  - one of the following:
    - member's A1c > 7.0% or does not meet documented target treatment; **or**
    - frequent hypoglycemia; **or**
    - fluctuations of more than 100 mg/dL in blood glucose before mealtime; **or**

- dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; **or**
- history of severe glycemic excursions; **and**

- one of the following:
  - requested quantity is ≤ 1 pod/3 days; **or**
  - medical necessity for one pod/two days as noted by one of the following:
    - injection site irritation and inadequate response to at least one mitigation strategy; **or**
    - history of adhesion failure and inadequate response to at least one mitigation strategy; **or**
    - member has lipoatrophy or lipohypertrophy at the injection site; **or**
    - pooling of insulin at the injection site.

†**Note**: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 79 - Pharmaceutical Compounds

Drug Category: Compounding Agents

Medication Class/Individual Agents: Various

I. Prior-Authorization Requirements

Pharmaceutical Compounds				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
cherry syrup			*	**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** This Table does not represent the complete list of drugs that can be used for pharmaceutical compounding. For information regarding the management of other drugs that could be used in pharmaceutical compounding, please see the appropriate Therapeutic Class Table. Compounded pharmaceutical products utilizing covered ingredients with a total allowed ingredient cost < $100 and non-intradermal/topical/transdermal route of administration are covered without PA. Please note, the following compounding ingredients are not covered. This list is subject to change at any time: • benzodiazepine powders (alprazolam, clonazepam, diazepam, lorazepam, midazolam powders) • chorionic gonadotropin, human, powder • clomiphene powder • cocaine crystals, powder • diethylpropion powder • flibanserin powder • hydroxyprogesterone powder • ketamine powder • methylphenidate powder • opioid powders (apomorphine, buprenorphine, cocaine,
compounded pharmaceutical product with a total allowed ingredient cost ≥ $100		PA	CP	
compounded pharmaceutical product with a total allowed ingredient cost <$100 and non-intradermal/topical/transdermal ROA			CP	
compounded pharmaceutical product with intradermal, topical or transdermal ROA		PA	CP	
gelatin capsule, empty			*	
glycerin			*	
hydrophilic ointment			*, A90	
lanolin			*	
Ora-Plus suspending vehicle			*	
Ora-Sweet oral syrup			*	
Ora-Sweet-SF oral syrup			*	
petrolatum			*, A90	
simple syrup			*	
zinc oxide			*	

	Clinical Notes
	codeine, fentanyl, hydrocodone, hydromorphone, levorphanol, methadone, morphine sulfate, oxycodone, sufentanil powders) • papaverine • PCCA compounding inactive ingredients • phentolamine • tadalafil powder

* The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

CP Compounded pharmaceutical products with a total allowed ingredient cost greater than or equal to $100 require PA. In addition, compounded pharmaceutical products with intradermal, topical, or transdermal route of administration (ROA) require PA. The following ROAs are excluded from the PA requirement for products with a total allowed ingredient cost greater than or equal to $100: infusion, intramuscular, intravenous, intravenous piggyback, intravenous push, subcutaneous. Compounded pharmaceutical products utilizing any PA-requiring agent or not covered ingredient as part of the compound require PA.

II. Therapeutic Uses

FDA-approved, for example:

- Various

Non-FDA-approved, for example:

- Various

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member’s condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested

medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

compounded pharmaceutical products with allowed ingredient cost ≥ $100, compounded pharmaceutical products with intradermal, topical, or transdermal route of administration, and compounded pharmaceutical products with PA-requiring or not covered ingredients

- Documentation of all of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - one of the following:
    - treatment of an FDA-approved indication; **or**
    - treatment of a clinically-appropriate indication supported by medical literature; **and**
  - requested indication is not excluded from coverage by MassHealth regulations; **and**
  - inadequate response or adverse reaction to two or contraindication to all other commercially available alternatives; **and**
  - one of the following:
    - requested compounded product is not commercially available; **or**
    - commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness; **or**
    - member has a medical necessity for a dosage form or dosage strength that is not commercially available; **and**
  - medical necessity for the use of inactive ingredients in the requested compounded product.

Please note: The MassHealth agency does not pay for any drug when used for excluded purposes as described in 130 CMR 406.413(B) "Limitations on Coverage of Drugs – Drug Exclusions" (see link below). https://www.mass.gov/regulations/130-CMR-406000-pharmacy-services

MassHealth Evaluation Criteria
Table 80 - Anti-Hemophilia Agents

Drug Category: Anti-Hemophilia Agents

Medication Class/Individual Agents: Anti-Hemophilia Agents

I. Prior-Authorization Requirements

Anti-Hemophilia Agents – Factor VIII Replacement Therapies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
antihemophilic factor, recombinant pegylated-Adynovate	Adynovate		
antihemophilic factor, recombinant pegylated-aucl-Jivi	Jivi PD		
antihemophilic factor, recombinant, fc-vwf-xten fusion protein-ehtl	Altuviiio		
antihemophilic factor, recombinant, single chain-Afstyla	Afstyla		
antihemophilic factor, recombinant-Advate	Advate		
antihemophilic factor, recombinant-Helixate	Helixate		
antihemophilic factor, recombinant-Hemofil-M	Hemofil-M		
antihemophilic factor, recombinant-Kogenate	Kogenate PD		
antihemophilic factor, recombinant-Kovaltry	Kovaltry PD		
antihemophilic factor, recombinant-Novoeight	Novoeight		
antihemophilic factor,	Nuwiq		

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Please note: One-time cell and gene therapies are part of the ACPP and MCO unified pharmacy policy. PA requests for one-time cell and gene therapies for members with ACPP and MCO plans are reviewed by the MassHealth Drug Utilization Review (DUR) Program.

etranacogene dezaparvovec-drlb, fidanacogene elaparvovec -dzkt, and valoctocogene roxaparvovec-rvox

- MassHealth Drug Utilization Review will be reaching out to prescribers after PA approval to verify administration date and at ongoing intervals for long-term monitoring of response.

Anti-Hemophilia Agents – Factor VIII Replacement Therapies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
recombinant-Nuwiq			
antihemophilic factor, recombinant-Recombinate	Recombinate		
antihemophilic factor, recombinant-Xyntha	Xyntha PD		
factor VIII recombinant, Fc fusion protein	Eloctate		
factor VIII recombinant, glycopegylated-exei	Esperoct		

Anti-Hemophilia Agents – Miscellaneous Hemophilia Therapies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
concizumab-mtci	Alhemo	PA	
marstacimab-hncq	Hympavzi	PA	

Anti-Hemophilia Agents – Human Plasma-Derived Factor VIII and Von Willebrand Factor Concentrates			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
antihemophilic factor / von willebrand factor complex, human	Alphanate		
antihemophilic factor, human-Humate-P	Humate-P		
antihemophilic factor, human-Koate-DVI	Koate-DVI		
von willebrand factor / coagulation factor VIII complex	Wilate		

Anti-Hemophilia Agents – Plasma-Derived Factor IX Concentrates			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
factor IX	Mononine		
factor IX, human	Alphanine SD		

Anti-Hemophilia Agents – Recombinant Factor IX Concentrates			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
coagulation factor IX recombinant, glycopegylated-Rebinyn	Rebinyn		
coagulation factor IX, recombinant	Rixubis		
factor IX human recombinant-Benefix	Benefix PD		
factor IX human recombinant-Ixinity	Ixinity		
factor IX recombinant, albumin fusion protein	Idelvion		
factor IX recombinant, Fc fusion protein	Alprolix		

Anti-Hemophilia Agents – Hemophilia B Gene Therapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
etranacogene dezaparvovec-drlb	Hemgenix	PA	CO
fidanacogene elaparvovec-dzkt	Beqvez	PA	CO

Anti-Hemophilia Agents – Human Plasma-Derived Factor X Concentrate			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
coagulation factor X, human	Coagadex		

Anti-Hemophilia Agents – Human Plasma-Derived Factor XIII Concentrate			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
factor XIII concentrate, human	Corifact		

Anti-Hemophilia Agents – Bypassing Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
anti-inhibitor coagulant complex-Feiba NF	Feiba NF		
coagulation factor VIIa, recombinant	Novoseven		
coagulation factor VIIa, recombinant	Sevenfact		

Anti-Hemophilia Agents – Human Plasma-Derived Fibrinogen Concentrate			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fibrinogen	Fibryga		
fibrinogen concentrate	Riastap		

Anti-Hemophilia Agents – Monoclonal Antibodies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
emicizumab-kxwh	Hemlibra PD		

Anti-Hemophilia Agents – Recombinant Factor VIII Concentrates for Patients with Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
antihemophilic factor, recombinant, porcine sequence -Obizur	Obizur		

Anti-Hemophilia Agents – Human Plasma-Derived Prothrombin Complex Concentrates			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
factor IX complex human-Profilnine SD	Profilnine SD		

Anti-Hemophilia Agents – Hemophilia A Gene Therapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
valoctocogene roxaparvovec-rvox	Roctavian	PA	CO

Anti-Hemophilia Agents – Recombinant Factor XIII-A Subunit			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
factor XIII A-subunit recombinant	Tretten		

Anti-Hemophilia Agents – Recombinant Von Willebrand Factor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
von willebrand factor, recombinant	Vonvendi		

CO Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements. All requests for one-time cell and gene therapies (as listed on the Acute Hospital Carve-Out Drug List), including for members enrolled in an Accountable Care Partnership Plan (ACPP) or Managed Care Organization (MCO), will be reviewed by the MassHealth Drug Utilization Review (DUR) Program.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

II. Therapeutic Uses

FDA-approved, for example:

- Hemophilia A
- Hemophilia B
- Factor deficiencies

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Alhemo

- Documentation of the following is required:
  - diagnosis of hemophilia A or hemophilia B; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - member's current weight; **and**
  - copy of test confirming member has FVIII inhibitor (for hemophilia A) or FIX inhibitor (for hemophilia B); **and**
  - attestation that member will not be receiving other hemophilia prophylaxis (e.g., bypassing agents) in conjunction with Alhemo; **and**
  - for a diagnosis of hemophilia A, both of the following:
    - inadequate response, adverse reaction, or contraindication to Hemlibra; **and**
    - inadequate response, adverse reaction, or contraindication to bypassing agents; **and**
  - for a diagnosis of hemophilia B, inadequate response, adverse reaction, or contraindication to bypassing agents; **and**
  - baseline ABR; **and**
  - appropriate dosing.

Beqvez

- Documentation of the following is required:
  - diagnosis of moderately severe to severe hemophilia B (FIX activity level ≤ 2 IU/dL or 2 %); **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - appropriate dosing; **and**
  - member's current weight; **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - member is a biologic male/male sex assigned at birth; **and**
  - copy of test confirming member does not have FIX inhibitor; **and**
  - copy of FDA-approved test confirming member does not have AAVRh74var NAb; **and**
  - member does not have active human immunodeficiency virus (HIV), hepatitis B (HBV), or hepatitis C (HCV) infection; **and**
  - member has not received any prior gene therapy for hemophilia B; **and**

- one of the following:
  - member currently uses FIX prophylaxis therapy; **or**
  - has current life-threatening hemorrhage; **or**
  - member has history of life-threatening hemorrhage; **or**
  - member has repeated, serious spontaneous bleeding episodes; **and**
- baseline annualized bleeding rate (ABR); **and**
- FIX activity level; **and**
- infusion will take place in a qualified treatment facility; **and**
- member does not have any of the following: hepatic fibrosis (stage 3 or 4), cirrhosis, liver related coagulopathy, hypoalbuminemia, persistent jaundice, portal hypertension, splenomegaly, hepatic encephalopathy.

Hemgenix

- Documentation of the following is required:
  - diagnosis of moderately severe to severe hemophilia B (FIX activity level ≤ 2 IU/dL or 2 %); **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - appropriate dosing; **and**
  - member's current weight; **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - member is a biologic male/male sex assigned at birth; **and**
  - copy of test confirming member does not have FIX inhibitor; **and**
  - copy of CLIA-validated test confirming AAV5 NAb titer; **and**
  - member does not have active human immunodeficiency virus (HIV), hepatitis B (HBV), or hepatitis C (HCV) infection; **and**
  - member has not received any prior gene therapy for hemophilia B; **and**
  - one of the following:
    - member currently uses FIX prophylaxis therapy; **or**
    - has current life-threatening hemorrhage; **or**
    - member has history of life-threatening hemorrhage; **or**
    - member has repeated, serious spontaneous bleeding episodes; **and**
  - baseline annualized bleeding rate (ABR); **and**
  - FIX activity level.

Hympavzi

- Documentation of the following is required:
  - one of the following:
    - diagnosis of severe hemophilia A (FVIII activity level ≤ 1 IU/dL or 1 %); **or**
    - diagnosis of moderately severe to severe hemophilia B (FIX activity level ≤ 2 IU/dL or 2 %); **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - baseline annualized bleeding rate (ABR); **and**
  - member's current weight is ≥ 35 kg; **and**
  - member is ≥ 12 years of age; **and**
  - member is a biologic male/male sex assigned at birth; **and**
  - for diagnosis of severe hemophilia A, all of the following:
    - copy of test confirming member does not have FVII inhibitor; **and**
    - inadequate response or adverse reaction or contraindication to Hemlibra; **and**
    - member will not be receiving other hemophilia A prophylaxis in conjunction with Hympavzi; **and**
    - member has not received any prior gene therapy for hemophilia A; **and**
  - for diagnosis of severe hemophilia B, all of the following:
    - copy of test confirming member does not have FIX inhibitor; **and**

    - member will not be receiving other hemophilia B prophylaxis in conjunction with Hympavzi; **and**
    - member has not received any prior gene therapy for hemophilia B; **and**
  - one of the following:
    - requested quantity is ≤ one prefilled pen per seven days; **or**
    - requested quantity is ≤ two prefilled pens per seven days and all of the following:
      - inadequate response to 150 mg weekly dosing; **and**
      - member 's current weight is ≥ 50 kg; **and**
      - member has been on therapy ≥ six months; **and**
      - member has ≥ two breakthrough bleeds within a six month period.
- For recertification, documentation of both of the following:
  - decrease in the member's ABR is maintained compared to baseline at the prescribed maintenance dose; **and**
  - member is not using any other therapy for prophylaxis.

Roctavian

- Documentation of the following is required:
  - diagnosis of severe hemophilia A (FVIII activity level ≤ 1 IU/dL or 1 %); **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - appropriate dosing; **and**
  - member's current weight; **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - member is a biologic male/male sex assigned at birth; **and**
  - member does not have active human immunodeficiency virus (HIV), hepatitis B (HBV), or hepatitis C (HCV) infection; **and**
  - copy of FDA-approved test confirming member does not have detectable preexisting immunity to AAV5; **and**
  - copy of test confirming member does not have factor VIII inhibitor; **and**
  - member currently uses one of the following: FVIII prophylaxis therapy or Hemlibra; **and**
  - baseline annualized bleeding rate (ABR); **and**
  - FVIII activity level; **and**
  - member does not have any of the following: hepatic fibrosis (stage 3 or 4), cirrhosis; **and**
  - member has not received any prior gene therapy for hemophilia A.

MassHealth Evaluation Criteria
Table 81 - Anti-Obesity Agents

Drug Category: Anti-Obesity Agents

Medication Class/Individual Agents: Anti-Obesity Agents

I. Prior-Authorization Requirements

Anti-Obesity Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
benzphetamine		PA	HSNE
diethylpropion		PA	HSNE
diethylpropion extended-release		PA	HSNE
liraglutide-Saxenda	Saxenda	PA	HSNE
orlistat	Xenical	PA	BP, HSNE, A90
phendimetrazine		PA	HSNE
phendimetrazine extended-release		PA	HSNE
phentermine 15 mg, 30 mg capsule		PA - < 12 years	HSNE
phentermine 37.5 mg capsule, tablet	Adipex-P	PA - < 12 years	# , HSNE
phentermine 8 mg tablet	Lomaira	PA - < 12 years or ≥ 18 years	HSNE
semaglutide injection-Wegovy for MassHealth	Wegovy	PA	HSNE
tirzepatide-Zepbound for MassHealth	Zepbound PD	PA	HSNE

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Effective January 1, 2025, Wegovy and Saxenda will no longer be covered for MassHealth members for the treatment of overweight or obesity for adults.

Please note: anti-obesity agents and/or drugs used for the treatment of obesity are not payable for Health Safety Net patients for weight loss. Wegovy and Zepbound may still be payable for other medically accepted indications.

Phentermine Contraindication

The following are acceptable contraindications to phentermine:

- Allergy to phentermine or any of the excipients
- Arrhythmia
- Bipolar disorder with mania
- Concomitant use of stimulants
- Concomitant use of monoamine oxidase inhibitor (MAOI)
- Congestive heart failure
- Coronary artery disease

	Clinical Notes
	• Glaucoma • History of myocardial infarction (MI) • History of psychosis • History of stroke • Hyperthyroidism • Pregnancy or lactation • Seizure disorder • Substance use disorder (SUD), opioid use disorder (OUD), alcohol use disorder, stimulant use disorder • Symptomatic peripheral artery disease • Uncontrolled anxiety despite pharmacotherapy • Uncontrolled hypertension defined as average blood pressure of ≥ 140/90 mm Hg despite pharmacotherapy

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
HSNE	This product is not payable under Health Safety Net for weight loss.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Obesity
- Overweight
- **Note:** The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

- **Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.**
- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or

clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.

- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

benzphetamine, diethylpropion, diethylpropion ER, phendimetrazine ER, phendimetrazine

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 17 years of age; **and**
  - member weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
  - member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
  - one of the following:
    - for diethylpropion ER or phendimetrazine ER, requested quantity is ≤ one unit/day; **or**
    - for benzphetamine, diethylpropion, or phendimetrazine, requested quantity is ≤ three units/day; **and**
  - one of the following:
    - inadequate response to phentermine with or without topiramate defined as all of the following:
      - member is adherent to phentermine (defined as ≥ 90 days out of 120 days)**; **and**
      - one of the following:
        - insufficient clinical response defined as < 5% reduction in body weight from baseline despite initial trial of ≥ three months of treatment with the maximally tolerated dose of phentermine; **or**
        - plateaued clinical response defined as no weight loss for at least ≥ three months of treatment with the maximally tolerated dose of phentermine; **and**
      - member's current BMI is ≥27 kg/m^2 (dated within the 90 days prior to treatment initiation of requested agent]); **or**
    - medical records documenting adverse reaction to phentermine that is allergic in nature or cannot be expected or managed as part of weight loss therapy; **or**
    - medical records documenting contraindication to phentermine; **and**
  - one of the following:
    - member BMI is ≥ 30 kg/m^2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **or**
    - both of the following:
      - member BMI is ≥ 27 kg/m^2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
      - one of the following weight-related comorbid conditions:
        - coronary heart disease or other atherosclerotic disease; **or**
        - dyslipidemia; **or**
        - hypertension; **or**
        - non-alcoholic steatohepatitis (NASH); **or**
        - obstructive sleep apnea; **or**
        - polycystic ovarian syndrome; **or**
        - prediabetes; **or**
        - systemic osteoarthritis; **or**
        - type 2 diabetes mellitus.

Lomaira, phentermine 37.5 mg capsule, tablet, and phentermine 15 mg, 30 mg capsule in members < 12 years of age

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
  - member BMI is in the 95th percentile or greater (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
  - member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
  - medical necessity to support the use of phentermine in a member < 12 years of age; **and**
  - one of the following:
    - for phentermine 15 mg, 30 mg capsule or phentermine 37.5 mg capsule or tablet, requested quantity is ≤ one unit/day; **or**
    - for Lomaira, requested quantity is ≤ three units/day.

Lomaira in members ≥ 18 years of age

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
  - member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
  - requested quantity is ≤ three units/day; **and**
  - one of the following:
    - inadequate response to phentermine 15 mg, 30 mg capsule or 37.5 mg tablet or capsule with or without topiramate defined as all of the following:
      - member is adherent to phentermine (defined as ≥ 90 days out of 120 days)**; **and**
      - one of the following:
        - insufficient clinical response defined as < 5% reduction in body weight from baseline despite initial trial of ≥ three months of treatment with the maximally tolerated dose of phentermine; **or**
        - plateaued clinical response defined as no weight loss for at least ≥ three months of treatment with the maximally tolerated dose of phentermine; **and**
      - member's current BMI is ≥ 27 kg/m^2 (dated within the 90 days prior to treatment initiation of requested agent]); **or**
    - medical records documenting adverse reaction to phentermine 15 mg, 30 mg capsule or 37.5 mg tablet or capsule that is allergic in nature or cannot be expected or managed as part of weight loss therapy; **or**
    - medical records documenting contraindication to phentermine 15 mg, 30 mg capsule or 37.5 mg tablet or capsule; **and**
  - one of the following:
    - member BMI is ≥ 30 kg/m^2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **or**
    - both of the following:
      - member BMI is ≥ 27 kg/m^2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
      - one of the following weight-related comorbid conditions:
        - coronary heart disease or other atherosclerotic disease; **or**
        - dyslipidemia; **or**
        - hypertension; **or**
        - non-alcoholic steatohepatitis (NASH); **or**
        - obstructive sleep apnea; **or**
        - polycystic ovarian syndrome; **or**

- prediabetes; **or**
- systemic osteoarthritis; **or**
- type 2 diabetes mellitus.

orlistat

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - appropriate dosing; **and**
  - member weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]; **and**
  - member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
  - requested quantity is ≤ three units/day; **and**
  - one of the following:
    - member BMI is ≥ 30 kg/m^2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **or**
    - both of the following:
      - member is ≥ 12 years and < 17 years of age; **and**
      - member BMI is in the 95th percentile or greater (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **or**
    - both of the following:
      - member BMI is ≥ 27 kg/m^2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
      - one of the following weight-related comorbid conditions:
        - coronary heart disease or other atherosclerotic disease; **or**
        - dyslipidemia; **or**
        - hypertension; **or**
        - non-alcoholic steatohepatitis (NASH); **or**
        - obstructive sleep apnea; **or**
        - polycystic ovarian syndrome; **or**
        - prediabetes; **or**
        - systemic osteoarthritis; **or**
        - type 2 diabetes mellitus.
- For recertification, documentation of the following is required:
  - member weight (dated within the last 90 days); **and**
  - one of the following:
    - weight loss of ≥ 5% from baseline body weight; **or**
    - both of the following:
      - improvement in secondary measures; **and**
      - attestation that the improvement in secondary measure is believed to be related to anti-obesity therapy despite lack of reduction in body weight.

Saxenda

- Documentation of the following is required for reduction of excess body weight and long-term maintenance of weight reduction in pediatric members with obesity or overweight:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years and < 18 of age; **and**
  - member weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested

agent]); **and**
- member BMI is in the 95th percentile or greater (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
- member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
- requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
- requested quantity is ≤ five pens/30 days; **and**
- one of the following*:
  - inadequate response to phentermine with or without topiramate defined as all of the following:
    - member is adherent to phentermine (defined as ≥ 90 days out of 120 days)**; **and**
    - one of the following:
      - insufficient clinical response defined as < 5% reduction in body weight from baseline despite initial trial of ≥ three months of treatment with the maximally tolerated dose of phentermine; **or**
      - plateaued clinical response defined as no weight loss for at least ≥ three months of treatment with the maximally tolerated dose of phentermine; **and**
    - member's current BMI is ≥ 27 kg/m2 (dated within the 90 days prior to treatment initiation of requested agent); **or**
  - medical records documenting adverse reaction to phentermine that is allergic in nature or cannot be expected or managed as part of weight loss therapy; **or**
  - medical records documenting contraindication to phentermine.
- For recertification in pediatric members, documentation of the following is required:
  - member weight (dated within the last 90 days); **and**
  - member is < 18 years of age; **and**
  - one of the following:
    - weight loss of ≥ 5% from baseline body weight; **or**
    - both of the following:
      - improvement in secondary measures; **and**
      - attestation that the improvement in secondary measure is believed to be related to anti-obesity therapy despite lack of reduction in body weight clinical.

Wegovy
- Documentation of the following is required for reduction of excess body weight and long-term maintenance of weight reduction in pediatric members with obesity or overweight:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years and < 18 of age; **and**
  - member weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
  - member BMI is in the 95th percentile or greater (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
  - member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
  - requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
  - requested quantity is ≤ four pens/28 days; **and**
  - one of the following*:
    - inadequate response to phentermine with or without topiramate defined as all of the following:
      - member is adherent to phentermine (defined as ≥ 90 days out of 120 days)**; **and**
      - one of the following:
        - insufficient clinical response defined as < 5% reduction in body weight from baseline despite initial trial of ≥ three months of treatment with the maximally tolerated dose of phentermine; **or**
        - plateaued clinical response defined as no weight loss for at least ≥ three months of treatment with the maximally tolerated dose of phentermine; **and**

    - member's current BMI is ≥ 27 kg/m2 (dated within the 90 days prior to treatment initiation of requested agent); **or**
  - medical records documenting adverse reaction to phentermine that is allergic in nature or cannot be expected or managed as part of weight loss therapy; **or**
  - medical records documenting contraindication to phentermine.
- For recertification in pediatric members, documentation of the following is required:
  - member weight (dated within the last 90 days); **and**
  - member is < 18 years of age; **and**
  - one of the following:
    - weight loss of ≥ 5% from baseline body weight; **or**
    - both of the following:
      - improvement in secondary measures; **and**
      - attestation that the improvement in secondary measure is believed to be related to anti-obesity therapy despite lack of reduction in body weight.

- Documentation of the following is required for risk reduction of major adverse cardiovascular events in members with established cardiovascular disease and obesity or overweight:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - member weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
  - member BMI is ≥ 27 kg/m2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
  - medical records documenting a diagnosis of cardiovascular disease defined as at least one of the following:
    - history of myocardial infarction (MI); **or**
    - history of stroke (ischemic or hemorrhagic stroke); **or**
    - symptomatic peripheral arterial disease (e.g., intermittent claudication with ankle–brachial index <0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease); **and**
  - attestation that the member does not have any of the following:
    - type 1 diabetes mellitus; **or**
    - type 2 diabetes mellitus; **or**
    - New York Heart Association class IV heart failure; **and**
  - member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
  - requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
  - requested quantity is ≤ four pens/28 days.
- For recertification in members ≥ 18 years of age, documentation of the following is required:
  - member weight (dated within the last 90 days); **and**
  - member requires Wegovy for cardiovascular protection and the benefit of cardiovascular protection outweighs the risk associated with the use of GLP-1 agents; **and**
  - medical records documenting one of the following:
    - history of myocardial infarction (MI); **or**
    - history of stroke (ischemic or hemorrhagic stroke); **or**
    - symptomatic peripheral arterial disease (e.g., intermittent claudication with ankle–brachial index <0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease).

Zepbound

- Documentation of the following is required for obesity, overweight, or moderate to severe obstructive sleep apnea (OSA) with obesity:
  - appropriate diagnosis; **and**

- member is ≥ 18 years of age; **and**
- member weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
- member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
- requested quantity is ≤ four pens/28 days; **and**
- requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
- one of the following*:
  - inadequate response to phentermine with or without topiramate defined as all of the following:
    - member is adherent to phentermine (defined as ≥ 90 out of the last 120 days)**; **and**
    - one of the following:
      - insufficient clinical response defined as < 5% reduction in body weight from baseline despite initial trial of ≥ three months of treatment with the maximally tolerated dose of phentermine; **or**
      - plateaued clinical response defined as no weight loss for at least ≥ three months of treatment with the maximally tolerated dose of phentermine; **and**
    - member's current BMI is ≥ 27 kg/m^2 (dated within the 90 days prior to treatment initiation of requested agent); **or**
  - medical records documenting adverse reaction to phentermine that is allergic in nature or cannot be expected or managed as part of weight loss therapy; **or**
  - medical records documenting contraindication to phentermine; **and**
- one of the following:
  - member BMI is ≥ 30 kg/m^2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); and
  - both of the following:
    - member BMI is ≥ 27 kg/m^2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
    - one of the following weight-related comorbid conditions:
      - coronary heart disease or other atherosclerotic disease; **or**
      - dyslipidemia; **or**
      - hypertension; **or**
      - non-alcoholic steatohepatitis (NASH); **or**
      - obstructive sleep apnea; **or**
      - polycystic ovarian syndrome; **or**
      - prediabetes; **or**
      - systemic osteoarthritis; **or**
      - type 2 diabetes mellitus.
- For recertification, documentation of the following is required:
  - member weight (dated within the last 90 days); **and**
  - one of the following:
    - weight loss of ≥ 5% from baseline body weight; **or**
    - both of the following:
      - improvement in secondary measures; **and**
      - attestation that the improvement in secondary measure is believed to be related to anti-obesity therapy despite lack of reduction in body weight; **or**
    - all of the following:
      - improvement in OSA symptoms, such as less daytime sleepiness, fewer sleep arousals, or fewer partner-reported snoring episodes or pauses in breathing; **and**
      - attestation that the improvement in OSA symptoms is believed to be related to anti-obesity therapy despite lack of reduction in body weight; **and**
      - medical records verifying baseline OR current OSA diagnosis with at ≥15 apnea-hypopnea index (AHI).

GLP-1 and GIP/GLP-1 Agonist Polypharmacy

- Documentation of all of the following is required:
  - individual drug prior authorization criteria must be met first where applicable; **and**
  - member is transitioning from one GLP-1 or GIP/GLP-1 agonist to another, and prior GLP-1 or GIP/GLP-1 agonist use will be discontinued.

*Please note, members who have paid MassHealth pharmacy claims for a GLP-1 agonist within the last 90 days may bypass the phentermine trial. For all other members, documentation of clinical rationale why the member is not new to GLP-1 therapy is required to bypass the phentermine trial.

**Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to these agents.

MassHealth Evaluation Criteria
Table 82 - Health Safety Net Formulary Exceptions

Drug Category: Health Safety Net Formulary Exceptions

Medication Class/Individual Agents: Health Safety Net Formulary Exceptions

I. Prior-Authorization Requirements

Health Safety Net Formulary Exceptions – Anti-Obesity Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
semaglutide injection-Wegovy for Health Safety Net	Wegovy	PA	HSNE	**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** **Please note: anti-obesity agents and/or drugs used for the treatment of obesity are not payable for Health Safety Net patients for weight loss. Wegovy and Zepbound may still be payable for other medically accepted indications.** **Wegovy** • Documentation of the following is required: • diagnosis of risk reduction of major adverse cardiovascular events in patients with established cardiovascular disease and obesity or overweight; **and** • patient is ≥ 18 years of age; **and** • prescriber is a cardiologist or consult notes from a cardiologist are provided; **and** • patient weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and** • patient BMI is ≥ 27 kg/m2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and** • attestation that the patient does not have any of the following: • type 1 diabetes mellitus; **or**
tirzepatide-Zepbound for Health Safety Net	Zepbound	PA	HSNE	

	Clinical Notes
	• type 2 diabetes mellitus; **or** • New York Heart Association class IV heart failure; **and** • patient has been counseled to continue reduced-calorie diet and increased physical activity; **and** • requested agent will not be used in combination with another GLP-1 receptor agonist; **and** • requested quantity is ≤ four pens/28 days; **and** • medical records documenting patient is receiving all clinically appropriate therapies for management of cardiovascular disease, adverse reaction, or contraindication to the following: • for history of myocardial infarction:antiplatelet; **and** • ACE-I or ARB; **and** • beta blocker; **and** • statin; **or** • for history of ischemic stroke: • antiplatelet or anticoagulant; **and** • blood pressure management regimen; **and** • statin; **or** • for history of hemorrhagic stroke: • blood pressure management regimen; **or** • for symptomatic peripheral artery disease: • antiplatelet; **and** • blood pressure management regimen; **and** • statin. • For recertification, documentation of the following is required: • patient weight (dated within the last 90 days); **and** • patient requires Wegovy for cardiovascular protection and the benefit of cardiovascular protection outweighs the risk associated with the use of GLP-1 agents; **and** • patient has been counseled to continue with reduced-calorie diet and increased physical activity; **and** • one of the following: • patient continues to receive appropriate therapies for management of cardiovascular disease; **or** • adverse reaction or contraindication to clinically appropriate therapies for management of cardiovascular disease. **Zepbound** • Documentation of the following is required: • diagnosis of moderate to severe obstructive sleep

	Clinical Notes

	apnea (OSA) in obesity; **and**
	• patient is ≥ 18 years of age; **and**
	• prescriber is a neurologist, pulmonologist, or sleep specialist or consult notes from a neurologist, pulmonologist, **or** sleep specialist, are provided; **and**
	• medical records documenting the results of the sleep study used to confirm narcolepsy (polysomnogram); **and**
	• medical records documenting apnea-hypopnea index (AHI) ≥15 events/hour; **and**
	• patient weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
	• patient BMI is ≥ 30 kg/m^2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); **and**
	• attestation that the patient does not have any of the following:
	  • type 1 diabetes mellitus; **or**
	  • type 2 diabetes mellitus; **or**
	  • central or mixed sleep apnea; **or**
	  • obesity hypoventilation syndrome or daytime hypercapnia; **or**
	  • major craniofacial abnormalities; **or**
	  • planned procedure for sleep apnea or obesity; **and**
	• patient has been counseled to continue reduced-calorie diet and increased physical activity; **and**
	• requested quantity is ≤ four pens/28 days; **and**
	• requested agent will not be used in combination with another GLP-1 receptor agonist.
	
	• For recertification, documentation of the following is required:
	  • patient weight (dated within the last 90 days); **and**
	  • improvement in OSA symptoms, such as less daytime sleepiness, fewer sleep arousals, or fewer partner-reported snoring episodes or pauses in breathing; **and**
	  • patient has been counseled to continue with reduced-calorie diet and increased physical activity.
	
	GLP-1 and GIP/GLP-1 Agonist Polypharmacy
	• Documentation of the following is required:
	  • individual drug prior authorization criteria must be met first where applicable; **and**

	Clinical Notes
	• patient is transitioning from one GLP-1 or GIP/GLP-1 agonist to another, and prior GLP-1 or GIP/GLP-1 agonist use will be discontinued.

HSNE This product is not payable under Health Safety Net for weight loss.

II. Therapeutic Uses

FDA-approved, for example:

- Moderate to severe OSA in obesity – Zepbound
- Risk reduction of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in patients with established cardiovascular disease and obesity or overweight – Wegovy

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of patient's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and patient's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Please see clinical criteria for agents requiring PA in the table above under the Clinical Notes section.

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Androgen Therapy
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested

- ☐ Androgel (testosterone 1% gel packet)
- ☐ Androgel (testosterone 1.62% gel packet)
- ☐ Aveed (testosterone undecanoate injection)[MB]
- ☐ Azmiro (testosterone cypionate)
- ☐ Jatenzo (testosterone undecanoate capsule)
- ☐ methyltestosterone
- ☐ Natesto (testosterone nasal gel)
- ☐ Testopel (testosterone intramuscular pellet)
- ☐ testosterone 1% gel tube
- ☐ testosterone 1.62% gel pump
- ☐ testosterone 2% gel pump
- ☐ testosterone cypionate
- ☐ testosterone enanthate
- ☐ testosterone 2% solution
- ☐ testosterone undecanoate capsule
- ☐ Tlando (testosterone undecanoate capsule)
- ☐ Vogelxo (testosterone 1% gel packet)
- ☐ Vogelxo (testosterone 1% gel pump)
- ☐ Xyosted (testosterone enanthate)
- ☐ Other*

Dose, frequency, and duration of medication requested

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

[MB] This drug is available through the healthcare professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other healthcare professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Delayed puberty
- ☐ Hypogonadism
- ☐ Gender dysphoria
- ☐ Metastatic mammary cancer
- ☐ Other (if none of the above apply)

Please note: MassHealth does not pay for any drug when used for the treatment of sexual dysfunction as described in 130 CMR 406.413(B): Drug Exclusions. For additional information go to: www.mass.gov/regulations/130-CMR-406000-pharmacy-services.

Is the member stabilized on the requested medication? ☐ Yes. Please provide start date. ☐ No

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Section I. Please provide any lab test results that confirm the diagnosis as indicated above.

1. Test ____ Lab value ____
   Reference range ____ Date obtained ____

2. Test Lab value

   Reference range Date obtained

3. Test Lab value

   Reference range Date obtained

Section II. Please complete for Aveed and Xyosted requests.

1. Has the member tried testosterone cypionate intramuscular injection?
   - ☐ Yes. Please describe the dates/duration of use and outcome.

     Dates/duration of use

     Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

     Briefly describe the details of adverse reaction, inadequate response, contraindication, or other.
   - ☐ No
2. Has the member tried testosterone enanthate intramuscular injection?
   - ☐ Yes. Please describe the dates/duration of use and outcome.

     Dates/duration of use

     Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

     Briefly describe the details of adverse reaction, inadequate response, contraindication, or other.
   - ☐ No
3. For Xyosted requests, is there a contraindication to testosterone cypionate intramuscular injection and testosterone enanthate intramuscular injection?
   - ☐ Yes. Please describe.
   - ☐ No
4. For Xyosted requests, does the member have needle phobia? ☐ Yes ☐ No

   If yes, has the member had a trial of two topical non-injectable formulations of testosterone?
   - ☐ Yes. Please list the drug names, dates/duration of use, and outcomes below.
   - ☐ No. Please describe if there is a contraindication to all topical non-injectable formulations of testosterone.

   Please provide details for the previous trials.

   Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Section III. Please complete for Azmiro requests.

1. Please provide medical necessity for use instead of testosterone cypionate injection (Depo-Testosterone).

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2. Has the member tried testosterone enanthate intramuscular injection?
   ☐ Yes. Please describe the drug name, dates/duration of use, and outcome.
   Drug Name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Please describe if there is a contraindication to testosterone enanthate intramuscular injection.

Section IV. Please complete for Jatenzo, methyltestosterone, testosterone undecanoate capsule, and Tlando requests.

1. Has the member tried two non-injectable formulations of testosterone?
   ☐ Yes. Please describe the drug names, dates/duration of use, and outcomes.
   Drug Name Dates/duration of use
   over
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, contraindication, or other.
   Drug Name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, contraindication, or other.
   ☐ No. Please describe if there is a contraindication to all non-injectable formulations of testosterone.
2. For methyltestosterone requests, has the member also tried testosterone undecanoate capsules?
   ☐ Yes. Please describe the dates/duration of use, and outcomes. Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, contraindication, or other.
   ☐ No. Please describe if there is a contraindication to testosterone undecanoate capsules.
3. For methyltestosterone capsule requests, please provide medical necessity for use instead of tablet formulation.

Section V. Please complete for requests for quantities above quantity limits.

Please describe the clinical rationale for exceeding the quantity limit.

over

Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Anti-Amyloid Monoclonal Antibodies
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ Kisunla (donanemab-azbt)
☐ Leqembi (lecanemab-irmb)

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Alzheimer's Disease (Specify stage of disease.)

☐ Mild cognitive impairment ☐ Mild dementia ☐ Other

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Is the prescriber a specialist in the treatment of dementia or Alzheimer's Disease?
☐ Yes
☐ No. Please attach consultation notes from a specialist in the treatment of dementia or Alzheimer's Disease (e.g., neurologist, geriatric psychiatrist, geriatrician who specializes in treating dementia).

Section I. Please complete for all requests.

Please note testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing amyloid related imaging abnormalities (ARIA). ApoE ε4 genotyping is covered with prior authorization obtained through the Provider Online Service Center (POSC).

1. Please provide baseline (within the past three months) score of one of the following tests.

   Mini Mental State Exam (MMSE) Date

   Montreal Cognitive Assessment (MoCA) Date

   Saint Louis University Mental Status Examination (SLUMS) Date

2. Does the member have confirmed evidence of clinically significant Alzheimer's Disease (AD) neuropathology based on one of the following? If yes, please attach supporting documentation.
   ☐ Yes, based on Cerebral Spinal Fluid (CSF) biomarkers. Please attach supporting documentation.
   ☐ Yes, based on Amyloid positron emission tomography (PET). Please attach supporting documentation.
   ☐ No
3. Has the member had a brain magnetic resonance imaging (MRI) in the previous 12 months?
   ☐ Yes. Date ☐ No
4. For Kisunla, has the member had a trial with Leqembi?
   ☐ Yes. Please list the dose and frequency, dates/duration of trials, and outcomes below.

   Dose and frequency Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please describe why Leqembi is not appropriate for this member.

Section II. Please complete for all recertification requests.

1. Has the member had follow-up MRIs completed in accordance with the FDA-approved label?
   ☐ Yes. Please describe.
   ☐ No
2. Please provide most recent score and date administered for one of the following tests.
   MMSE Date
   MoCA Date
   SLUMS Date
3. For Lequembi, after completion of 18 months of treatment, is the requested dose every four weeks?
   ☐ Yes
   ☐ No. Please provide clinical rationale for requested dose.

Section III. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

over

4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
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☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Anti-Hemophilia Non-Gene Therapy Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ Alhemo (concizumab-mtci)
☐ Hympavzi (marstacimab-hncq)

Dose and frequency of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Hemophilia A
☐ Hemophilia B
☐ Other

Please indicate severity. ☐ Moderately severe to severe ☐ Severe
Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Is this member a referral candidate for care coordination? ☐ Yes ☐ No
If yes, MassHealth will offer care coordination services to this member**.** Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete questions for all requests.

1. Member's current weight Date
2. Is the prescriber a hematologist? ☐ Yes ☐ No. Please attach consultation notes from a hematologist.
3. Baseline annual bleeding rate (ABR) Date
4. For Alhemo, has the member tried bypassing agents?
   ☐ Yes. Please describe the dates/duration of use and outcome.
   Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Please describe why bypassing agents are not appropriate for this member.
5. For Hympavzi, has the member received any prior gene therapy for the requested diagnosis?
   ☐ Yes. Please describe. ☐ No

6. For Hympavzi, is the member able to maintain venous access for infusions? ☐ Yes ☐ No
7. For Hympavzi 300 mg weekly dosing, has the member tried 150 mg weekly dosing?
   ☐ Yes. Please describe the dates/duration of use and outcome.
   Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Please explain why not.
8. For Hympavzi 300 mg weekly dosing, has the member had breakthrough bleeds within a 6-month period?
   ☐ Yes. Please provide the number of breakthrough bleeds, including dates.
   ☐ No

Section II. Please also complete for hemophilia A.

1. Does the member have factor VIII inhibitor? (Please attach a copy of test.) ☐ Yes ☐ No
2. Has the member tried Hemlibra?
   ☐ Yes. Please describe the dates/duration of use and outcome.
   Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Please describe why Hemlibra is not appropriate for this member.
3. For Hympavzi, has the member tried factor VIII products? ☐ Yes. Please complete questions below. ☐ No
   If used as on-demand therapy, has the member had ≥ 6 acute bleeding episodes that required coagulation with factor VIII infusion within 6 months before discontinuation? ☐ Yes ☐ No
   Please provide details.
   If used as prophylaxis therapy, has the member had an inadequate response or adverse reaction while compliant (defined as ≥ 80% compliance with factor VIII regimen within 6 months before discontinuation)?
   ☐ Yes ☐ No
   Please provide details.
4. Will the member be receiving other hemophilia A prophylaxis (e.g., factor VIII products or Hemlibra for Hympavzi, bypassing agents for Alhemo) in conjunction with requested agent?
   ☐ Yes. Please provide details. ☐ No

Section III. Please also complete for moderately severe to severe hemophilia B.

1. Does the member have factor IX inhibitor? (Please attach a copy of test.) ☐ Yes ☐ No
2. For Hympavzi, has the member tried factor IX products? ☐ Yes. Please complete questions below. ☐ No
   If used as on-demand therapy, has the member had ≥ 6 acute bleeding episodes that required coagulation with factor IX infusion within 6 months before discontinuation? ☐ Yes ☐ No
   Please provide details.
   If used as prophylaxis therapy, has the member had an inadequate response or adverse reaction while compliant (defined as ≥ 80% compliance with factor IX regimen within 6 months before discontinuation)?
   ☐ Yes ☐ No

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Please provide details.

3. Will the member be receiving other hemophilia B prophylaxis (e.g., factor IX products for Hympavzi, bypassing agents for Alhemo) in conjunction with requested agent?

☐ Yes. Please provide details. ☐ No

Section IV. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen? ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, and Children's Medical Security Plan
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MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Anti-Obesity Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication Requested

- ☐ benzphetamine
- ☐ diethylpropion
- ☐ diethylpropion ER
- ☐ Lomaira (phentermine 8 mg tablet) < 12 years or ≥ 18 years
- ☐ orlistat
- ☐ phendimetrazine
- ☐ phendimetrazine ER
- ☐ phentermine 15 mg, 30 mg capsule < 12 years
- ☐ phentermine 37.5 mg capsule, tablet < 12 years
- ☐ Saxenda (liraglutide)
- ☐ Wegovy (semaglutide injection)
- ☐ Zepbound (tirzepatide)
- ☐ Other

Dose and frequency of medication requested

Is the member stabilized on the requested medication? ☐ Yes. Please provide start date. ☐ No

Indication or ICD-10 code, if applicable

- ☐ Obesity*
- ☐ Overweight*
- ☐ Risk reduction of major adverse cardiovascular events with established cardiovascular disease and obesity or overweight
- ☐ Moderate to severe obstructive sleep apnea (OSA) with obesity
- ☐ Other

**Please note, Saxenda and Wegovy are not covered for MassHealth members for the treatment of overweight or obesity for adults. In addition, anti-obesity agents are not payable for Health Safety Net patients for weight loss. Wegovy and Zepbound may still be payable for other medically accepted indications, please utilize Health Safety Net Formulary Exceptions Prior Authorization Request form.*

Section I. Please complete for all requests.

1. Member's baseline weight ____ kg Date ____
2. Member's current weight ____ kg Date ____
3. Member's current height ____ cm Date ____
4. Member's baseline BMI ____ kg/m^2 Date ____
5. Member's current BMI ____ kg/m^2 Date ____
6. Has the member been counseled to continue reduced-calorie diet and increased physical activity?
   ☐ Yes ☐ No

7. Does the member have any of the following weight-related comorbid conditions?

Coronary heart disease or other atherosclerotic disease	☐ Yes	☐ No
Dyslipidemia	☐ Yes	☐ No
Hypertension	☐ Yes	☐ No
Non-alcoholic steatohepatitis (NASH)	☐ Yes	☐ No
Obstructive sleep apnea	☐ Yes	☐ No
Polycystic ovarian syndrome	☐ Yes	☐ No
Prediabetes	☐ Yes	☐ No
Systemic osteoarthritis	☐ Yes	☐ No
Type 2 diabetes mellitus	☐ Yes	☐ No
Other comorbidity	☐ Yes	☐ No

8. For Saxenda, Wegovy and Zepbound requests, will the requested agent be used in combination with another GLP-1 receptor agonist? ☐ Yes ☐ No
9. For members < 12 years of age for Lomaira and phentermine requests, please provide medical necessity to support the use of phentermine in a member < 12 years of age.
10. For benzphetamine, diethylpropion, diethylpropion ER, Lomaira, phendimetrazine, phendimetrazine ER, Saxenda for members <18 years of age, Wegovy for members <18 years of age, and Zepbound requests, has the member had a trial with phentermine with or without topiramate?
    ☐ Yes. Please list the dates/duration of trials and outcomes below. If the member had an adverse reaction, please attach medical records documenting adverse reaction.
    Drug name Dates/duration of use
    Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
    Briefly describe details of adverse reaction, inadequate response, or other.
    ☐ No. Please attach medical records documenting a contraindication to phentermine.

Section II. Please also complete for indication of risk reduction of major adverse cardiovascular events for Wegovy requests.

1. Please indicate if the member has any of the following cardiovascular conditions. Check all that apply and please provide medical records documenting cardiovascular condition(s).
   ☐ History of myocardial infarction
   ☐ History of stroke (ischemic or hemorrhagic)
   ☐ Symptomatic peripheral arterial disease (e.g., intermittent claudication with ankle–brachial index <0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease)
2. Does the member have any of the following chronic medical conditions?

Type 1 diabetes mellitus	☐ Yes	☐ No
Type 2 diabetes mellitus	☐ Yes	☐ No
New York Heart Association Class IV Heart Failure	☐ Yes	☐ No

Section III. Please complete for recertification requests.

For recertification requests for Zepbound for members with diagnosis of moderate to severe obstructive sleep apnea (OSA) with obesity, please provide medical records verifying baseline or current OSA diagnosis with ≥ 15 AHI and complete questions 5 – 6.

1. Member's current weight Date

over

2. Does the member have improvement in measures of comorbid conditions? ☐ Yes ☐ No

   If yes, please describe.
3. Does the member have improvement in measures of comorbid conditions believed to be related to anti-obesity therapy despite lack of reduction in body weight? ☐ Yes ☐ No

   If yes, please describe.
4. For Wegovy recertification requests, does the member require use of Wegovy for cardiovascular protection and the benefit of cardiovascular protection outweighs the risk associated with use of GLP-1 agents?

   ☐ Yes, please explain and provide medical records documenting cardiovascular condition(s).

   ☐ No
5. Does the member have improvement in OSA symptoms, such as less daytime sleepiness, fewer sleep arousals, or fewer-partner reported snoring episodes or pauses in breathing? ☐ Yes ☐ No

   If yes, please describe.
6. Does the member have improvement in OSA symptoms believed to be related to anti-obesity therapy despite lack of reduction in body weight? ☐ Yes ☐ No

Section V. Please complete for GLP-1 and GIP/GLP-1 agonist polypharmacy requests.

Please complete information for medications requested and select the reason for polypharmacy.

1. Drug name Dates/duration of use
2. Drug name Dates/duration of use

☐ Member is transitioning from one GLP-1 or GIP/GLP-1 agonist to another and prior GLP-1 or GIP/GLP-1 agonist use will be discontinued.

☐ Other, please explain.

Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

over

If yes, please provide details for the previous trial.

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

_____

_____

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details. _____

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Anticoagulant and Antiplatelet Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Anticoagulants

- ☐ Pradaxa (dabigatran oral pellet)
- ☐ rivaroxaban 2.5 mg tablet > 2 units/day
- ☐ Savaysa (edoxaban)
- ☐ Xarelto (rivaroxaban suspension) ≥ 18 years

Antiplatelet

- ☐ Zontivity (vorapaxar)

Dose and frequency of medication requested _____ **Duration requested** _____

Indication for Anticoagulant (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Nonvalvular atrial fibrillation
- ☐ Reduce the risk of major cardiovascular (CV) events in coronary artery disease (CAD)/peripheral artery disease (PAD)
- ☐ Reduce the risk of recurrence of DVT and PE
- ☐ Thromboprophylaxis in pediatric member with congenital heart disease after Fontan procedure
- ☐ Treatment of DVT
- ☐ Treatment of PE
- ☐ Other _____

Indication for Antiplatelet (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Non-ST elevation myocardial infarction (MI)
- ☐ PAD
- ☐ ST elevation MI
- ☐ Other _____

Section I. Please complete for Pradaxa oral pellet requests.

1. Member's current weight _____ Date _____
2. Has the member received or will the member receive ≥ five days of injectable or intravenous anticoagulation prior to starting the requested agent? ☐ Yes ☐ No
3. Has the member had a trial with Xarelto suspension or rivaroxaban tablets?
   - ☐ Yes. Please list the drug name, dose and frequency, dates/duration of trials, and outcomes below.

     Drug name _____ Dose and frequency _____ Dates/duration of use _____

     Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

     Briefly describe details of adverse reaction, inadequate response, or other.

     _____
   - ☐ No. Please describe why Xarelto suspension or rivaroxaban tablets are not appropriate for this member.

     _____

4. For members ≥ eight years of age, has the member had a trial with dabigatran capsule?
   ☐ Yes. Please list the dates/duration of trials and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why dabigatran capsule is not appropriate for this member, or describe if there is medical necessity for the oral pellet formulation.

Section II. Please complete for Savaysa requests.

1. Has the member had a trial with dabigatran capsule?
   ☐ Yes. Please list the dates/duration of trials and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why dabigatran capsule is not appropriate for this member.

2. Has the member had a trial with Eliquis?
   ☐ Yes. Please list the dates/duration of trials and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why Eliquis is not appropriate for this member.

3. Has the member had a trial with rivaroxaban?
   ☐ Yes. Please list the dates/duration of trials and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why rivaroxaban is not appropriate for this member.

Section III. Please complete for rivaroxaban 2.5 mg tablet requests > 2 units/day.

Please describe the medical necessity for use above the established quantity limit.

over

Section IV. Please complete for Xarelto suspension requests for members ≥ 18 years of age.

Please describe the medical necessity for the suspension formulation of Xarelto.

Section V. Please complete for Zontivity requests.

1. Does the member have a history of stroke, transient ischemic attack, or intracranial hemorrhage?
   ☐ Yes ☐ No
2. Is the member receiving concurrent aspirin and/or clopidogrel therapy?
   ☐ Yes. Drug Dose Frequency
   ☐ No

Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Anticonvulsant
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about anticonvulsants and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form**.

Medication information

Medication requested (Check one or all that apply.)

- ☐ Briviact (brivaracetam solution, tablet)
- ☐ Diacomit (stiripentol)
- ☐ diazepam rectal gel > 5 kits (10 syringes)/30 days
- ☐ Elepsia XR (levetiracetam extended-release)
- ☐ Epidiolex (cannabidiol)
- ☐ Eprontia (topiramate solution)
- ☐ eslicarbazepine
- ☐ everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg
- ☐ everolimus tablets for oral suspension
- ☐ Fintepla (fenfluramine)
- ☐ Fycompa (perampanel)
- ☐ gabapentin >3600 mg/day
- ☐ Lamictal XR starter kit, lamotrigine extended-release
- ☐ lamotrigine orally disintegrating tablet (ODT), ODT starter kit
- ☐ lamotrigine tablet starter kit
- ☐ Libervant (diazepam buccal film) > 10 units/30 days or ≥ 6 years of age
- ☐ levetiracetam tablet for oral suspension
- ☐ Motpoly XR (lacosamide extended-release capsule)
- ☐ Nayzilam (midazolam nasal spray) >10 units/30 days
- ☐ oxcarbazepine extended-release
- ☐ pregabalin > 600 mg/day
- ☐ rufinamide
- ☐ Sympazan (clobazam film)
- ☐ tiagabine
- ☐ topiramate extended-release capsule [Trokendi XR]
- ☐ Valtoco (diazepam nasal spray) >10 units/30 days
- ☐ vigabatrin powder packet, tablet
- ☐ Vigafyde (vigabatrin solution)
- ☐ Xcopri (cenobamate)
- ☐ Zonisade (zonisamide suspension)
- ☐ Ztalmy (ganaxolone)
- ☐ Other*

Dose, frequency, and duration of medication requested

Drug NDC (if known) or service code

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Bipolar disorder
- ☐ Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) (provide documentation of genetic testing)
- ☐ Diabetic peripheral neuropathy
- ☐ Dravet syndrome
- ☐ Epilepsy or seizure disorder
  Type
- ☐ Epilepsy associated with tuberous sclerosis complex
- ☐ Fibromyalgia
- ☐ Infantile spasms
- ☐ Lennox-Gastaut syndrome
- ☐ Migraine prophylaxis
- ☐ Pain associated with trigeminal neuralgia
- ☐ Postherpetic neuralgia
- ☐ Other

Please list all other medications currently prescribed for the member for this indication.

Please indicate prescriber specialty below.

☐ Neurology ☐ Psychiatry ☐ Other

If prescriber is not a specialist, please attach consult notes from specialist.

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

1. Drug Dates of Use Outcome
2. Drug Dates of Use Outcome
3. Drug Dates of Use Outcome
4. Drug Dates of Use Outcome

**Attach a letter with additional information regarding medication trials as applicable.*

Section II. Please also complete for requests for Elepsia XR, Eprontia, Lamictal XR starter kit, lamotrigine extended-release, lamotrigine tablet starter kit, levetiracetam tablet for oral suspension, Motpoly XR, oxcarbazepine extended-release, topiramate extended-release capsule [Trokendi XR], Vigafyde, and Zonisade.

Please provide medical necessity for the use of the requested formulation instead of the respective formulation(s) that is available without prior authorization. For Motpoly XR and Vigafyde, please also provide the member's current weight.

Section III. Please complete for requests for gabapentin containing agents > 3600 mg/day and pregabalin containing agents > 600 mg/day.

Please provide clinical rationale for exceeding the maximum daily dose limit.

over

Section IV. Please complete for requests for Diacomit.

1. Has the member experienced an inadequate response or adverse reaction to other anticonvulsants?
   ☐ Yes. Please complete Section I above.
   ☐ No. Explain why other anticonvulsants have not been tried.
2. Will the requested agent be used in combination with clobazam? ☐ Yes ☐ No

Section V. For requests for Epidiolex, please attach medical records supporting the diagnosis.

Section VI. Please complete for requests for lamotrigine ODT.

1. Does the member have a medical condition in which they are not able to swallow pills?
   ☐ Yes. Please describe. ☐ No
2. Has the member experienced an inadequate response or adverse reaction to lamotrigine dispersible tablets?
   ☐ Yes. Please describe trial below.
   Dose and frequency Dates of Use Outcome
   ☐ No. Explain why lamotrigine dispersible tablets have not been tried.

Section VII. Please complete for requests for diazepam rectal gel (> 5 kits/month), Libervant (> 10 units/30 days), Nayzilam (> 10 units/30 days), and Valtoco (> 10 units/30 days).

1. Is the diagnosis for as needed (intermittent) treatment of acute seizure clusters that are distinct from a member's usual seizure pattern? ☐ Yes ☐ No
2. Please describe the medical necessity for use over quantity limits.

Section VIII. Please complete for requests for Libervant for members ≥ six years of age.

1. Is the diagnosis for as needed (intermittent) treatment of acute seizure clusters that are distinct from a member's usual seizure pattern? ☐ Yes ☐ No
2. Has the member experienced an inadequate response or adverse reaction to Valtoco?
   ☐ Yes. Please describe trial below.
   Dose and frequency Dates of Use Outcome
   ☐ No. Explain why Valtoco has not been tried.

Section IX. Concomitant gabapentin and pregabalin for all formulations. Complete this section for all members, if request will result in prescription of concomitant gabapentin and pregabalin.

Please document complete treatment plan.

1. gabapentin dose/frequency Indication
2. pregabalin dose/frequency Indication
3. Other(s)

over

Please document clinical rationale for concomitant use of gabapentin and pregabalin for this member.

Please document monotherapy trials (include dose/frequency, dates/duration of use, and outcome) with gabapentin and pregabalin.*

Has the member experienced an inadequate response or adverse reaction to at least two other alternative agents for the requested indication(s)?

☐ Yes. Please complete Section I above.

☐ No. Explain why other alternative agents have not been tried.

Section X. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

over

MassHealth Pediatric Behavioral Health Medication Initiative

Please fill out all the sections below, as applicable, for pediatric members only. You may also use the Pediatric Behavioral Health Medication Initiative PA Request Form if the member is prescribed other behavioral health medications.

Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name _____ Dose/frequency _____ Indication _____
2. Medication name _____ Dose/frequency _____ Indication _____
3. Medication name _____ Dose/frequency _____ Indication _____
4. Medication name _____ Dose/frequency _____ Indication _____
5. Medication name _____ Dose/frequency _____ Indication _____
6. Medication name _____ Dose/frequency _____ Indication _____
7. Other(s) _____

Is the member currently in an acute care setting?

☐ Yes (Inpatient) ☐ Yes (Community Based Acute Treatment)
☐ Yes (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.

Prescriber name _____ Contact information _____

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months. _____
☐ No

On the current regimen, is the member considered to be a severe risk of harm to self or others?

☐ Yes. Please provide details. _____ ☐ No

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g., weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain. _____

Has informed consent from a parent or legal guardian been obtained?* ☐ Yes ☐ No

Please indicate prescriber specialty below.

☐ Psychiatry ☐ Neurology ☐ Other _____
☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

_____

Name(s) of the specialist(s) _____ Date(s) of last visit or consult _____

Contact information _____

over

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility

☐ Uncertain ☐ Other

Please document agency involvement.

☐ DCF ☐ Department of Mental Health (DMH) ☐ Department of Developmental Services (DDS)

☐ Department of Youth Services (DYS)

Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions below, if applicable. ☐ No

Psychiatric care provided is coordinated with other psychotherapeutic and community based services. ☐ Yes ☐ No

** Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information go to https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information.*

Please complete for members who have been on one of the following for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation): a polypharmacy regimen, members < six years of age who have been on an applicable behavioral health medication, and members < ten years of age who have been on an antipsychotic.

Have previous efforts to reduce or simplify the regimen in the past 24 months resulted in symptom exacerbation? ☐ Yes ☐ No

The family or caregiver does not support the regimen change at this time due to risk of exacerbation. ☐ Yes ☐ No

Is there another significant barrier for therapy discontinuation? ☐ Yes ☐ No

If yes, please explain.

Section II. Mood Stabilizer Polypharmacy. Complete this section for all members < 18 years of age, if request will result in prescription of three or more mood stabilizers for ≥ 60 days within a 90-day period (agents considered to be used only for seizure diagnoses are not included).

Please document if monotherapy trials (include drug name, dates/duration of use, and outcome) with mood stabilizers were tried before prescribing polypharmacy with three or more mood stabilizers in this member.*

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

over

Has the member been on a mood stabilizer polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?
☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Section III. Mood Stabilizer Request for Members < six years of age (agents considered to be used only for seizure diagnoses are not included).

Please document any previous medication trial(s). Include the drug name, dates/duration of use, and outcome.*

Please document clinical rationale for use of a mood stabilizer for this member < six years of age.

Has the member been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Section IV. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.*

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen

Has the member been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Antidepressant
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about antidepressants and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form**.

Medication information

Medication requested

- ☐ amoxapine
- ☐ Aplenzin (bupropion hydrobromide extended-release)
- ☐ Auvelity (dextromethorphan/bupropion)
- ☐ bupropion XL > 1 unit/day
- ☐ bupropion hydrochloride extended-release 450 mg tablet
- ☐ citalopram capsule
- ☐ clomipramine
- ☐ desipramine
- ☐ desvenlafaxine extended-release
- ☐ desvenlafaxine succinate extended-release 25 mg, 50 mg tablet > 1 unit/day
- ☐ desvenlafaxine succinate extended-release 100 mg tablet > 4 units/day
- ☐ Drizalma (duloxetine sprinkle capsule)
- ☐ duloxetine 40 mg capsule
- ☐ Emsam (selegiline)
- ☐ Fetzima (levomilnacipran)
- ☐ fluoxetine 60 mg tablet
- ☐ fluoxetine 90 mg delayed-release capsule
- ☐ fluvoxamine extended-release
- ☐ imipramine pamoate tablet
- ☐ Ketalar (ketamine injection)[MB]
- ☐ Marplan (isocarboxazid)
- ☐ mirtazapine orally disintegrating tablet
- ☐ olanzapine/fluoxetine
- ☐ paroxetine controlled-release
- ☐ protriptyline
- ☐ sertraline capsule
- ☐ Spravato (esketamine)
- ☐ trazodone 300 mg tablet
- ☐ trimipramine
- ☐ Trintellix (vortioxetine)
- ☐ venlafaxine besylate extended-release tablet
- ☐ venlafaxine hydrochloride extended-release tablet
- ☐ vilazodone
- ☐ Zurzuvae (zuranolone)
- ☐ Other* _____

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

[MB] This drug is available through the healthcare professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other healthcare professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

Dose, frequency, and duration of medication requested _____

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Requests for Spravato for *treatment resistant depression*, please select one of the following dosing regimens:

Weeks 1 to 4:	☐ 56 mg twice weekly	☐ 84 mg twice weekly
Weeks 5 to 8:	☐ 56 mg once weekly	☐ 84 mg once weekly
Weeks 9 to 52:	☐ 56 mg once weekly	☐ 56 mg once every other week
	☐ 84 mg once weekly	☐ 84 mg once every other week
Greater than 52 weeks:	☐ 56 mg once weekly	☐ 56 mg once every other week
	☐ 84 mg once weekly	☐ 84 mg once every other week

☐ Other. Week of therapy

Please explain requested dosing.

Requests for Spravato for *Major depressive disorder* (*MDD) with acute suicidal ideation or behavior*, please select dosing regimen.

☐ 84 mg twice weekly for four weeks

☐ Other

Please explain requested dosing.

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Major depressive disorder
☐ Obsessive-compulsive disorder
☐ Premenstrual dysphoric disorder
☐ Panic disorder
☐ Postpartum depression
☐ Other (describe)

Please list all other psychotropic medications currently prescribed for the member.

Has member been hospitalized for this condition?

☐ Yes. Dates of most recent hospitalization ☐ No

Is the member under the care of psychiatrist? ☐ Yes ☐ No

Name of psychiatrist

Telephone no. Date of last visit or consult with psychiatrist

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for Aplenzin, bupropion hydrochloride extended-release 450 mg tablet, citalopram capsule, desvenlafaxine extended-release, duloxetine 40 mg capsule, fluoxetine 60 mg tablet, fluoxetine 90 mg delayed-release capsule, fluvoxamine extended-release, imipramine pamoate, sertraline capsule, trazodone 300 mg tablet, venlafaxine besylate extended-release tablet, and venlafaxine hydrochloride extended-release tablet.

Please attach medical records documenting an inadequate response (defined as at least four weeks of therapy) or adverse reaction to the respective formulation of the agent requested at an equivalent dose that is available without prior authorization.

over

Section II. Please complete for requests for amoxapine, Auvelity, clomipramine, desipramine, Fetzima, Marplan, protriptyline, trimipramine, Trintellix, and vilazodone.

Please describe applicable antidepressant trials and outcomes (attach a letter with additional information regarding trials as applicable).

Drug name Dates/duration of use Dose and frequency
Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use Dose and frequency
Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

Section III. Please complete for requests for Emsam.

1. Has the member had a trial with one SSRI and one non-SSRI antidepressant?
   ☐ Yes. Please list the drug name, dose and frequency, dates/duration of trials, and outcomes below.

   Drug name Dose and frequency Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   Drug name Dose and frequency Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain why not.
2. Is there a medical necessity for the transdermal formulation? ☐ Yes ☐ No
   If yes, please explain.

Section IV. Please complete for requests for Drizalma

Please document medical necessity for the requested formulation instead of the solid oral formulation.

Section V. Please complete for requests for mirtazapine orally disintegrating tablet.

Is there a medical necessity for the specific dosage formulation?

☐ Yes. Please explain.
☐ No. Has the member tried mirtazapine tablets?
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

over

Section VI. Please complete for requests for olanzapine/fluoxetine.

Please describe the medical necessity for use of the combination product instead of the commercially available separate agents.

Section VII. Please complete for requests for Ketalar and Spravato.

Requests for Ketalar and Spravato for *treatment resistant depression* and subsequent requests for Spravato *for MDD with acute suicidal ideation or behavior* please complete questions 1 and 2. Initial requests for Spravato for *major depressive disorder (MDD) with acute suicidal ideation or behavior*, please complete questions 3 and 4.

1. Please attach medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one SSRI and one non-SSRI antidepressant. If there is a contraindication to SSRI and non-SSRI antidepressants, attach medical records documenting the contraindication.
2. Please attach medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction with one of the following used in combination with an SSRI or other non-SSRI: second-generation antipsychotic, a mood stabilizer such as lithium or lamotrigine, a second antidepressant from a different class, thyroid hormone. If there is a contraindication to all antidepressant augmentation strategies, attach medical records documenting the contraindication.
3. Please attach medical records documenting either current acute suicidal ideation or behavior related to depressive symptoms of MDD, or that the member was stabilized on Spravato during a psychiatric hospitalization.
4. Will the requested agent be used in combination with an oral antidepressant? ☐ Yes ☐ No

Section VIII. Please complete for requests for bupropion XL > 1 unit/day, desvenlafaxine succinate extended-release 25 mg, 50 mg tablet > 1 unit/day or desvenlafaxine succinate extended-release 100 mg tablet > 4 units/day

Has dose consolidation been attempted? ☐ Yes ☐ No. Please describe medical necessity for quantities above 1 unit/day.

Section IX. Please complete for requests for Zurzuvae.

1. Is the member ≤ 12 months postpartum? ☐ Yes. Please document date of delivery. ☐ No
2. Is the member currently pregnant? ☐ Yes ☐ No
3. Has the member had a trial with one of the following: bupropion, citalopram, duloxetine, escitalopram, fluoxetine, mirtazapine, sertraline, venlafaxine?
   ☐ Yes. Please list the drug name, dose and frequency, dates/duration of trials, and outcomes below.
   Drug name Dose and frequency Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Please explain why not.
4. Does the member have a requirement for rapid symptom reduction? ☐ Yes ☐ No

over

5. Requests for 30 mg capsule, does the member have severe hepatic impairment (Child-Pugh Class C) or moderate to severe renal impairment (eGFR < 60 mL/min/1.73m^2)?

   ☐ Yes. Please describe.
   ☐ No
6. For recertification requests, please provide the last day of treatment with the requested agent and the total number of treatments including the current request.

   Last day of treatment with requested agent

   Total number of treatments including the current request

Section X. Antidepressant Polypharmacy for members ≥ 18 years of age. Please complete information for medications requested and select the reason for polypharmacy with antidepressants (two or more SSRI, SNRI, or Serotonin Modulator antidepressants for ≥ 60 days within a 90-day period).

1. Antidepressant name/dose/frequency Indication
2. Antidepressant name/dose/frequency Indication
3. Antidepressant name/dose/frequency Indication

Is member under the care of a psychiatrist?
☐ Yes. Please attach specialist consult details (if the prescriber submitting the request is not a specialist). ☐ No
For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

☐ Member was recently discharged from an inpatient setting on requested medications and is currently stable.
☐ Member experienced an inadequate response or adverse reaction to two monotherapy trials with antidepressants.

Drug name 1 Dates/Duration of use (if available)

Drug name 2 Dates/Duration of use (if available)

☐ Member is transitioning from one antidepressant to the other.

☐ Other, please explain.

Section XI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

over

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details. _____
   ☐ No

MassHealth Pediatric Behavioral Health Medication Initiative

Please fill out all the sections below, as applicable, for pediatric members only. You may also use the Pediatric Behavioral Health Medication Initiative PA Request Form if the member is prescribed other behavioral health medications.

Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name _____ Dose/frequency _____ Indication _____
2. Medication name _____ Dose/frequency _____ Indication _____
3. Medication name _____ Dose/frequency _____ Indication _____
4. Medication name _____ Dose/frequency _____ Indication _____
5. Medication name _____ Dose/frequency _____ Indication _____
6. Medication name _____ Dose/frequency _____ Indication _____
7. Other(s) _____

Is the member currently in an acute care setting?
☐ Yes (Inpatient) ☐ Yes (Community Based Acute treatment)
☐ Yes (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.
Prescriber name _____ Contact information _____

Has the member been hospitalized for a psychiatric condition within the past three months?
☐ Yes. Please document dates of hospitalization within the past three months. _____
☐ No

On the current regimen, is the member considered to be a severe risk of harm to self or others?
☐ Yes. Please provide details. _____
☐ No

over

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g., weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain.

Has informed consent from a parent or legal guardian been obtained?* ☐ Yes ☐ No

Please indicate prescriber specialty: ☐ Psychiatry ☐ Neurology ☐ Other

☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

Name(s) of the specialist(s) Date(s) of last visit or consult

Contact information

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility ☐ Uncertain

☐ Other

Please document agency involvement.

☐ DCF ☐ Department of Mental Health (DMH) ☐ Department of Developmental Services (DDS)

☐ Department of Youth Services (DYS)

Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions below, if applicable. ☐ No

Psychiatric care provided is coordinated with other psychotherapeutic and community based services. ☐ Yes ☐ No

* *Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information, go to* https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information.

Please complete for members who have been on one of the following for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation): a polypharmacy regimen, members < six years of age who have been on an applicable behavioral health medication, and members < ten years of age who have been on an antipsychotic.

Have previous efforts to reduce or simplify the regimen in the past 24 months resulted in symptom exacerbation? ☐ Yes ☐ No

The family or caregiver does not support the regimen change at this time due to risk of exacerbation.

☐ Yes ☐ No

Is there another significant barrier for therapy discontinuation? ☐ Yes ☐ No

If yes, please explain.

Section II. Antidepressant Polypharmacy. Complete this section for all members < 18 years of age, if request will result in prescription of two or more antidepressants ≥ 60 days within a 90-day period.

over

Please document if monotherapy trials (include drug name, dates/duration of use, and outcome) with antidepressants were tried before prescribing polypharmacy with two or more antidepressants in this member.*

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on an antidepressant polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?
☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Section III. Antidepressant Request for Members < six years of age.

Please document any previous medication trial(s). Include the drug name, dates/duration of use, and outcome.*

Please document clinical rationale for use of an antidepressant for this member < six years of age.

Has the member been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Section IV. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.*

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Antidiabetic Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested (Check one or all that apply. Where applicable, the brand name is provided in brackets for reference.)

Single Injectable Agents

- ☐ Bydureon Bcise (exenatide extended-release auto-injection)
- ☐ Byetta (exenatide 5 mcg) > 1.2 mL/30 days
- ☐ Byetta (exenatide 10 mcg) > 2.4 mL/30 days
- ☐ liraglutide [Victoza] > 9 mL/30 days
- ☐ Mounjaro (tirzepatide)
- ☐ Ozempic (semaglutide injection)
- ☐ Trulicity (dulaglutide) > 2 mL/28 days
- ☐ Tzield (teplizumab-mzwv)

Single Oral Agents

- ☐ alogliptin
- ☐ glimepiride 3 mg tablet
- ☐ Inpefa (sotagliflozin)
- ☐ Invokana (canagliflozin)
- ☐ metformin extended-release, gastric tablet [Glumetza]
- ☐ metformin extended-release, osmotic tablet
- ☐ metformin immediate-release 625 mg tablet
- ☐ metformin immediate-release solution ≥ 13 years of age
- ☐ miglitol
- ☐ Riomet ER (metformin extended-release suspension)
- ☐ Rybelsus (semaglutide tablet)
- ☐ saxagliptin
- ☐ Steglatro (ertugliflozin)
- ☐ Zituvio (sitagliptin)

Combination Injectable Agents

- ☐ Soliqua (insulin glargine/lixisenatide)
- ☐ Xultophy (insulin degludec/liraglutide)

Insulin Agents

- ☐ Admelog (insulin lispro)
- ☐ Afrezza (insulin human inhalation powder)
- ☐ Apidra (insulin glulisine)
- ☐ Basaglar (insulin glargine)
- ☐ Basaglar Tempo (insulin glargine)
- ☐ Fiasp (insulin aspart)
- ☐ Humalog Tempo (insulin lispro)
- ☐ Humulin N (insulin NPH)
- ☐ insulin aspart [Novolog]
- ☐ insulin glargine-yfgn
- ☐ Lyumjev (insulin lispro-aabc)
- ☐ Lyumjev Tempo (insulin lispro-aabc)
- ☐ Rezvoglar (insulin glargine-aglr)

Combination Oral Agents

- ☐ alogliptin/metformin
- ☐ alogliptin/pioglitazone
- ☐ Glyxambi (empagliflozin/linagliptin)
- ☐ Invokamet (canagliflozin/metformin)
- ☐ Invokamet XR (canagliflozin/metformin extended release)
- ☐ pioglitazone/glimepiride
- ☐ Qtern (dapagliflozin/saxagliptin)
- ☐ repaglinide/metformin
- ☐ saxagliptin/metformin extended release
- ☐ Segluromet (ertugliflozin/metformin)
- ☐ Steglujan (ertugliflozin/sitagliptin)
- ☐ Trijardy XR (empagliflozin/linagliptin/metformin extended-release)
- ☐ Zituvimet (sitagliptin/metformin) ‡
- ☐ Zituvimet XR (sitagliptin/metformin extended-release)

‡ *Generic sitagliptin/metformin [Zituvimet] is available without prior authorization.*

Other Medication

☐ Other*

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Dose and frequency of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Type 1 Diabetes Mellitus ☐ Type 2 Diabetes Mellitus

☐ Stage What is the member's most recent hemoglobin A1C? Date

☐ Reduction of risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit

☐ Type 2 diabetes mellitus and diabetic nephropathy with albuminuria

☐ Cardiovascular risk factors

☐ Chronic kidney disease

☐ Other

Please list all other antidiabetic medications currently prescribed for the member for this indication.

Drug Dose and Frequency Dates of use

Drug Dose and Frequency Dates of use

Drug Dose and Frequency Dates of use

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for combination oral agents.

1. Has the member tried metformin used in combination with at least one of the non-metformin agents in the requested combination?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. If the answer to question 1 is no, has the member tried metformin?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcome in Section XVIII below.* ☐ No
3. If the answer to question 1 is no, has the member tried at least one of the non-metformin agents in the requested combination?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
4. For Trijardy XR, please provide medical necessity for use instead of the commercially-available separate agents.

Section II. Please complete for single and combination injectable agents (excluding Byetta, Trulicity, Tzield, and liraglutide [generic Victoza]) and Rybelsus.

1. Has the member tried metformin used in combination with Byetta, liraglutide (generic Victoza), or Trulicity?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No

over

2. If the answer to question 1 is no, has the member tried metformin?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcome in Section XVIII below.* ☐ No
3. If the answer to question 1 is no, has the member tried Byetta, liraglutide (generic Victoza), or Trulicity?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.*
   ☐ No. Please describe if there is a contraindication to Byetta, liraglutide (generic Victoza), and Trulicity.
4. If the request is for quantities exceeding the quantity limit, please complete Section XVII below.
5. For Bydureon Bcise, Mounjaro, Ozempic, Rybelsus, Soliqua, and Xultophy, will the requested agent be used in combination with a GLP-1 receptor agonist?
   ☐ Yes ☐ No
   If yes, please provide clinical rationale for concurrent use with a GLP-1 receptor agonist.
6. For Mounjaro, has the member tried Ozempic?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.*
   ☐ No. Please describe if there is a contraindication to Ozempic.

Section III. Please complete for alogliptin, saxagliptin, and Zituvio requests.

1. Has the member tried metformin used in combination with Januvia or Tradjenta?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. If the answer to question 1 is no, has the member tried metformin?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcome in Section XVIII below.* ☐ No
3. If the answer to question 1 is no, has the member tried Januvia or Tradjenta?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.*
   ☐ No. Please describe if there is a contraindication to Januvia and Tradjenta.
4. If the request is for greater than one tablet per day, please complete Section XVII below.

Section IV. Please complete for glimepiride 3 mg tablet requests.

Please provide medical necessity for the use of the requested agent instead of glimepiride tablets that are available without prior authorization.

Section V. Please complete for Invokana and Steglatro requests.

For Invokana for type 2 diabetes mellitus and diabetic nephropathy with albuminuria requests, only question 4 is required.

1. Has the member tried metformin used in combination with dapagliflozin or Jardiance?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. If the answer to question 1 is no, has the member tried metformin?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcome in Section XVIII below.* ☐ No
3. If the answer to question 1 is no, has the member tried dapagliflozin or Jardiance?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.*
   ☐ No. Please describe if there is a contraindication to dapagliflozin and Jardiance.
4. If the request is for greater than one tablet per day, please complete Section XVII below.

over

Section VI. Please complete for Tzield requests.

1. Is the prescriber an endocrinologist? ☐ Yes ☐ No. Please attach consultation notes from an endocrinologist addressing the use of the requested agent.
2. Please attach lab results documenting ≥ two islet autoantibodies.
3. Please complete the below lab test results as applicable.

   Fasting Plasma Glucose (FPG) _____ Date obtained _____

   2-hour Plasma Glucose (2-h PG) _____ Date obtained _____

   A1C: please document lab values from previous 12 months below.

   Lab value _____ Date obtained _____

   Lab value _____ Date obtained _____
4. Has the member been treated with Tzield previously? ☐ Yes ☐ No

Section VII. Please complete for Basaglar, Basaglar Tempo, insulin glargine-vfgn, and Rezvoglar requests.

1. Has the member had an inadequate response or adverse reaction to insulin glargine (generic Lantus) prefilled syringe or vial?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. For Basaglar and Basaglar Tempo, has the member had an inadequate response or adverse reaction to insulin glargine-vfgn prefilled syringe or vial or Rezvoglar?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
3. For Basaglar Tempo, please provide medical necessity for use of the Tempo Pen formulation instead of the KwikPen formulation.

Section VIII. Please complete for Admelog, Apidra, Fiasp, insulin aspart (generic Novolog), Lyumjev, and Lyumjev Tempo requests.

1. Has the member had a trial with insulin lispro (generic Humalog)?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. For Lyumjev Tempo, please provide medical necessity for use of the Tempo Pen formulation instead of the KwikPen formulation.

Section IX. Please complete for Afrezza requests.

Please provide medical necessity for the use of an inhaled insulin product instead of an injectable or prefilled insulin syringe.

Section X. Please complete for Humalog Tempo requests.

Please provide medical necessity for use of the Tempo Pen formulation instead of the KwikPen formulation.

over

Section XI. Please complete for Humulin N requests.

Has the member had an inadequate response or adverse reaction to Novolin N?

☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No

Section XII. Please complete for metformin extended-release, gastric tablet (generic Glumetza), and metformin extended-release, osmotic tablet requests.

1. Please attach medical records documenting an inadequate response (defined as ≥ 90 days of therapy) or adverse reaction, at the requested dose, to the metformin extended-release, XR tablet formulation available without prior authorization.
2. For metformin extended-release, gastric tablet (generic Glumetza), please provide medical necessity for the use of the requested product instead of other metformin formulations available without prior authorization.

Section XIII. Please complete for metformin immediate-release solution and Riomet ER requests.

1. Is there a medical necessity for the liquid formulation?
   ☐ Yes. Please explain.
   ☐ No. Please attach medical records documenting an inadequate response (defined as ≥ 90 days of therapy), allergic reaction, or adverse reaction to metformin tablets.
2. For Riomet ER, please attach medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin immediate-release solution formulation.

Section XIV. Please complete for metformin immediate-release 625 mg tablet requests.

Please provide medical necessity for the requested formulation instead of metformin tablets available without prior authorization.

Section XV. Please complete for miglitol requests.

1. Has the member tried metformin used in combination with acarbose?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. If the answer to question 1 is no, has the member tried metformin?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcome in Section XVIII below.* ☐ No
3. If the answer to question 1 is no, has the member tried acarbose?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.*
   ☐ No. Please describe if there is a contraindication to acarbose.
4. If the request is for greater than three tablets per day, please complete Section XVII below.

Section XVI. Please complete for Inpefa requests.

1. For an indication of reduction of risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit, has the member tried or does the member have a contraindication to both dapagliflozin and Jardiance?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No

over

2. For an indication of reduction of risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in type 2 diabetes mellitus and chronic kidney disease with other cardiovascular risk factors, has the member tried two or does the member have a contraindication to all of the following: dapagliflozin, Invokana, Jardiance?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcome in Section XVIII below.* ☐ No
3. If the request is for greater than one tablet per day, please complete Section XVII below.

Section XVII. Please complete for requests for quantities above quantity limits.

1. Please describe the clinical rationale for exceeding the quantity limit or why dose cannot be consolidated.
2. For Byetta, Trulicity, and Victoza, will the requested agent be used in combination with another GLP-1 receptor agonist? ☐ Yes ☐ No

Section XVIII. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

** Please attach a letter documenting additional trials as necessary.*

Section XIX. Please complete for GLP-1 and GIP/GLP-1 agonist polypharmacy requests.

Please complete information for medications requested and select the reason for polypharmacy.

1. Drug name Dates/duration of use
2. Drug name Dates/duration of use

over

☐ Member is transitioning from one GLP-1 or GIP/GLP-1 agonist to another and prior GLP-1 or GIP/GLP-1 agonist use will be discontinued.

☐ Other, please explain.

Section XX. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Antiemetics
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Akynzeo (fosnetupitant/palonosetron injection) > 2 units/28 days
- ☐ Akynzeo (netupitant/palonosetron capsule) > 2 units/28 days
- ☐ Anzemet (dolasetron)
- ☐ aprepitant 40 mg, 125 mg capsule > 2 units/28 days
- ☐ aprepitant 80 mg > 4 units/28 days
- ☐ aprepitant trifold pack > 2 packs/28 days
- ☐ Bonjesta (doxylamine/pyridoxine extended-release)
- ☐ Cinvanti (aprepitant injectable emulsion)
- ☐ doxylamine/pyridoxine delayed-release
- ☐ Emend (aprepitant 125 mg powder for oral suspension) > 6 units/28 days
- ☐ Focinvez (fosaprepitant injection)
- ☐ fosaprepitant injection > 2 units/28 day
- ☐ granisetron tablet > 2 units/28 days
- ☐ ondansetron 16 mg orally disintegrating tablet
- ☐ ondansetron solution ≥ 13 years
- ☐ palonosetron 0.25 mg/2 mL injection > 2 units/28 days
- ☐ palonosetron 0.25 mg/5 mL injection > 2 units/28 days
- ☐ Sancuso (granisetron transdermal system)
- ☐ Sustol (granisetron extended-release injection) > 2 units/28 days

Dose, frequency and duration of requested medication

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Chemotherapy-induced nausea and vomiting (CINV)
- ☐ Hyperemesis gravidarum
- ☐ Postoperative nausea and vomiting (PONV)
- ☐ Radiation-induced nausea and vomiting (RINV)
- ☐ Other

Section I. Please complete for Cinvanti requests.

Has the member had a trial of oral aprepitant or fosaprepitant injection?

☐ Yes. Please list the dates/duration of trial and outcomes below.

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please explain why.

Section II. Please complete for Akynzeo, aprepitant, fosaprepitant injection, palonosetron, and Sustol requests exceeding the quantity limit.

Please describe the medical necessity for exceeding the quantity limit.

Section III. Please complete for ondansetron solution requests.

Does the member have a medical condition in which they are unable to swallow tablets/capsules?

☐ Yes. Please list reason.

☐ No. Please provide clinical rationale why conventional dosage forms cannot be used.

Section IV. Please complete for Sancuso requests.

Has the member had a trial of ondansetron ODT?

☐ Yes. Please list the dates/duration of trial and outcomes below.

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please explain why.

Section V. Please complete for Bonjesta and doxylamine/pyridoxine delayed-release requests.

1. Has the member had a trial of pyridoxine?

   ☐ Yes. Please list the dates/duration of trial and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please explain why.

2. Has the member had a trial of doxylamine?

   ☐ Yes. Please list the dates/duration of trial and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please explain why.

3. For Bonjesta requests, has the member had a trial of doxylamine/pyridoxine delayed-release?

   ☐ Yes. Please list the dates/duration of trial and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please explain why.

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Section VI. Please complete for Anzemet requests.

1. Has the member had a trial of granisetron tablet?
   ☐ Yes. Please list the dates/duration of trial and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please explain why.
2. Has the member had a trial of ondansetron tablet or ondansetron ODT?
   ☐ Yes. Please list the dates/duration of trial and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please explain why.

Section VII. Please complete for Focinvez requests.

Please describe the clinical rationale for use of the requested agent instead of fosaprepitant injection (Emend).

Section VIII. Please complete for ondansetron 16 mg ODT requests.

Please describe the clinical rationale for use of the requested agent instead of ondansetron ODT at an equivalent dose that is available without prior authorization.

Section IX. Please complete for granisetron tablet requests exceeding the quantity limit.

1. Please describe the medical necessity for exceeding the quantity limit.
2. Has the member had a trial of ondansetron oral tablets or ondansetron ODT?
   ☐ Yes. Please list the dates/duration of trial and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please explain why.
3. Is the member on an anti-cancer treatment regimen that includes an oral agent? ☐ Yes ☐ No
4. Does the member require additional breakthrough treatment for CINV and is already on an antiemetic agent from a different therapeutic class? ☐ Yes ☐ No

   If yes, please list the additional antiemetic agent below.

over

Section X. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

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Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Antihistamine Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested (Check one or all that apply.)

Intranasal Antihistamines

- ☐ azelastine 0.15% nasal spray
- ☐ olopatadine nasal spray

Single Oral Antihistamines

- ☐ carbinoxamine 6 mg tablet
- ☐ carbinoxamine extended-release
- ☐ carbinoxamine solution
- ☐ clemastine syrup
- ☐ desloratadine orally disintegrating tablet (ODT)
- ☐ desloratadine tablet
- ☐ dexchlorpheniramine solution
- ☐ levocetirizine solution

Combination Oral Antihistamines

- ☐ Clarinex-D (desloratadine/pseudoephedrine)

Dose and frequency of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Allergic Rhinitis
- ☐ Non-allergic Rhinitis
- ☐ Urticaria
- ☐ Other

Please list all other medications currently prescribed for the member for this indication.

Section I. Please complete for desloratadine ODT and levocetirizine solution requests.

1. Please provide medical necessity for requested formulation (e.g., member utilizes a feeding tube, has a swallowing disorder or condition affecting ability to swallow, is < 13 years of age).
2. Has the member had a trial with cetirizine syrup and loratadine solution?
   - ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section VII below.*
   - ☐ No. Please explain why cetirizine syrup and loratadine solution are not appropriate for this member.

Section II. Please complete for Clarinex-D requests.

1. Has the member had a trial with an intranasal corticosteroid?
   - ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section VII below.*
   - ☐ No. Please describe why intranasal corticosteroids are not appropriate for this member.

2. Has the member had a trial with two of the following: cetirizine/pseudoephedrine, loratadine/pseudoephedrine, fexofenadine/pseudoephedrine?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section VII below.*
   ☐ No. Please describe why cetirizine/pseudoephedrine, loratadine/pseudoephedrine, and fexofenadine/pseudoephedrine are not appropriate for this member.

Section III. Please complete for azelastine 0.15% nasal spray and olopatadine nasal spray requests.

1. Has the member had a trial with two of the following: an intranasal corticosteroid, azelastine 137 mcg nasal spray, or azelastine/fluticasone propionate?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section VII below.*
   ☐ No. Please describe why intranasal corticosteroids, azelastine 137 mcg nasal spray, and azelastine/fluticasone propionate are not appropriate for this member.
2. For requests for any agent at a quantity > 1 inhaler/30 days, please document an inadequate response to the manufacturer's recommended dosing.

Section IV. Please complete for carbinoxamine 6 mg tablet, carbinoxamine extended-release, and carbinoxamine solution requests.

1. Has the member had a trial with an intranasal corticosteroid and two non-selective antihistamines?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section VII below.*
   ☐ No. Please describe why intranasal corticosteroids and non-selective antihistamines are not appropriate for this member.
2. For carbinoxamine 6 mg tablet requests, has the member had a trial with carbinoxamine 4 mg tablet?
   ☐ Yes. Please list the dates/duration of trials and outcomes in Section VII below.*
   ☐ No. Please describe why carbinoxamine 4 mg tablet is not appropriate for this member.
3. For carbinoxamine extended-release and carbinoxamine solution requests, please provide medical necessity for requested formulation (e.g., member utilizes a feeding tube, has a swallowing disorder or condition affecting ability to swallow, is < 13 years of age).
4. For carbinoxamine extended-release requests, has the member had a trial with carbinoxamine immediate-release solution?
   ☐ Yes. Please list the dates/duration of trials and outcomes in Section VII below.*
   ☐ No. Please describe why carbinoxamine immediate-release solution is not appropriate for this member.

Section V. Please complete for clemastine syrup and dexchlorpheniramine solution requests.

1. Please provide medical necessity for requested formulation (e.g., member utilizes a feeding tube, has a swallowing disorder or condition affecting ability to swallow, is < 13 years of age).

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2. Has the member had a trial with cetirizine syrup and loratadine solution?
   - ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section VII below.*
   - ☐ No. Please explain why cetirizine syrup and loratadine solution are not appropriate for this member.

Section VI. Please complete for desloratadine tablet requests.

Has the member had a trial with cetirizine, fexofenadine, levocetirizine, or loratadine?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section VII below.*

☐ No. Please describe why cetirizine, fexofenadine, levocetirizine, and loratadine are not appropriate for this member.

Section VII. Please complete for all requests as needed.

Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name ______ Dates/duration of use ______

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ______ Dates/duration of use ______

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ______ Dates/duration of use ______

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ______ Dates/duration of use ______

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

**Please attach a letter documenting additional trials as necessary.*

Section VIII. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

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3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

   _____

   _____

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details. _____

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Antipsychotic
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about antipsychotics and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form**.

Medication information

Medication(s) requested

- ☐ Abilify Asimtufii (aripiprazole extended-release injection)
- ☐ Abilify Maintena (aripiprazole extended-release injection)
- ☐ Abilify Mycite (aripiprazole tablet with sensor)
- ☐ aripiprazole orally disintegrating tablet (ODT)
- ☐ aripiprazole solution ≥ 13 years and ≥ 10 mL/day
- ☐ aripiprazole tablet > 2 units/day
- ☐ asenapine sublingual tablet
- ☐ Caplyta (lumateperone)
- ☐ clozapine ODT
- ☐ Cobenfy (xanomeline/trospium)
- ☐ Erzofri (paliperidone extended-release 1-month injection)
- ☐ Fanapt (iloperidone)
- ☐ lurasidone > quantity limits
- ☐ Lybalvi (olanzapine/samidorphan)
- ☐ olanzapine ODT > quantity limits
- ☐ olanzapine tablet > quantity limits
- ☐ Opipza (aripiprazole film)
- ☐ paliperidone tablet > quantity limits
- ☐ perphenazine/amitriptyline
- ☐ Perseris (risperidone 90 mg, 120 mg extended-release subcutaneous injection) > 1 injection/ 28 days
- ☐ quetiapine > 3 units/day
- ☐ quetiapine extended-release > 2 units/day
- ☐ Rexulti (brexpiprazole)
- ☐ risperidone ODT 3 mg, 4 mg
- ☐ risperidone ODT 0.25 mg, 0.5 mg, 1 mg, 2 mg > 2 units/day
- ☐ risperidone 12.5 mg, 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection [Risperdal Consta] > 2 injections/28 days
- ☐ risperidone solution > 16 mL/day
- ☐ risperidone tablet > quantity limits
- ☐ Rykindo (risperidone 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection)
- ☐ Secuado (asenapine transdermal)
- ☐ Uzedy (risperidone 50 mg, 75 mg, 100 mg, 125 mg extended-release subcutaneous injection) > 1 injection/28 days
- ☐ Uzedy (risperidone 150 mg, 200 mg, 250 mg extended-release subcutaneous injection) > 1 injection/56 days
- ☐ Versacloz (clozapine suspension)
- ☐ Vraylar (cariprazine)
- ☐ ziprasidone > 2 units/day
- ☐ Other

Dose and frequency of medication requested

For long-acting injectable agents, please indicate billing preference:

☐ Pharmacy ☐ Prescriber in-office ☐ Inpatient Psychiatry Unit

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Agitation associated with dementia due to Alzheimer's Disease
- ☐ Bipolar disorder
  - ☐ Bipolar depression
- ☐ Irritability associated with autistic disorder
- ☐ Major depressive disorder
- ☐ Psychosis, unspecified

☐ Schizophrenia
☐ Treatment-resistant depression
☐ Other

Is this member a referral candidate for care coordination? ☐ Yes ☐ No
If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Monotherapy

Please select previous medication trial(s) as applicable.*

**For aripiprazole ODT or solution for irritability associated with autistic disorder, a trial with risperidone alone is sufficient. For Abilify Asimtufii and Abilify Maintena requests, please document a trial of Aristada, or provide clinical rationale for use of the requested agent instead of Aristada. For Rykindo requests, please document a trial of risperidone extended-release intramuscular injection (generic Risperdal Consta), Perseris, and Uzedy, or provide clinical rationale for use of the requested agent instead of risperidone extended-release intramuscular injection (generic Risperdal Consta), Perseris, and Uzedy.*

☐ Trial(s) of second-generation (atypical) antipsychotics (Check all that apply.)

☐ aripiprazole ☐ clozapine ☐ olanzapine ☐ quetiapine ☐ risperidone ☐ ziprasidone ☐ Other

☐ Trial of other antipsychotics (Please specify below.)

Drug name 1 Drug name 2

☐ If requesting for major depressive disorder or treatment-resistant depression, please document trial(s) of antidepressants.

Drug name 1 Dates/Duration of use
Drug name 2 Dates/Duration of use

☐ If requesting Caplyta or Vraylar for bipolar depression, in addition to trials with other second-generation (atypical) antipsychotics, please document trials with olanzapine monotherapy or combination therapy with fluoxetine and quetiapine immediate-release or extended-release, if applicable.

Drug name 1 Dates/Duration of use
Drug name 2 Dates/Duration of use

Please select reason(s) for medical necessity as applicable.

☐ Member is new to MassHealth and has been previously stabilized on requested medication.

☐ If request is for major depressive disorder or treatment-resistant depression, please note if the requested agent will be used as adjunctive therapy with current antidepressant treatment or provide clinical rationale why the member is not a candidate for antidepressant therapy.

☐ If requesting ODT, solution, or transdermal formulation, please also describe medical necessity for the specific dosage formulation.

☐ If requesting Cobenfy, please also document the complete treatment plan, including whether Cobenfy will be used as monotherapy or in conjunction with antipsychotic therapy. If the member is tapering off an antipsychotic, please also describe the taper plan below.

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☐ If requesting Abilify Mycite, please also describe the medical necessity for monitoring the member's ingestion of oral aripiprazole, and the member's training to use the Abilify Mycite system.

☐ If requesting perphenazine/amitriptyline, please also describe the medical necessity for the use of the combination product instead of the commercially available separate agents.

☐ If requesting Lybalvi, please also complete the questions below.

1. Is the member being treated with an opioid? ☐ Yes ☐ No
2. Is the member being treated for acute opioid withdrawal? ☐ Yes ☐ No

☐ If requesting Caplyta 10.5 mg or 21 mg capsules, please also describe if the member has any of the following: hepatic impairment, utilization of a CYP3A4 inhibitor, side effects with Caplyta 42 mg dose, high sensitivity to antipsychotic medications requiring initiation at a lower dose.

☐ Other, please explain.

Section II. Antipsychotic Polypharmacy for members ≥ 18 years of age. Please complete information for medications requested and select the reason for polypharmacy with antipsychotics (two or more first-generation and/or second-generation antipsychotics for ≥ 60 days within a 90-day period).

1. Antipsychotic name/dose/frequency Indication
2. Antipsychotic name/dose/frequency Indication
3. Antipsychotic name/dose/frequency Indication

Is member under the care of a specialist (e.g., psychiatry, neurology, or developmental/behavioral health)?
☐ Yes. Please attach specialist consult details (if the prescriber submitting the request is not a specialist). ☐ No
For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

☐ Member was recently discharged from an inpatient setting on requested medications and is currently stable.
☐ Member experienced an inadequate response or adverse reaction to two monotherapy trials with antipsychotics.

Drug name 1 Dates/Duration of use (if available)
Drug name 2 Dates/Duration of use (if available)

☐ Member is transitioning from one antipsychotic to the other.
☐ Member is stable on the current regimen.
☐ Other, please explain.

over

Section III. Quantity Limits. Please complete information for medication requested and select the reason for exceeding established quantity limits.

Drug, dose, and frequency of requested antipsychotic

☐ Member is not a candidate for dose consolidation (e.g., lurasidone 20 mg two times daily can be consolidated to lurasidone 40 mg once daily, which is available without PA).

☐ Other. Please describe medical necessity for exceeding quantity limits.

☐ For aripiprazole solution ≥ 10 mL/day, has the member had an inadequate response, adverse reaction, or contraindication to aripiprazole ODT at an equivalent dose? ☐ Yes ☐ No

Section IV. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

MassHealth Pediatric Behavioral Health Medication Initiative

Please fill out all the sections below, as applicable, for pediatric members only. You may also use the Pediatric Behavioral Health Medication Initiative PA Request Form if the member is prescribed other behavioral health medications.

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Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name _____ Dose/frequency _____ Indication _____
2. Medication name _____ Dose/frequency _____ Indication _____
3. Medication name _____ Dose/frequency _____ Indication _____
4. Medication name _____ Dose/frequency _____ Indication _____
5. Medication name _____ Dose/frequency _____ Indication _____
6. Medication name _____ Dose/frequency _____ Indication _____
7. Other(s) _____

Is the member currently in an acute care setting?

☐ Yes (Inpatient) ☐ Yes (Community Based Acute Treatment)
☐ Yes (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.

Prescriber name _____ Contact information _____

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months.

_____

☐ No

On the current regimen, is the member considered to be a severe risk of harm to self or others?

☐ Yes. Please provide details. _____
☐ No

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g., weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain. _____

Has informed consent from a parent or legal guardian been obtained?* ☐ Yes ☐ No

Please indicate prescriber specialty below.

☐ Psychiatry ☐ Neurology ☐ Other _____
☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

_____

Name(s) of the specialist(s) _____ Date(s) of last visit or consult _____

Contact information _____

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

_____

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

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Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility

☐ Uncertain ☐ Other

Please document agency involvement.

☐ DCF ☐ Department of Mental Health (DMH) ☐ Department of Developmental Services (DDS)

☐ Department of Youth Services (DYS)

Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions below, if applicable. ☐ No

Psychiatric care provided is coordinated with other psychotherapeutic and community based services. ☐ Yes ☐ No

** Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information go to: https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information*

Please complete for members who have been on one of the following for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation): a polypharmacy regimen, members < six years of age who have been on an applicable behavioral health medication, and members < ten years of age who have been on an antipsychotic.

Have previous efforts to reduce or simplify the regimen in the past 24 months resulted in symptom exacerbation? ☐ Yes ☐ No

The family or caregiver does not support the regimen change at this time due to risk of exacerbation.

☐ Yes ☐ No

Is there another significant barrier for therapy discontinuation? ☐ Yes ☐ No

If yes, please explain.

Section II. Antipsychotic Polypharmacy. Complete this section for all members < 18 years of age if request will result in prescription of two or more antipsychotics for ≥ 60 days within a 90-day period.

Please select the stage of treatment and clinical rationale for antipsychotic polypharmacy.

☐ **Acute stage** (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects)

☐ Member experienced an inadequate response or adverse reaction to two monotherapy trials with antipsychotics.

Drug name 1 Dates/Duration of use

Drug name 2 Dates/Duration of use

☐ Member is transitioning from one antipsychotic to the other.

☐ Other, please explain.

☐ **Maintenance stage** (response to antipsychotic treatment with goal of remission or recovery)

1. Is the regimen effective, therapy benefits outweigh risks, and appropriate monitoring is in place?
   ☐ Yes ☐ No
2. Has the member been on an antipsychotic polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?
   ☐ Yes. Please complete the applicable question in Section I. ☐ No

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☐ **Discontinuation stage** (clinically indicated that the antipsychotic regimen can likely be successfully tapered)

☐ Member is transitioning from one antipsychotic to the other.

☐ Member is tapering antipsychotic. Please describe taper plan including duration.

Section III. Antipsychotic Request for Members < ten years of age.

Please select the stage of treatment and clinical rationale for use of an antipsychotic for this member < ten years of age.

☐ **Acute stage** (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects)

☐ **Maintenance stage** (response to antipsychotic treatment with goal of remission or recovery)

1. Is the regimen effective, therapy benefits outweigh risks, and appropriate monitoring is in place?
   ☐ Yes ☐ No
2. Has the member been on an antipsychotic agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?
   ☐ Yes. Please complete the applicable question in Section I. ☐ No

☐ **Discontinuation stage** (clinically indicated that the antipsychotic regimen can likely be successfully tapered)

☐ Member is transitioning from one antipsychotic to the other.

☐ Member is tapering antipsychotic. Please describe taper plan including duration.

Section IV. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.*

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Antiretroviral Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Antiretroviral requested

- ☐ Cimduo (lamivudine/tenofovir disoproxil fumarate)
- ☐ efavirenz/lamivudine/tenofovir disoproxil fumarate (600 mg/300 mg/300 mg)
- ☐ efavirenz/lamivudine/tenofovir disoproxil fumarate (400 mg/300 mg/300 mg)
- ☐ fosamprenavir
- ☐ maraviroc
- ☐ nevirapine extended-release
- ☐ Rukobia (fostemsavir)
- ☐ Sunlenca (lenacapavir)
- ☐ tenofovir disoproxil fumarate tablet > 1 unit/day
- ☐ Tivicay (dolutegravir) > 1 unit/day
- ☐ Trogarzo (ibalizumab-uiyk)
- ☐ Viread (tenofovir disoproxil fumarate) powder ≥ 13 years of age

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ HIV-1 Current viral load and date
- ☐ pre-exposure prophylaxis (PreEP)
- ☐ Chronic Hepatitis B
- ☐ Other (specify)

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for requests for tenofovir disoproxil fumarate tablet > 1 unit/day.

Please describe medical necessity for exceeding the quantity limit.

Section II. Please complete for requests for Viread powder for members ≥ 13 years of age.

Please describe medical necessity for use of the requested formulation.

Section III. Please complete for Tivicay requests > 1 unit/day.

1. Will the member be taking the requested medication concurrently with carbamazepine, efavirenz, fosamprenavir/ritonavir, Aptivus (tipranavir)/ritonavir, or rifampin?
   ☐ Yes. Please document drug name with dose and frequency. ☐ No
   Drug _____ Dose and Frequency _____
2. Does the member have integrase strand transfer inhibitor (INSTI)-associated resistance substitutions or clinically suspected INSTI-resistance?
   ☐ Yes ☐ No

Section IV. Please complete for fosamprenavir requests.

1. Has the member tried an antiretroviral regimen containing atazanavir, darunavir, or ritonavir?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   _____
   ☐ No. Explain why atazanavir, darunavir, and ritonavir are not appropriate for this member.
   _____
2. Will the member be taking the requested medication concurrently with at least one other antiretroviral?
   ☐ Yes. Please document drug name with dose and frequency. ☐ No
   Drug _____ Dose and Frequency _____

Section V. Please complete for nevirapine extended-release requests.

Please attach medical records documenting an inadequate response or adverse reaction to nevirapine immediate-release formulation.

Section VI. Please complete for Cimduo and efavirenz/lamivudine/tenofovir disoproxil fumarate requests.

1. Does the member experience any of the following? (Check all that apply.)
   ☐ Yes
   ☐ Significant psychiatric diagnosis leading to documented difficulty with adherence.
   Please document diagnosis. _____
   ☐ Homelessness and difficulty storing larger amounts of medications.
   ☐ Difficulty with adherence leading to complications.
   ☐ Developmental issues without adequate support to properly manage their own HIV regimen.
   ☐ No. Please provide medical necessity for use of the combination product instead of the commercially available separate agents.
   _____
   _____
2. For members < 18 years of age, please provide member's current weight. _____
3. For Cimduo, will the member be taking the requested medication concurrently with at least one other antiretroviral?
   ☐ Yes. Please document drug name with dose and frequency. ☐ No
   Drug _____ Dose and Frequency _____

over

Section VII. Please complete for Rukobia and Sunlenca requests.

1. Is the member antiretroviral-experienced with documented historical or baseline resistance, intolerability, and/or contraindication to antiretroviral?

☐ Yes. Please document drug name and outcome.* ☐ No

Drug ☐ Intolerability ☐ Resistant ☐ Other

Briefly describe details of intolerability, resistance, or other.

2. Has the member failed current antiretroviral regimen due to resistance, intolerance, or safety considerations?

☐ Yes. Please document drug name and outcome.* ☐ No

Drug ☐ Intolerability ☐ Resistant ☐ Other

Briefly describe details of intolerability, resistance, or other.

3. Will the member be taking the requested medication concurrently with at least one other antiretroviral?

☐ Yes. Please document drug name with dose and frequency. ☐ No

Drug Dose and Frequency

Section VIII. Please complete for Trogarzo requests.

1. Does the member have resistance to one agent from each of the three classes of antiretrovirals [nucleoside analog reverse transcriptase inhibitor (NRTI), non-nucleoside reverse transcriptase inhibitor (NNRTI), protease inhibitor (PI)]?

☐ Yes. Please document drug names and outcomes.* ☐ No

NRTI ☐ Resistant ☐ Other

NNRTI ☐ Resistant ☐ Other

PI ☐ Resistant ☐ Other

Briefly describe details of resistance or other.

2. Will the member be taking the requested medication concurrently with at least one other antiretroviral?

☐ Yes. Please document drug name with dose and frequency. ☐ No

Drug Dose and Frequency

3. Has the member tried Rukobia or Sunlenca?

☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe the details of adverse reaction, inadequate response, or other.

☐ No. Explain why Rukobia and Sunlenca are not appropriate for this member.

Section IX. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

If yes, briefly describe details of contraindication, adverse reaction, or harm.

over

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Asthma/Allergy Monoclonal Antibodies
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ Cinqair (reslizumab) [MB]
☐ Dupixent (dupilumab)
☐ Fasenra (benralizumab)
☐ Nemluvio (nemolizumab-ilto)
☐ Nucala (mepolizumab)
☐ Tezspire (tezepelumab-ekko)
☐ Xolair (omalizumab)

Dose, frequency, and duration of medication requested

☐ Naïve to therapy ☐ Continuation of therapy

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Chronic idiopathic urticaria
☐ Chronic obstructive pulmonary disease (COPD)
☐ Chronic rhinosinusitis with nasal polyps
☐ Eosinophilic esophagitis
☐ Eosinophilic granulomatosis with polyangiitis
☐ Hypereosinophilic syndrome
☐ IgE-mediated food allergy
☐ Moderate-to-severe allergy-related asthma
☐ Moderate-to-severe eosinophilic asthma
☐ Moderate-to-severe atopic dermatitis
☐ Oral corticosteroid-dependent asthma
☐ Prurigo nodularis
☐ Severe asthma
☐ Other (Please indicate.)

Please complete the following for all requests.

1. Member's current weight ____ Date ____
2. Please indicate prescriber specialty. ☐ Allergy & immunology ☐ Dermatology ☐ Otolaryngology ☐ Pulmonology ☐ Other (Please specify.) ____
3. Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.
4. Is this member a referral candidate for care coordination? ☐ Yes ☐ No
   If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for Xolair for the diagnosis of moderate-to-severe allergy-related asthma, for Cinqair, Fasenra, and Nucala for the diagnosis of severe eosinophilic asthma, and for Tezspire for the diagnosis of severe asthma.

For Xolair, please complete questions 1 through 4. For Cinqair, Fasenra, and Nucala, complete questions 3 and 4. For Tezspire, complete question 4.

1. Pretreatment serum IgE level _____ Test date _____
   Does the member have a history of positive skin test or radioallergosorbent test (RAST) to an aeroallergen(s)?
   ☐ Yes. Please list the allergens. _____
   ☐ No
2. For requests for the 150 mg and 300 mg syringe or auto-injection, please provide medical necessity for the requested formulation instead of the vial formulation.
   _____
3. Does the member have evidence of an eosinophilic phenotype of asthma?
   ☐ Yes. Please explain. _____
   ☐ No
4. Has the member tried other medications to treat this condition [including beta agonists, inhaled and oral corticosteroids, leukotriene modifiers, or combination therapies (LABA/ICS)]?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please explain why not. _____

Section II. Please complete for Xolair requests for the diagnosis of chronic idiopathic urticaria.

1. Has the member tried two different histamine$_1$ antihistamines?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   Drug name _____ Dates/duration of use _____

over

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe why histamine$_1$ antihistamines are not appropriate for this member.

2. Has the member tried a histamine$_2$ antihistamine?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why histamine$_2$ antihistamines are not appropriate for this member.

3. For requests for the 150 mg and 300 mg syringe or auto-injection, please provide medical necessity for the requested formulation instead of the vial formulation.

Section III. Please complete for Xolair requests for the diagnosis of IgE-mediated food allergy.

1. Pretreatment serum IgE level Test date
2. Does the member have a history of positive skin test or radioallergosorbent test (RAST) to food allergen(s)?
   ☐ Yes. Please list the allergens.
   ☐ No
3. For requests for the 150 mg and 300 mg syringe or auto-injection, please provide medical necessity for the requested formulation instead of the vial formulation.

Section IV. Please complete for Fasenra and Nucala requests for the diagnosis of eosinophilic granulomatosis with polyangiitis.

1. Has the member tried a systemic glucocorticoid?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why systemic glucocorticoids are not appropriate for this member.

2. For Nucala, has the member tried Fasenra for this condition?
   ☐ Yes. Please list the dose and frequency, dates/duration of use, and outcomes below.*
   Dose and frequency Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

over

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe why Fasenra is not appropriate for this member.

Section V. Please complete for Nucala requests for hypereosinophilic syndrome.

1. Has a non-hematologic secondary cause been excluded? ☐ Yes ☐ No
2. Has the member tried a systemic glucocorticoid?

   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why systemic glucocorticoids are not appropriate for this member.
3. Has the member tried hydroxyurea, interferon alfa, or methotrexate?

   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why hydroxyurea, interferon alfa, and methotrexate are not appropriate for this member.

Section VI. Please complete for Dupixent and Nemluvio requests for moderate-to-severe atopic dermatitis.

1. Has the member tried a superpotent or potent topical corticosteroid to treat this condition?

   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why a superpotent or potent topical corticosteroid is not appropriate for this member.
2. Has the member tried topical tacrolimus or Eucrisa to treat this condition?

   ☐ Yes. Please list the dates/duration of trial and outcome.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why topical tacrolimus and Eucrisa are not appropriate for this member.

over

3. Has the member tried a systemic immunomodulatory agent to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please describe why a systemic immunomodulatory agent is not appropriate for this member.
   _____
4. For requests for Nemluvio, has the member tried two of the following: Adbry, Dupixent, and Ebglyss?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please describe why Adbry, Dupixent, and Ebglyss are not appropriate for this member.
   _____
5. For recertification requests for Nemluvio, has the member had a positive response to therapy?
   ☐ Yes. ☐ No.
   For recertification requests for Nemluvio, is the request to continue every four-week dosing (after week 16 of therapy)? ☐ Yes. ☐ No.
   If yes, briefly describe rationale for continuing every four-week dosing.
   _____
   _____

Section VII. Please complete for Dupixent requests for moderate-to-severe eosinophilic asthma and oral corticosteroid-dependent asthma.

For requests for oral corticosteroid-dependent asthma, only question 1 is required.

1. Has the member tried other medications to treat this condition (including combination inhaler, combination of an inhaled corticosteroid and a long-acting beta agonist inhaler or chronic oral corticosteroids)?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____

over

☐ No. Please describe why other medications are not appropriate for this member.

2. Does the member have evidence of an eosinophilic phenotype of asthma?

☐ Yes. Please explain.

☐ No

Section VIII. Please complete for Dupixent requests for COPD.

1. Has the member tried Breztri, Trelegy, or any combination of equivalent separate inhalers (*triple inhaled therapy containing a corticosteroid*)?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe why Breztri, Trelegy and any combination of equivalent separate inhalers (*triple inhaled therapy containing a corticosteroid*) are not appropriate for this member.

2. Has the member tried Bevespi, Duaklir, Stiolto, umeclidinium/vilanterol or any combination of equivalent separate inhalers *(dual inhaled therapy)*?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below. *

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe why Bevespi, Duaklir, Stiolto, umeclidinium/vilanterol, and any combination of equivalent separate inhalers (*dual inhaled therapy*) are not appropriate for this member.

3. Does the member have evidence of an eosinophilic phenotype?

☐ Yes. Please explain.

☐ No

4. Will the requested agent be used as adjunctive therapy with either dual or triple inhaled therapy?

☐ Yes

☐ No. Please describe why not.

over

Section IX. Please complete for Dupixent, Nucala, and Xolair requests for nasal polyps.

1. Has the member tried an oral corticosteroid to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why oral corticosteroids are not appropriate for this member.
2. Has the member tried an intranasal corticosteroid to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*

   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why intranasal corticosteroids are not appropriate for this member.
3. For requests for Dupixent, has the member failed a prior nasal surgery? ☐ Yes ☐ No
4. Will the requested agent be used as adjunctive therapy?
   ☐ Yes

   ☐ No. Please describe why not. _____
5. For requests for Xolair 150 mg and 300 mg syringe or auto-injection, please provide medical necessity for the requested formulation instead of the vial formulation.

Section X. Please complete for Dupixent requests for eosinophilic esophagitis.

1. Has the member tried a proton pump inhibitor to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*

   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why proton pump inhibitors are not appropriate for this member.
2. Has the member tried budesonide or fluticasone propionate to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*

   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why budesonide and fluticasone propionate are not appropriate for this member.

over

Section XI. Please complete for Dupixent and Nemluvio requests for prurigo nodularis.

1. Has the member tried a superpotent or potent topical corticosteroid to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please describe why a superpotent or potent topical corticosteroid is not appropriate for this member.
   _____
2. Has the member tried an intralesional corticosteroid to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please describe why intralesional corticosteroids are not appropriate for this member.
   _____
3. Has the member tried phototherapy to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*
   Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please describe why phototherapy is not appropriate for this member.
   _____
4. For Nemluvio, has the member tried Dupixent to treat this condition?
   ☐ Yes. Please list the dose and frequency, dates/durations of use, and outcomes below.*
   Dose and frequency _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please describe why Dupixent is not appropriate for this member.
   _____

* *Please attach a letter documenting additional trials as necessary.*

Section XII. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
   _____
   _____
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No

over

If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Benign Prostatic Hyperplasia (BPH) Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

BPH medication requested

☐ dutasteride/tamsulosin
☐ silodosin
☐ tadalafil tablet

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ BPH
☐ Lower urinary tract symptoms (LUTS)
☐ S/P transurethral resection of the prostate (TURP)
☐ Other

Please note: MassHealth does not pay for any drug when used for the treatment of sexual dysfunction, cosmetic purposes, or for hair growth as described in 130 CMR 406.413(B): Drug Exclusions. For additional information go to: www.mass.gov/regulations/130-CMR-406000-pharmacy-services.

Section I. Please complete for silodosin requests.

Has the member had a trial with two of the following: alfuzosin, doxazosin, tamsulosin, terazosin?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please provide clinical rationale for not using alfuzosin, doxazosin, tamsulosin, and terazosin.

Section II. Please complete for dutasteride/tamsulosin requests.

Please provide medical necessity for use of the combination product instead of the commercially available separate agents.

Section III. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details.

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Benzodiazepines and Other Antianxiety Agents Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about benzodiazepines or other antianxiety agents and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form**

Medication information

Medication requested (check one or all that apply.)

- ☐ alprazolam extended-release (ER) >2 units/day
- ☐ alprazolam orally disintegrating tablet (ODT)
- ☐ alprazolam solution ≥ 13 years of age
- ☐ amitriptyline/chlordiazepoxide
- ☐ Byfavo (remimazolam) MB
- ☐ clonazepam ODT 0.125 mg, 0.25 mg, 0.5 mg, 1 mg >3 units/day
- ☐ clonazepam ODT 2 mg >2 units/day
- ☐ clorazepate
- ☐ diazepam 25 mg/5 mL solution
- ☐ estazolam >1 unit/day
- ☐ flurazepam
- ☐ lorazepam solution ≥ 13 years of age
- ☐ Loreev XR (lorazepam extended-release)
- ☐ meprobamate
- ☐ oxazepam
- ☐ quazepam
- ☐ temazepam 7.5 mg, 15 mg, 30 mg >1 unit/day
- ☐ temazepam 22.5 mg
- ☐ triazolam >1 unit/day
- ☐ Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

MB *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested _____ **Quantity requested per month** _____

Indication(s) or ICD-10 code(s), if applicable _____

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code _____

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

_____

Section I. Concomitant Opioid and Benzodiazepine Polypharmacy. Please complete information for medications requested and clinical rationale for polypharmacy with opioids and benzodiazepines [one or more benzodiazepine(s), excluding clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations, and one or more opioid(s) for ≥15 days within a 45-day period].

Please document the indication or ICD-10 code(s), if applicable, for the agents requested.

1. Benzodiazepine

   Name/dose/frequency _____ Indication _____

   Name/dose/frequency _____ Indication _____

   Name/dose/frequency _____ Indication _____

2. Opioid

   Name/dose/frequency _____ Indication _____

   Name/dose/frequency _____ Indication _____

   Name/dose/frequency _____ Indication _____

Please document clinical rationale for concomitant use of opioids and benzodiazepines for this member.

_____

_____

Please describe the ongoing treatment plan for continued use.

_____

_____

For the diagnosis of a seizure disorder, is the member currently receiving a non-benzodiazepine anticonvulsant?

☐ Yes. Drug name _____ Dates _____ Outcome _____

☐ No. Please explain why not. _____

For the diagnosis of a sleep disorder, has the member had trials with three non-benzodiazepine sleep medications?

☐ Yes. Drug name _____ Dates _____ Outcome _____

Drug name _____ Dates _____ Outcome _____

Drug name _____ Dates _____ Outcome _____

☐ No. Please explain why not. _____

For the diagnosis of a psychiatric disorder (e.g., generalized anxiety disorder, panic disorder, post-traumatic stress disorder, etc.), has the member had trials with three antidepressants?

☐ Yes. Drug name _____ Dates _____ Outcome _____

Drug name _____ Dates _____ Outcome _____

Drug name _____ Dates _____ Outcome _____

☐ No. Please explain why not. _____

over

For the diagnosis of a musculoskeletal disorder, has the member had trials with three skeletal muscle relaxants?

☐ Yes. Drug name Dates Outcome

Drug name Dates Outcome

Drug name Dates Outcome

☐ No. Please explain why not.

Has consideration been given for possible taper of benzodiazepine or opioid?

☐ Yes. Please describe plan for taper and plan to reevaluate in the future.

☐ No. Please describe why taper is not possible at this time and plan to reevaluate in the future.

Has the member been hospitalized for a psychiatric condition (non-overdose related) within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months.

☐ No

On the current regimen, is the member considered to be a risk of harm to self or others?

☐ Yes. Please provide details.

☐ No

Has the member been offered and/or given a prescription for naloxone treatment?

☐ Yes ☐ No. Please provide details.

**Attach a letter with additional information regarding medication trials as applicable.*

Section II. Benzodiazepine Polypharmacy for members ≥ 18 years of age. Please complete information for medications requested and clinical rationale for polypharmacy with benzodiazepines (two or more benzodiazepines, excluding clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations for ≥ 60 days within a 90-day period).

Please document complete treatment plan (include all agents requested from the same medication class and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Benzodiazepine name/dose/frequency Indication
2. Benzodiazepine name/dose/frequency Indication
3. Benzodiazepine name/dose/frequency Indication

Please document clinical rationale for polypharmacy within the same medication class for this member (include prior therapy trials, severity of symptoms, etc.)

Has consideration been given for consolidation to a single benzodiazepine agent?

☐ Yes. Please describe plan for cross-titration or taper.

☐ No

over

Please describe why dose consolidation is not possible at this time and plan to reevaluate in the future.

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months.

☐ No

On the current regimen, is the member considered to be a risk of harm to self or others?

☐ Yes. Please provide details.

☐ No

Section III. Please complete for requests for alprazolam ODT, alprazolam oral solution for members ≥ 13 years of age, diazepam 25 mg/5 mL oral solution, and lorazepam oral solution for members ≥ 13 years of age.

Please describe the medical necessity for use of the requested dosage formulation. Include prior trials of agents and describe dose consolidation as appropriate.

Section IV. Please complete for requests for > 2 units/day of alprazolam ER and clonazepam ODT 2 mg, and > 3 units/day of clonazepam ODT 0.125 mg, 0.25 mg, 0.5 mg, and 1 mg.

1. Can the dose be consolidated within quantity limits? ☐ Yes ☐ No
2. Please describe clinical rationale for dosing higher than the FDA approved limits.
3. Please attach medical records documenting titration of medication up to current dose.
4. For clonazepam ODT, please indicate prescriber specialty below.

☐ Psychiatry ☐ Neurology ☐ Other

☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

Name(s) of the specialist(s) Date(s) of last visit or consult

Contact information

Section V. Please complete for requests for flurazepam, quazepam and temazepam 22.5 mg.

For requests for flurazepam, quazepam and ≤1 unit/day of temazepam 22.5 mg, please complete question 1. For requests for 2 units/day of temazepam 22.5 mg, please complete all of the following questions.

1. Has the member had a trial of estazolam, temazepam 7.5 mg, 15 mg, or 30 mg, and triazolam?

☐ Yes

Drug name	Dates	Outcome
Drug name	Dates	Outcome
Drug name	Dates	Outcome
Drug name	Dates	Outcome

☐ No. Please explain why not.

over

2. Has the member had an inadequate response to a dose of 30 mg/day? ☐ Yes ☐ No
3. Please attach medical records documenting titration of medication up to current dose.
4. Please describe clinical rationale for dosing higher than the FDA approved limits.

Section VI. Please complete for requests for > 1 unit/day of estazolam, flurazepam, temazepam (7.5 mg, 15 mg, 22.5 mg, and 30 mg), triazolam, and quazepam.

1. Can the dose be consolidated within quantity limits? ☐ Yes ☐ No
2. Was a higher dose effective in alleviating symptoms? ☐ Yes ☐ No
3. Has the member had an inadequate response to 1 unit/day? ☐ Yes ☐ No
4. For triazolam 0.25 mg, has the member had an inadequate response to a dose of 0.25 mg/day? ☐ Yes ☐ No
5. For requests exceeding the FDA-approved maximum dose, has the member experienced an inadequate response or adverse reaction to other alternatives for sleep?
   ☐ Yes

   Drug name Dates Outcome

   Drug name Dates Outcome

   Drug name Dates Outcome

   Drug name Dates Outcome

☐ No. Please explain why not.

Section VII. Please complete for requests for meprobamate.

1. Has the member had a trial with at least two benzodiazepines?
   ☐ Yes

   Drug name Dates Outcome

   Drug name Dates Outcome

   ☐ No. Please explain why not.
2. If requesting recertification, please provide clinical rationale for continued therapy and details of trials with alternatives (e.g., SSRIs, SNRIs, TCAs, buspirone).

Section VIII. Please complete for requests for Byfavo.

1. Will Byfavo be used for induction and maintenance of procedural sedation?
   ☐ Yes. Please provide procedure date.
   ☐ No.
2. Please provide clinical rationale for use instead of intravenous midazolam.

over

Section IX. Please complete for requests for amitriptyline/chlordiazepoxide.

Please describe the medical necessity for use of the combination product instead of the commercially available separate agents.

Section X. Please complete for requests for clorazepate and oxazepam.

Has the member had a trial with two of the following benzodiazepines: alprazolam, chlordiazepoxide, clonazepam, diazepam, or lorazepam?

☐ Yes. Please list the drug names, dates/duration of use, and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not.

**Attach a letter with additional information regarding medication trials as applicable.*

Section XI. Please complete for requests for Loreev XR.

Please attach medical records documenting stability with lorazepam tablets in three evenly divided daily doses and trials with two intermediate/long- or long-acting benzodiazepines. If all other long-acting benzodiazepines are contraindicated, please describe. For requests for > 1 unit/day, describe medical necessity for exceeding the quantity limit.

Section XII. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

over

☐ Yes ☐ No

If yes, please provide details for the previous trial.

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

_____

_____

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

☐ Yes. Please provide details. _____

☐ No

MassHealth Pediatric Behavioral Health Medication Initiative

Please fill out all the sections below, as applicable, for pediatric members only. You may also use the Pediatric Behavioral Health Medication Initiative PA Request Form if the member is prescribed other behavioral health medications.

Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name _____ Dose/frequency _____ Indication _____
2. Medication name _____ Dose/frequency _____ Indication _____
3. Medication name _____ Dose/frequency _____ Indication _____
4. Medication name _____ Dose/frequency _____ Indication _____
5. Medication name _____ Dose/frequency _____ Indication _____
6. Medication name _____ Dose/frequency _____ Indication _____
7. Other(s) _____

Is the member currently in an acute care setting?

☐ Yes (Inpatient) ☐ Yes (Community Based Acute Treatment)

☐ Yes (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.

Prescriber name _____ Contact information _____

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months. _____

☐ No

On the current regimen, is the member considered to be a risk of harm to self or others?

☐ Yes. Please provide details. _____

☐ No

over

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g. weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain.

Has informed consent from a parent or legal guardian been obtained? * ☐ Yes ☐ No

Please indicate prescriber specialty below.

☐ Psychiatry ☐ Neurology ☐ Other

☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

Name(s) of the specialist(s) Date(s) of last visit or consult

Contact information

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility

☐ Uncertain ☐ Other

Please document agency involvement.

☐ Department of Children and Families (DCF) ☐ Department of Mental Health (DMH)

☐ Department of Developmental Services (DDS) ☐ Department of Youth Services (DYS)

Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions, if applicable.

☐ No

Psychiatric care provided is coordinated with other psychotherapeutic and community based services. ☐ Yes ☐ No

* *Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information go to:* *https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information*

Please complete for members who have been on one of the following for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation): a polypharmacy regimen, members < six years of age who have been on an applicable behavioral health medication, and members < ten years of age who have been on an antipsychotic.

Have previous efforts to reduce or simplify the regimen in the past 24 months resulted in symptom exacerbation? ☐ Yes ☐ No

The family or caregiver does not support the regimen change at this time due to risk of exacerbation.

☐ Yes ☐ No

Is there another significant barrier for therapy discontinuation? ☐ Yes ☐ No

If yes, please explain.

over

Section II. Benzodiazepine Polypharmacy. Complete this section for all members < 18 years of age, if request will result in prescription of two or more benzodiazepine agents for ≥ 60 days within a 90-day period (excluding hypnotic benzodiazepine agents, clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations).

Please document if monotherapy trials (include drug name, dates/duration of use, and outcome) with benzodiazepine agents were tried before prescribing polypharmacy with two or more benzodiazepine agents in this member. *

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Other(s)

Please document clinical rationale for polypharmacy within the same medication class for this member.

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Section III. Benzodiazepine Request for Members < six years of age.

Please document if member has other behavioral health comorbidities (e.g., anxiety, sleep disorder).

For hypnotic benzodiazepine requests, please document medication trials with melatonin and/or clonidine, if clinically appropriate. Include drug name, dates/duration of use, and outcome.*

Please document clinical rationale for the use of a benzodiazepine agent in this member < six years of age.

Has the member been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Section IV. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

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Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.*

Please document clinical rationale for use of multiple behavioral health medications for this member < 18 years of age.

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease Agents Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Adakveo (crizanlizumab-tmca) [MB]
- ☐ l-glutamine
- ☐ Reblozyl (luspatercept-aamt) [MB]
- ☐ Rytelo (imetelstat) [MB]
- ☐ Siklos (hydroxyurea tablet)
- ☐ Xromi (hydroxyurea solution)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Beta Thalassemia (provide documentation of genetic testing)
- ☐ Myelodysplastic syndromes associated anemia
- ☐ Sickle Cell Disease (SCD)
- ☐ Other

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Is the prescriber a hematologist?

- ☐ Yes
- ☐ No. Please attach consultation notes from a hematologist addressing the use of the requested agent.

Member's current weight Date

Section I. Please complete for Adakveo requests.

1. Has the member experienced two or more sickle cell crises in the last 12 months?
   ☐ Yes. Please provide dates. ☐ No
2. Has the member had an inadequate response to hydroxyurea for at least three months? Please note: trial will be evaluated to ensure titration to maximally tolerated dose.*
   ☐ Yes. Please note: requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to this agent.
   Dose and frequency Dates of use Outcome

Please attach hematologic laboratory data (e.g., absolute neutrophil count [ANC], platelet count, hemoglobin, reticulocyte count) supporting dosing regimen.

☐ No

3. Has the member tried hydroxyurea and had an adverse reaction or does the member have a contraindication to this agent?*

☐ Yes. Please explain. ☐ No

4. For recertification requests, please attach medical records documenting positive response to therapy (e.g., follow up information on vaso-occlusive crises, pain management, hospitalizations, and/or member's improvement).

Section II. Please complete for l-glutamine requests.

1. Has the member experienced two or more sickle cell crises in the last 12 months?

☐ Yes. Please provide dates. ☐ No

2. Has the member had a trial with hydroxyurea?*

☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration of use ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not.

Section III. Please complete for Reblozyl for beta thalassemia requests.

1. Please attach a copy of genetic test confirming diagnosis of beta thalassemia.
2. Is the member transfusion-dependent?

☐ Yes. Please attach medical records supporting regular blood transfusions and/or chronic iron chelator use.

☐ No

3. For recertification requests, please attach medical records documenting positive response to therapy (e.g., follow up information on transfusion requirements and/or member's improvement).

Section IV. Please complete for Siklos and Xromi requests.

Please document medical necessity for the use of the requested formulation.

Section V. Please complete for Rytelo requests.

1. Has the member required ≥ four RBC transfusions within the last eight weeks?

☐ Yes. Please describe. ☐ No

2. Has the member had a trial with an erythropoiesis stimulating agent (e.g., epoetin, darbepoetin)?

☐ Yes. Please list the drug name, dose and frequency, dates/duration of use, and outcomes below.

Drug name Dose and frequency

Dates/duration of use ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not.

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3. If the member has MDS with ring sideroblasts, has the member had a trial with Reblozyl?
   ☐ Yes. Please list the dose and frequency, dates/duration of use, and outcomes below.
   Dose and frequency _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   _____
   ☐ No. Please explain why not. _____
4. If the member has MDS associated with a del 5q cytogenic abnormality, has the member had a trial with lenalidomide?
   ☐ Yes. Please list the dose and frequency, dates/duration of use, and outcomes below.
   Dose and frequency _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   _____
   ☐ No. Please explain why not. _____

Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
   _____
   _____
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
   _____
   _____
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details. _____
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Brand-Name and Non-Preferred Generic Drug Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Dose, frequency, and duration of medication requested

Height Weight Date

Drug NDC (if known) or service code

Indication or ICD-10 code, if applicable

Section I. Please complete for brand-name requests.

Has the member tried a generic product therapeutically equivalent to the brand-name product requested?

☐ Yes. Please list the drug name, dates/duration of use, and outcomes below. In addition, provide supporting documentation (e.g., copies of medical records and/or office notes).

Drug name Dates/duration of use

Dose and frequency

Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not. Attach a letter with additional information regarding trials as applicable.

Section II. Please complete for non-preferred generic requests.

Has the member tried a brand-name product therapeutically equivalent to the non-preferred generic product requested?

☐ Yes. Please list the drug name, dates/duration of use, and outcomes below. In addition, provide supporting documentation (e.g., copies of medical records and/or office notes).

Drug name Dates/duration of use

Dose and frequency

Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not. Attach a letter with additional information regarding trials as applicable.

Section III. Please complete for all requests for non-preferred drug products if one or more preferred drug products have been designated for this class of drugs.

If one or more preferred drug products have been designated for this class of drugs, and if you are requesting PA for a non-preferred drug product, please provide medical necessity for prescribing the non-preferred drug product rather than the preferred drug product.

Section IV. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Breast Cancer Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested

- ☐ Datroway (datopotamab deruxtecan-dlnk) [MB]
- ☐ Enhertu (fam-trastuzumab deruxtecan-nxki) [MB]
- ☐ everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg
- ☐ everolimus tablets for oral suspension
- ☐ fulvestrant [MB]
- ☐ eribulin [MB]
- ☐ Herceptin (trastuzumab) [MB]
- ☐ Herceptin Hylecta (trastuzumab-hyaluronidase-oysk) [MB]
- ☐ Hercessi (trastuzumab-strf) [MB]
- ☐ Herzuma (trastuzumab-pkrb) [MB]
- ☐ Ibrance (palbociclib)
- ☐ Itovebi (inavolisib)
- ☐ Kadcyla (ado-trastuzumab) [MB]
- ☐ Kanjinti (trastuzumab-anns) [MB]
- ☐ Kisqali (ribociclib)
- ☐ Kisqali-Femara Co-Pack (ribociclib/letrozole)
- ☐ Margenza (margetuximab-cmkb) [MB]
- ☐ Nerlynx (neratinib)
- ☐ Ogivri (trastuzumab-dkst) [MB]
- ☐ Ontruzant (trastuzumab-dttb) [MB]
- ☐ Orserdu (elacestrant)
- ☐ Perjeta (pertuzumab) [MB]
- ☐ Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf) [MB]
- ☐ Piqray (alpelisib)
- ☐ Trazimera (trastuzumab-qyyp) [MB]
- ☐ Trodelvy (sacituzumab govitecan-hziy) [MB]
- ☐ Truqap (capivasertib)
- ☐ Tukysa (tucatinib)
- ☐ Verzenio (abemaciclib)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Height Weight Date

Please indicate prescriber specialty below.

☐ Oncology ☐ Other

Will the requested agent be used as monotherapy for this indication? ☐ Yes ☐ No

If no, please list all other medications currently prescribed for the member that will be used concomitantly for this indication.

Will the requested agent be used as adjuvant or neoadjuvant therapy for this indication? ☐ Yes ☐ No

If yes, please describe. ☐ Adjuvant ☐ Neoadjuvant

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ **Breast cancer**

☐ Early ☐ Advanced ☐ Metastatic ☐ Recurrent ☐ Unresectable

Other Oncologic Indications

☐ Liposarcoma
☐ Locally advanced or metastatic urothelial cancer
☐ Metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma
☐ Metastatic non-small cell lung cancer (NSCLC) with activating HER2 (ERBB2) mutations
☐ Unresectable or metastatic colorectal cancer

Please describe pertinent mutations if applicable.

☐ AKT1
☐ ER-positive
☐ ER-negative
☐ ERBB2
☐ ESR1
☐ HER2-positive
☐ HER2-negative
☐ HER2-low
☐ HR-positive
☐ HR-negative
☐ PIK3CA
☐ PTEN
☐ RAS wild-type
☐ Triple negative
☐ Other

Please describe the stage and severity of disease.

Has the member had persistent or recurring disease following surgery and/or radiation therapy? ☐ Yes ☐ No

Is the member a candidate for surgery and/or radiation?

☐ Yes ☐ No. Please describe.

Section I. Please complete for all requests.

Please list any other prior trials. Please list the drug names, dates/duration of use and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

over

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

** Please attach a letter documenting additional trials as necessary.*

Section II. Please complete for requests for agents with a preferred alternative.

Please describe the clinical rationale for use of the requested agent instead of the preferred alternative.

Section III. Please complete for requests for quantities above quantity limits.

Please describe the clinical rationale for exceeding the quantity limit, including a detailed treatment plan.

Section IV. Please include any other pertinent information (if needed).

Section V. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

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3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details. _____
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Cerebral Stimulant and ADHD Drugs
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about ADHD medications and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form.**

Medication information

Medication requested (Check all that apply. Where applicable, the brand name is provided in brackets for reference.)

Long-Acting Cerebral Stimulants

- ☐ Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablet)
- ☐ amphetamine extended-release 1.25 mg/mL oral suspension
- ☐ amphetamine salts extended-release [Adderall XR] > 2 units/day
- ☐ amphetamine salts extended-release [Mydayis]
- ☐ Azstarys (serdexmethylphenidate/ dexmethylphenidate)
- ☐ Cotempla XR-ODT (methylphenidate extended-release orally disintegrating tablet)
- ☐ dexmethylphenidate extended-release [Focalin XR] > 2 units/day
- ☐ Dyanavel XR (amphetamine extended-release 2.5 mg/mL oral suspension)
- ☐ Dyanavel XR (amphetamine extended-release chewable tablet)
- ☐ Jornay PM (methylphenidate extended-release)
- ☐ lisdexamfetamine capsule > 2 units/day
- ☐ lisdexamfetamine chewable tablet
- ☐ methylphenidate extended-release [Aptensio XR]
- ☐ methylphenidate extended-release [Concerta] > 2 units/day
- ☐ methylphenidate extended-release 72 mg tablet
- ☐ methylphenidate extended-release, CD
- ☐ methylphenidate long-acting capsule [Ritalin LA]
- ☐ methylphenidate transdermal [Daytrana] > 1 unit/day
- ☐ Quillichew ER (methylphenidate extended-release chewable tablet)
- ☐ Quillivant XR (methylphenidate extended-release oral suspension)
- ☐ Relexxii (methylphenidate extended-release tablet)
- ☐ Xelstrym (dextroamphetamine transdermal)

Intermediate/Short-Acting Cerebral Stimulants

- ☐ amphetamine salts [Adderall] > 3 units/day
- ☐ amphetamine sulfate
- ☐ dexmethylphenidate [Focalin] > 3 units/day
- ☐ dextroamphetamine 5 mg, 10 mg, 15 mg capsule [Dexedrine Spansule] > 3 units/day
- ☐ dextroamphetamine 2.5 mg, 7.5 mg, 15 mg, 20 mg, 30 mg tablet
- ☐ dextroamphetamine 5 mg, 10 mg tablet > 3 units/day
- ☐ dextroamphetamine solution > 40 mL/day
- ☐ Evekeo ODT (amphetamine sulfate orally disintegrating tablet)
- ☐ methylphenidate [Ritalin] > 3 units/day
- ☐ methylphenidate chewable tablet > 3 units/day
- ☐ methylphenidate oral solution [Methylin oral solution] > 30 mL/day
- ☐ methylphenidate sustained-release tablet > 3 units/day

Non-Stimulant Medications

- ☐ clonidine extended-release 0.1 mg tablet > 4 units/day
- ☐ Qelbree (viloxazine)
- ☐ Onyda XR (clonidine extended-release suspension)

Other Medication

- ☐ Other* _____

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/ or office notes regarding adverse reaction or inadequate response to the preferred product).*

Dose, frequency, and duration of requested drug

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Attention Deficit Hyperactivity Disorder (ADHD) ☐ Narcolepsy ☐ Other

Quantity requested per month **Total quantity of all stimulants combined**

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for cerebral stimulant requests above quantity limits.

1. Has dose consolidation been attempted? ☐ Yes ☐ No. Please explain why not.
2. Is the member under the care of a psychiatrist or behavioral specialist? ☐ Yes ☐ No
3. Please list all medications currently prescribed for this member for this condition.
4. Please describe your new treatment plan for managing this member's condition, including discontinuation of any medications because of the addition of medication requested.

Section II. Please complete for dextroamphetamine 2.5 mg, 7.5 mg, 15 mg, 20 mg, and 30 mg tablet requests.

Please provide medical necessity for requested strength instead of dextroamphetamine 5 mg and 10 mg tablets available without prior authorization.

Section III. Please complete for Azstarys, Cotempla XR-ODT, Jornay PM, methylphenidate extended-release [Aptensio XR] and long-acting capsule [Ritalin LA], methylphenidate extended-release CD, Quillichew ER, and Quillivant XR requests.

1. Please provide clinical rationale for use of the requested agent instead of Concerta (methylphenidate extended-release), or medical necessity for requested formulation instead of solid oral formulations.
2. For Azstarys, Cotempla XR-ODT, Jornay PM, methylphenidate extended-release [Aptensio XR], Quillichew ER, and Quillivant XR requests, please provide clinical rationale for use of the requested agent instead ofmethylphenidate transdermal and Focalin XR (dexmethylphenidate extended-release).

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3. For methylphenidate long-acting capsule [Ritalin LA] and methylphenidate extended-release CD, please provide clinical rationale for use of the requested agent instead of Focalin XR (dexmethylphenidate extended-release).

Section IV. Please complete for Adzenys XR-ODT, amphetamine extended-release 1.25 mg/mL oral suspension, amphetamine salts extended-release [Mydayis], Dyanavel XR chewable tablet and oral suspension, lisdexamfetamine chewable tablet, and Xelstrym requests.

Please provide clinical rationale for use of the requested agent instead of Adderall XR (amphetamine salts extended-release) and lisdexamfetamine capsule.

Section V. Please complete for amphetamine sulfate requests.

Has the member tried an amphetamine immediate-release product that is available without prior authorization to treat this condition?

☐ Yes. Attach documentation of trials, including drug name, dose and frequency, dates of use, and outcomes.

☐ No. Explain why not.

Section VI. Please complete for methylphenidate extended-release 72 mg tablet and Relexxii requests.

Please provide clinical rationale for requested agent instead of Concerta (methylphenidate extended-release) (including use of two tablets to achieve the requested dose when applicable), methylphenidate transdermal, and Focalin XR (dexmethylphenidate extended-release).

Section VII. Please complete for Evekeo ODT requests.

Please provide medical necessity for requested formulation instead of solid oral formulations.

Section VIII. Please complete for Qelbree requests.

Has the member tried atomoxetine to treat this condition?

☐ Yes. Please list the dates/duration of use, dose and frequency, and outcome below.

Dates of use Dose and frequency

Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Explain why not.

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Section IX. Please complete for Onyda XR requests.

1. Has the member tried clonidine immediate-release tablets to treat this condition?
   ☐ Yes. Please list the dates/duration of use, dose and frequency, and outcome below.
   Dates of use Dose and frequency
   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why not.
2. Has the member tried clonidine patches to treat this condition?
   ☐ Yes. Please list the dates/duration of use, dose and frequency, and outcome below.
   Dates of use Dose and frequency
   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why not.
3. Has the member tried clonidine extended-release tablets to treat this condition?
   ☐ Yes. Please list the dates/duration of use, dose and frequency, and outcome below.
   Dates of use Dose and frequency
   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why not.
4. Is there a medical necessity for the suspension formulation instead of solid oral formulations? ☐ Yes ☐ No
   If yes, please explain.
5. Has the member tried a liquid stimulant (amphetamine or methylphenidate product) that is available without prior authorization to treat this condition?
   ☐ Yes. Please describe the drug names, dates/duration of use, and outcomes.
   Drug Name Dates/duration of use
   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Please describe if there is a contraindication to all stimulants.

Section X. Please also complete for members ≥ 21 years of age (new to therapy).

1. For a diagnosis of ADHD, were symptoms present before 12 years of age according to the DSM-5 diagnostic criteria? ☐ Yes ☐ No ☐ Unknown
   Please provide detail regarding diagnosis if answered no or unknown.
2. For all other diagnoses, please describe alternative first-line treatment options and non-pharmacologic interventions that have been implemented or trialed prior to cerebral stimulants.

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Section XI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

MassHealth Pediatric Behavioral Health Medication Initiative

Please fill out all the sections below, as applicable, for pediatric members only. You may also use the Pediatric Behavioral Health Medication Initiative PA Request Form if the member is prescribed other behavioral health medications.

Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name Dose/frequency Indication
2. Medication name Dose/frequency Indication
3. Medication name Dose/frequency Indication
4. Medication name Dose/frequency Indication
5. Medication name Dose/frequency Indication

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6. Medication name _____ Dose/frequency _____ Indication _____

7. Other(s) _____

Is the member currently in an acute care setting?

☐ Yes (Inpatient) ☐ Yes (Community Based Acute treatment)

☐ Yes (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.

Prescriber name _____ Contact information _____

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months.

_____ ☐ No

On the current regimen, is the member considered to be a severe risk of harm to self or others?

☐ Yes. Please provide details. _____ ☐ No

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g., weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain. _____

Has informed consent from a parent or legal guardian been obtained?* ☐ Yes ☐ No

Please indicate prescriber specialty below.

☐ Psychiatry ☐ Neurology ☐ Other _____

☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

_____

Name(s) of the specialist(s) _____ Date(s) of last visit or consult _____

Contact information _____

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable. _____

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility

☐ Uncertain ☐ Other _____

Please document agency involvement.

☐ DCF ☐ Department of Mental Health (DMH) ☐ Department of Developmental Services (DDS)

☐ Department of Youth Services (DYS)

Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions below, if applicable. ☐ No

_____

Psychiatric care provided is coordinated with other psychotherapeutic and community based services. ☐ Yes ☐ No

** Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information, go to https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information.*

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Section II. Cerebral Stimulant Polypharmacy. Complete this section for all members < 18 years of age, if request will result in prescription of two or more cerebral stimulants for ≥ 60 days within a 90-day period. Please note, immediate-release and extended-release formulations of the same chemical entity are counted as one.

Please document amphetamine and methylphenidate monotherapy trials (include drug name, dates/duration of use, and outcome) and rationale for polypharmacy with two or more cerebral stimulants in this member.*

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

** Attach a letter with additional information regarding medication trials as applicable.*

Section III. Alpha$_2$ Agonist or Cerebral Stimulant Request for Members < three years of age.

Please document any previous medication trial(s). Include the drug name, dates/duration of use, and outcome. For requests for an amphetamine product, include drug name, dates/duration of use, and outcome to a trial with a methylphenidate product.*

Please document clinical rationale for use of an alpha$_2$ agonist or cerebral stimulant for this member < three years of age.

** Attach a letter with additional information regarding medication trials as applicable.*

Section IV. Atomoxetine or Qelbree Request for Members < six years of age.

Please document any previous medication trial(s). Include the drug name, dates/duration of use, and outcome.*

Please document clinical rationale for use of atomoxetine or viloxazine for this member < six years of age.

** Attach a letter with additional information regarding medication trials as applicable.*

Section V. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

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Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.*

Please document clinical rationale for use of multiple behavioral health medications for this member < 18 years of age.

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

** Attach a letter with additional information regarding medication trials as applicable.*

Please continue to next page and complete Prescriber and Provider Information section.

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Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Constipation Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Constipation agent requested

- ☐ Ibsrela (tenapanor 50 mg tablet)
- ☐ lactulose packet
- ☐ lubiprostone
- ☐ Movantik (naloxegol)
- ☐ prucalopride
- ☐ Relistor (methylnaltrexone)
- ☐ Symproic (naldemedine)
- ☐ Trulance (plecanatide)

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Chronic idiopathic constipation (CIC)
- ☐ Irritable bowel syndrome with constipation (IBS-C)
- ☐ Opioid-induced constipation
- ☐ Other

Section I. Please complete for all requests, excluding lactulose packet. For Ibsrela, Movantik, prucalopride, Relistor, Symproic, and Trulance requests, please also complete Section II below as appropriate.

1. Has the member had a trial with a bulk-forming laxative? ☐ Yes. Drug name ☐ No
2. Has the member had a trial with a saline laxative? ☐ Yes. Drug name ☐ No
3. Has the member had a trial with an osmotic laxative? ☐ Yes. Drug name ☐ No
4. Has the member had a trial with a stimulant laxative? ☐ Yes. Drug name ☐ No
5. For lubiprostone for the treatment of IBS-C or CIC, has the member had a trial with Linzess?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use Outcome
   ☐ No. Please document if there is a contraindication to Linzess therapy.
6. For lubiprostone for the treatment of IBS-C or CIC, has the member had a trial with Trulance?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use Outcome
   ☐ No. Please document if there is a contraindication to Trulance therapy.
7. For lubiprostone, Movantik, Relistor, and Symproic does the member have chronic, non-cancer pain?
   ☐ Yes ☐ No

8. For Relistor, does the member have an advanced illness for which the member is receiving palliative care?
   ☐ Yes. Diagnosis _____ ☐ No
9. For Relistor injection, please provide medical necessity for use of the requested formulation instead of the tablet formulation.

Section II. Please also complete for Ibsrela, Movantik, prucalopride, Relistor, Symproic, and Trulance requests. Please complete Section I above as appropriate.

1. Has the member had a trial with lubiprostone?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use _____ Outcome _____
   ☐ No. Please document if there is a contraindication to lubiprostone therapy.
2. Has the member had a trial with Linzess?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use _____ Outcome _____
   ☐ No. Please document if there is a contraindication to Linzess therapy.
3. For Relistor, has the member had a trial with Movantik?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use _____ Outcome _____
   ☐ No. Please document if there is a contraindication to Movantik therapy.
4. For Ibsrela and prucalopride, has the member had a trial with Trulance?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use _____ Outcome _____
   ☐ No. Please document if there is a contraindication to Trulance therapy.
5. For Movantik, has the member had a trial with Symproic?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use _____ Outcome _____
   ☐ No. Please document if there is a contraindication to Symproic therapy.

Section III. Please complete for lactulose packet requests.

Please attach medical records documenting an adverse reaction or contraindication to lactulose solution.

** Attach a letter with additional information regarding medication trials as applicable.*

Section IV. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

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2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

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Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Cystic Fibrosis Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested (Where applicable, the brand name is provided in brackets for reference.)

- ☐ Alyftrek (vanzacaftor/tezacaftor/deutivacaftor)
- ☐ Bronchitol (mannitol inhalation powder)
- ☐ Kalydeco (ivacaftor)
- ☐ Orkambi (lumacaftor/ivacaftor)
- ☐ Symdeko (tezacaftor/ivacaftor)
- ☐ Tobi Podhaler (tobramycin inhalation powder)
- ☐ tobramycin inhalation solution [Bethkis]
- ☐ tobramycin inhalation solution [Kitabis Pak]
- ☐ Trikafta (elexacaftor/tezacaftor/ivacaftor)

Dose, frequency, and duration of medication requested

Is the member stabilized on the requested medication? ☐ Yes. Please provide start date. ☐ No

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Cystic Fibrosis [Please specify genetic mutation(s) below.]

Does the member have *Pseudomonas aeruginosa*? ☐ Yes ☐ No

☐ Other

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for initial requests for Alyftrek, Kalydeco, Orkambi, Symdeko, and Trikafta.

1. Please document member's baseline body mass index (BMI). Date
2. For members > 6 years of age, please document member's baseline percent predicted forced expiratory volume in one second (ppFEV1). Date

Section II. Please complete for recertification requests for Kalydeco, Orkambi, Symdeko, and Trikafta.

1. Please document member's current BMI. Date
   Has the member demonstrated an improvement in BMI? ☐ Yes ☐ No
2. For members > 6 years of age, please document member's current ppFEV1.
   Date
   Has the member demonstrated an improvement in lung function? ☐ Yes ☐ No

3. Has the member demonstrated a reduced frequency of clinical exacerbations since initiating the requested medication? ☐ Yes ☐ No

   If yes, please describe.

4. If member has not demonstrated improvement in the ppFEV1, BMI or frequency of clinical exacerbations, please document response to therapy.

Section III. Please complete for Tobi Podhaler and tobramycin inhalation solution (generic Bethkis and Kitabis Pak) requests.

Has the member had a trial with tobramycin inhalation solution (generic Tobi)?

☐ Yes. Please list the dose and frequency, dates/duration of trials, and outcomes below.

Dose and frequency Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain.

Section IV. Please complete for Bronchitol requests.

1. Documentation that member has passed the Bronchitol Tolerance Test ☐ Yes ☐ No
2. Has the member had a trial with Pulmozyme?

   ☐ Yes. Please list the dose and frequency, dates/duration of trials, and outcomes below.

   Dose and frequency Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

3. Has the member had a trial with sodium chloride for inhalation?

   ☐ Yes. Please list the dose and frequency, dates/duration of trials, and outcomes below.

   Dose and frequency Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

Section V. Please include any other pertinent information (if needed).

Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

over

If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

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Printed legal name and title of signatory above

Date

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Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Dermatological Agents (Topical Chemotherapy and Genital Wart Therapy) Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication requested

☐ Ameluz (aminolevulinic acid) [MB]
☐ imiquimod 3.75% cream
☐ Levulan (aminolevulinic acid) [MB]
☐ Veregen (sinecatechins)
☐ Ycanth (cantharidin) [MB]
☐ Zyclara (imiquimod 2.5% cream)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Indication (Check all that apply) or ICD-10 code, if applicable

☐ Actinic keratosis
  ☐ Face ☐ Scalp ☐ Upper extremities
☐ External genital warts
☐ Perianal warts
☐ Molluscum contagiosum
☐ Other
(Attach a letter regarding medical necessity.)

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Is the prescriber a dermatologist?
☐ Yes
☐ No. For Ameluz and Levulan requests, please attach consultation notes from a dermatologist addressing the use of the requested agent.

Section I. Please complete for treatment of actinic keratosis with imiquimod 3.75% cream, or Zyclara.

1. Has the member had a trial with topical fluorouracil?
   ☐ Yes. Please list the dates/duration of use and outcomes below.
   Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Please document if there is a contraindication to topical fluorouracil therapy.
2. If the request is for imiquimod 3.75% cream or Zyclara, has the member tried imiquimod 5% cream?
   ☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please document if there is a contraindication to imiquimod 5% cream.

Section II. Please complete for Ameluz and Levulan requests.

1. Has the member had a trial with topical fluorouracil or topical imiquimod?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcomes below.

   Drug name

   Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please document if there is a contraindication to topical fluorouracil and topical imiquimod.
2. Has the member tried and failed cryosurgery? ☐ Yes ☐ No
3. Will the requested agent be used in conjunction with photodynamic therapy? ☐ Yes ☐ No
4. If the request is for Ameluz, has the member had a trial with Levulan used in conjunction with photodynamic therapy?
   ☐ Yes. Please list the dates/duration of use and outcomes below.

   Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please document if there is a contraindication to Levulan used in conjunction with photodynamic therapy.

Section III. Please complete for Ycanth requests.

1. Has the member had a trial with topical podofilox?
   ☐ Yes. Please list the dates/duration of use and outcomes below.

   Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please document if there is a contraindication to topical podofilox.
2. Has the member tried and failed cryotherapy? ☐ Yes ☐ No
3. Has the member tried and failed curettage? ☐ Yes ☐ No

Section IV. Please complete for treatment of external genital warts or perianal warts with imiquimod 3.75% cream or Veregen.

1. Has the member had a trial with topical podofilox, or podophyllum resin applied by a provider?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcomes below.

   Drug name

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Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please document if there is a contraindication to topical podofilox and podophyllum resin.

2. If the request is for imiquimod 3.75% cream, has the member had a trial with imiquimod 5% cream?

Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please document if there is a contraindication to imiquimod 5% cream.

Section V. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen? ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details.

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Diabetes Medical Supplies
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Product information

Device requested

- ☐ Cequr Simplicity
  - ☐ Cequr Simplicity 2U 3-Day Patch
  - ☐ Cequr Simplicity 2U 4-Day Patch
  - ☐ Cequr Simplicity Inserter
- ☐ Dexcom G6
  - ☐ Receiver
  - ☐ Sensor
  - ☐ Transmitter
- ☐ Dexcom G7
  - ☐ Receiver
  - ☐ Sensor
- ☐ Freestyle Libre 14 Day
  - ☐ Reader
  - ☐ Sensor
- ☐ Freestyle Libre 2
  - ☐ Reader
  - ☐ Sensor
  - ☐ Sensor Plus
- ☐ Freestyle Libre 3
  - ☐ Reader
  - ☐ Sensor
  - ☐ Sensor Plus
- ☐ Omnipod 5
  - ☐ Omnipod 5 Pod Pack
  - ☐ Omnipod 5 Intro Kit

  Please specify brand (e.g., G6/G7, G6/Libre 2 Plus)

- ☐ Omnipod Classic
  - ☐ Omnipod Classic Personal Diabetes Manager
  - ☐ Omnipod Classic Pod Pack
- ☐ Omnipod Dash
  - ☐ Omnipod Dash Intro Kit
  - ☐ Omnipod Dash Personal Diabetes Manager
  - ☐ Omnipod Dash Pod Pack
- ☐ V-Go

Non-drug product requested	**Qty/30 days**
☐ Blood glucose testing strips > 100 units/30 days	
☐ Freestyle	
☐ Freestyle Insulinx	
☐ Freestyle Lite	
☐ Freestyle Neo	
☐ Precision Xtra	

☐ Non-preferred blood glucose testing strips (Please specify brand.)

Dose, frequency, and duration of medication or medical supplies requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Type 1 Diabetes Mellitus ☐ Type 2 Diabetes Mellitus ☐ Other

What is the member's most recent hemoglobin A1C? Date

Is this member a referral candidate for care coordination? ☐ Yes ☐ No
If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for Dexcom G6, Dexcom G7, Freestyle Libre 14 Day, Freestyle Libre 2, and Freestyle Libre 3 requests.

1. Is the member stabilized on the requested device? ☐ Yes. Please provide start date. ☐ No
2. Is the member currently receiving treatment with insulin administration or an insulin pump? ☐ Yes ☐ No
   Please explain.
3. Has the member experienced any of the following? (Check all that apply.)
   ☐ Yes
   - ☐ Two hypoglycemic events with blood glucose of < 54 mg/dL (3.0mmol/L) within the last 12 months
   - ☐ One hypoglycemic event with blood glucose of < 54 mg/dL (3.0mmol/L) that required third-party assistance for treatment within the past 12 months

   ☐ No. Please explain why the member is a candidate for continuous blood glucose monitoring.

Section II. Please complete for Cequr Simplicity, Omnipod 5, Omnipod Classic, Omnipod Dash, Omnipod Go, and V-Go requests.

1. Is the member stabilized on the requested device? ☐ Yes. Please provide start date. ☐ No
2. Is the member currently testing blood glucose at least four times per day or using continuous glucose monitoring? ☐ Yes ☐ No
3. Is the member currently receiving treatment with insulin administration at least three times per day or an insulin pump? ☐ Yes ☐ No
4. Does the member have an A1c >7%, or does not meet documented target treatment? ☐ Yes ☐ No
5. Does the member exhibit any of the following clinical characteristics? (Check all that apply.)
   ☐ Yes
   - ☐ Frequent hypoglycemia
   - ☐ Fluctuations of more than 100 mg/dL in blood glucose before mealtime
   - ☐ Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
   - ☐ History of severe glycemic excursions

   ☐ No. Please explain why the member is a candidate for continuous subcutaneous insulin infusion.

Section III. Please complete for Cequr Simplicity, Dexcom G6, Dexcom G7, Freestyle Libre 14 Day, Freestyle Libre 2, Freestyle Libre 3, Omnipod 5, Omnipod Classic, Omnipod Dash, Omnipod Go, and V-Go recertification requests.

For Cequr Simplicity, Omnipod 5, Omnipod Classic, Omnipod Dash, Omnipod Go, and V-Go, only question 1 is required.

1. Has the member demonstrated improvement in diabetic control or relative stability?
   ☐ Yes
   ☐ No. Please describe why not.

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2. Has the member's continuous blood glucose monitoring data been reviewed and used to monitor or adjust the antidiabetic treatment plan?
   ☐ Yes
   ☐ No. Please describe why not.

Section IV. Please complete for all requests exceeding the quantity limit.

1. Is the member currently receiving treatment with insulin administration or an insulin pump?
   ☐ Yes. Please provide units/day.
   ☐ No
2. Does the member exhibit any of the following clinical characteristics? (Check all that apply.)
   ☐ Yes
   ☐ Injection site irritation. Were mitigation strategies attempted? ☐ Yes ☐ No
   ☐ Adhesion failure. Were mitigation strategies attempted? ☐ Yes ☐ No
   ☐ Lipoatrophy or lipohypertrophy at the injection site
   ☐ Pooling of insulin at the injection site
   ☐ No. Please provide medical necessity for the requested quantity.

Section V. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

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Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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Erythropoiesis-Stimulating Agents
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Drug name requested

Dose, frequency, and duration

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Section I. Please complete for all requests.

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ **Anemia due to chronic renal failure**

Is the member receiving hemodialysis? ☐ Yes ☐ No (Please note, if the member is receiving hemodialysis, contact the dialysis clinic for proper billing procedure.)

Current hemoglobin Date

Glomerular Filtration Rate (GFR)

☐ **Anemia due to chemotherapy treatment for cancer**

Current hemoglobin Date

☐ **Anemia due to a myelosuppressive medication regimen for HIV**

Is member currently on zidovudine or zidovudine-containing products? ☐ Yes ☐ No

If yes, please provide current medication regimen.

Have other causes of anemia been ruled out (hemolysis, iron, vitamin B12, and folate deficiency)?
☐ Yes ☐ No. If no, please provide medical necessity for the use of requested agent.

Current hemoglobin Date

☐ **Decrease need for blood transfusions due to surgery**

Type of procedure Date of procedure

Please provide medical necessity for the use of requested agent.

☐ **Other**

Please provide medical necessity for the use of erythropoietin (including diagnosis with etiology, current hemoglobin, other disease states, etc.).

Section II. Please also complete for recertification requests.

1. Is the member's hemoglobin currently > 12 g/dL?
   ☐ Yes. Please answer both questions below.
   Please provide the treatment plan to hold or reduce the erythropoietin dose.

   Date last erythropoietin dose was administered
   ☐ No
2. For members with anemia due to chemotherapy or myelosuppressive medication, please provide the most recent date of use for the causative agent.
   Medication(s) Date

Section III. Please complete for Procrit requests.

Please provide clinical rationale for use of the requested agent instead of Epogen and Retacrit.

Section IV. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use

over

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

☐ Yes. Please provide details.
☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

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Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

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Gastrointestinal Agents — Antidiarrheals and Bowel Preparation Agents Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Antidiarrheals (See Sections I and II as applicable.)

☐ alosetron ☐ Mytesi (crofelemer) ☐ opium tincture ☐ Viberzi (eluxadoline)

Bowel Preparation Agents (See Section III.)

☐ Clenpiq (sodium picosulfate/magnesium oxide/anhydrous citric acid)

☐ Suflave (polyethylene glycol 3350/sodium sulfate/potassium chloride/magnesium sulfate/and sodium chloride)

☐ Sutab (sodium sulfate/magnesium sulfate/potassium chloride)

Dose and frequency of medication requested

Section I. Please complete for all Antidiarrheal Agent requests.

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Chronic diarrhea ☐ Irritable bowel syndrome with diarrhea ☐ Diarrhea in an HIV/AIDS member

☐ Other

Previous Trials (Check all that apply.)

Antidiarrheals

☐ bismuth subsalicylate
☐ diphenoxylate/atropine
☐ loperamide

☐ Bile acid sequestrant
☐ Selective serotonin reuptake inhibitor
☐ Tricyclic antidepressant
☐ Other (please specify)

Other

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

If the member has a contraindication to these trials please describe.

Section II. Please also complete for alosetron and Viberzi requests.

Is the prescriber a gastroenterologist? ☐ Yes ☐ No. Please attach consultation notes from a gastroenterologist addressing the use of the requested agent.

Please provide details for the previous trials.

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response. _____

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response. _____

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response. _____

Section III. Please complete for Bowel Preparation Agent requests.

Has the member had a trial with one bowel prep product that is available without prior authorization?

☐ Yes. Please provide details for the previous trial.

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response. _____

☐ No. Please explain why. _____

Section IV. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

   _____

   _____

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

   _____

   _____

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name _____ Dates/duration of use _____

over

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

☐ Yes. Please provide details.
☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

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Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

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☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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General Drug
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Please note: the requested drug may have a specific form that contains information pertinent to this PA request. Please see more drug-specific PA forms within the MassHealth Drug List at **www.mass.gov/druglist.**

In addition, the **Pediatric Behavioral Health Medication Initiative** requires PA for pediatric members (generally members < 18 years of age) for certain behavioral health medication classes and/or specific medication combinations (i.e., polypharmacy) that have limited evidence for safety and efficacy in the pediatric population.

Additional information about medications and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form.**

Medication information

Medication requested

Dose, frequency, and duration of medication requested

Height Weight Date

Drug NDC (if known) or service code

Indication or ICD-10 code, if applicable

Section I. Please complete the following for all requests.

1. Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.
2. Has member tried other medications to treat this condition?
   ☐ Yes. Provide the information below. You may be asked to provide supporting documentation (e.g., copies of medical records, office notes, and/or completed FDA MedWatch form).

   Drug name Dates of use

   Dose and frequency

   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   Drug name Dates of use

   Dose and frequency

   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Explain why not (attach a letter describing medical necessity as applicable).

Section II. Please complete the following as applicable for all requests.

Explain medical necessity of requested drug.

List all current medications.

Diagnostic studies and/or laboratory tests performed (include dates and results).

Please include any other pertinent information (if needed).

Section III. Please complete for all requests for non-preferred drug products if one or more preferred drug products have been designated for this class of drugs.

If one or more preferred drug products have been designated for this class of drugs, and if you are requesting PA for a non-preferred drug product, please provide medical necessity for prescribing the non-preferred drug product rather than the preferred drug product.

Section IV. Please complete for all requests for pharmaceutical compounds.

1. Please list all submitted ingredients of the pharmaceutical compound requested.

Ingredient

Ingredient

Ingredient

Ingredient

Ingredient

over

Other(s)

Please attach a letter documenting additional ingredients as applicable.

2. For topical route of administration, please describe medical necessity for use of the requested product for the requested route of administration.
3. Is the requested compounded product commercially available? ☐ Yes ☐ No
4. Have commercial products been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness? ☐ Yes ☐ No
5. Does the member have a medical need for a dosage form or dosage strength that is not commercially available?

   ☐ Yes. Please describe.

   ☐ No
6. Please describe the medical necessity for the included inactive ingredients.

Section V. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details.

   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Glaucoma Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested (Where applicable, the brand name is provided in brackets for reference.)

- ☐ bimatoprost 0.03% ophthalmic solution
- ☐ dorzolamide/timolol preservative free
- ☐ Durysta (bimatoprost implant) [MB]
- ☐ Idose TR (travoprost intracameral implant) [MB]
- ☐ Iyuzeh (latanoprost solution)
- ☐ Rhopressa (netarsudil)
- ☐ Rocklatan (netarsudil/latanoprost)
- ☐ tafluprost
- ☐ timolol [Betimol]
- ☐ timolol ophthalmic gel forming solution
- ☐ timolol ophthalmic unit dose solution
- ☐ Vyzulta (latanoprostene)
- ☐ Xelpros (latanoprost emulsion)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Open-angle glaucoma ☐ Ocular hypertension ☐ Other

Dose, frequency, and duration of medication requested

Drug NDC (if known) or service code

Section I. Please complete for timolol [Betimol], timolol ophthalmic gel forming solution and timolol ophthalmic unit dose solution requests.

Has the member had a trial with an ophthalmic timolol formulation that is available without PA?

☐ Yes ☐ No. Please provide clinical rationale for not using an ophthalmic timolol formulation that is available without PA.

Section II. Please complete for bimatoprost 0.03% requests.

1. Has the member had a trial with latanoprost solution or travoprost 0.004% eye drop?

   ☐ Yes. Please list the drug name, dates/duration of use, and outcomes below.

   Drug name Dates/duration

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please provide clinical rationale for not using latanoprost solution and travoprost 0.004% eye drops.

2. Has the member had a trial with Lumigan?

☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please provide clinical rationale for not using Lumigan.

Section III. Please complete for Durysta requests.

1. Has the member had a trial with Lumigan?

☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please describe medical necessity for an implantable formulation instead of eye drops.

2. Please specify affected eye. ☐ Left eye ☐ Right eye
3. Is the request for retreatment of the same eye? ☐ Yes ☐ No

Section IV. Please complete for dorzolamide/timolol preservative free and Xelpros requests.

Has the member experienced sensitivity to benzalkonium chloride or any other preservatives used in ophthalmic preparations?

☐ Yes ☐ No. Please provide clinical rationale for the use of the requested formulation instead of the respective formulation that is available without PA.

Section V. Please complete for Rhopressa and Rocklatan requests.

1. Has the member had a trial of combination therapy with a prostaglandin analog and an ophthalmic beta-blocker?

☐ Yes. Please list the drug names, dates/duration of use and outcomes below.*

☐ No. Please provide clinical rationale for not using combination therapy with a prostaglandin analog and an ophthalmic beta-blocker.

2. Does the member have a contraindication to ophthalmic beta-blockers?

☐ Yes. Please describe. ☐ No

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If yes, has the member had a trial of combination therapy with a prostaglandin analog and either an ophthalmic alpha-2 adrenergic agonist, parasympathomimetic, or carbonic anhydrase inhibitor?

☐ Yes. Please list the drug names, dates/duration of use and outcomes below.* ☐ No

3. For Rhopressa, does the member have a contraindication to prostaglandin analogs?

☐ Yes. Please describe. ☐ No

If yes, has the member had a trial of combination therapy with an ophthalmic beta-blocker and either an ophthalmic alpha-2 adrenergic agonist, parasympathomimetic, or carbonic anhydrase inhibitor?

☐ Yes. Please list the drug names, dates/duration of use and outcomes below.* ☐ No

Please provide details for the previous trials.

Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

**Please attach a letter documenting additional trials as necessary.*

Section VI. Please complete for Vyzulta requests.

Has the member had an inadequate response to a trial of combination therapy with latanoprost solution and an ophthalmic beta-blocker? ☐ Yes ☐ No.

If no, has the member had a trial with latanoprost solution?

☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration Outcome

If no, has the member had an adverse reaction to an ophthalmic beta-blocker?

☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration Outcome

☐ No. Please provide clinical rationale for not using ophthalmic beta-blocker.

Section VII. Please complete for Iyuzeh and tafluprost requests.

1. Has the member had a trial with latanoprost solution available without PA?

☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please provide clinical rationale for not using latanoprost solution available without PA.

2. Has the member had a trial with Xelpros?

☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please provide clinical rationale for not using Xelpros.

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Section VIII. Please complete for Idose TR.

1. Have the affected eye(s) been previously treated with IdoseTR? ☐ Yes ☐ No
2. Has the member had a trial with travoprost 0.004% ophthalmic solution?
   ☐ Yes. Please list the dates/duration of use and outcomes below.

   Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe medical necessity for an implantable formulation instead of eye drops.

Section IX. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Gonadotropin-Releasing Hormone Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Camcevi (leuprolide)
- ☐ Eligard (leuprolide)
- ☐ Fensolvi (leuprolide)
- ☐ Firmagon (degarelix)
- ☐ leuprolide 22.5 mg vial
- ☐ Lupron (leuprolide)
- ☐ Myfembree (relugolix/estradiol/norethindrone)
- ☐ Orgovyx (relugolix)
- ☐ Oriahnn (elagolix/estradiol/norethindrone)
- ☐ Orilissa (elagolix)
- ☐ Supprelin LA (histrelin) [MB]
- ☐ Synarel (nafarelin)
- ☐ Trelstar (triptorelin) [MB]
- ☐ Triptodur (triptorelin)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Advanced breast cancer
- ☐ Advanced prostate cancer
- ☐ Endometrial thinning prior to ablation for abnormal uterine bleeding
- ☐ Endometriosis
- ☐ Gender Dysphoria
- ☐ Idiopathic or neurogenic central precocious puberty (CPP)
- ☐ Uterine leiomyomata (fibroids)
- ☐ Other

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Section I. Please complete for requests for idiopathic or neurogenic CPP.

1. Provide age of secondary sex characteristics onset.
2. Is the member under the care of a pediatric endocrinologist?
   - ☐ Yes. Name of member's pediatric endocrinologist Date of last visit
   - ☐ No. Please attach medical records of a consultation with a pediatric endocrinologist.
3. For members ≥11 years of age and < 12 years of age (female sex assigned at birth/biologic females) or ≥12 years of age and <13 years of age (male sex assigned at birth/biologic males), does the member require one additional year of prolonged therapy due to developmental delay? ☐ Yes. ☐ No.

4. For Triptodur, has the member tried Fensolvi or Lupron Ped and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please provide date and outcome for trial.
   Date(s) _____ Outcome(s) _____
   ☐ No. Please explain. _____

Section II. Please complete for requests for endometriosis.

1. Has the member tried non-steroidal anti-inflammatory drugs (NSAIDs) and experienced an adverse reaction or inadequate response?
   ☐ Yes. Provide drug names, dates, and outcomes for trials below.
   Drug name(s) _____ Date(s) _____ Outcome(s) _____
   ☐ No. Please explain if there is a contraindication to this trial. _____
2. Has the member tried hormonal contraceptives and experienced an adverse reaction or inadequate response?
   ☐ Yes. Provide drug names, dates, and outcomes for trials below.
   Drug name(s) _____ Date(s) _____ Outcome(s) _____
   ☐ No. Please explain if there is a contraindication to this trial. _____
3. For Myfembree and Orilissa, has the member tried Lupron and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please provide date and outcome for trial.
   Date(s) _____ Outcome(s) _____
   ☐ No. Please explain if there is a contraindication to this trial. _____

Section III. Please complete for requests for endometrial thinning prior to ablation for abnormal uterine bleeding and uterine leiomyomata (fibroids).

1. Is surgery planned?
   ☐ Yes. Please provide anticipated date of surgery. _____
   ☐ No. Please explain. _____
2. Has the member tried hormonal contraceptives and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please provide date and outcome for trial.
   Date(s) _____ Outcome(s) _____
   ☐ No. Please explain. _____
3. For Myfembree and Oriahnn, has the member tried Lupron and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please provide date and outcome for trial.
   Date(s) _____ Outcome(s) _____
   ☐ No. Please explain. _____
4. For Myfembree, has the member tried Oriahnn and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please provide date and outcome for trial.
   Date(s) _____ Outcome(s) _____

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☐ No. Please explain.

Section IV. Please complete for requests for advanced prostate cancer.

1. Please indicate prescriber specialty. ☐ Oncology ☐ Urology ☐ Other
2. For Lupron Depot 7.5 mg, Lupron Depot 22.5 mg, Lupron Depot 30 mg or Lupron Depot 45 mg, please describe clinical rationale for use instead of the equivalent dose of Eligard.
3. For Orgovyx, has the member tried Eligard, leuprolide 22.5 mg vial, or Lupron Depot and experienced an adverse reaction or inadequate response?
   ☐ Yes. Provide drug names, dates, and outcomes for trials below.
   Drug name(s) Date(s) Outcome(s)
   ☐ No. Please explain.
4. For Orgovyx, has the member tried Firmagon and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please provide date and outcome for trial.
   Date(s) Outcome(s)
   ☐ No. Please explain.

Section V. Please complete for requests for gender dysphoria.

For Lupron 7.5 mg, 22.5 mg, 30 mg, and 45 mg adult kit, please describe clinical rationale for use instead of the equivalent dose of Eligard.

Section VI. Please complete for all other diagnoses, excluding advanced breast cancer.

Please describe the medical necessity for the use of gonadotropin-releasing hormone, including previous trials and outcomes, and dates of any relevant lab tests (including but not limited to bone mineral density).

Section VII. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

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2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Gout Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested

- ☐ allopurinol 200 mg tablet
- ☐ colchicine capsule
- ☐ febuxostat
- ☐ Gloperba (colchicine solution)
- ☐ Krystexxa (pegloticase) [MB]

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose and frequency of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Prophylaxis of gout
- ☐ Treatment of gout
- ☐ Other (Attach a letter regarding medical necessity.)

Please provide any serum urate level results and date obtained.

1. Lab value ____ Date obtained ____
2. Lab value ____ Date obtained ____
3. Lab value ____ Date obtained ____
4. Lab value ____ Date obtained ____

Please provide creatinine clearance level result and date obtained. ____ Date obtained ____

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Section I. Please complete for prophylactic use of colchicine capsule or Gloperba (colchicine solution) for gout with urate lowering therapy.*

1. Will the member be taking the requested medication concurrently with a new start of allopurinol, febuxostat, or probenecid?
   - ☐ Yes. Please document drug name with dose and frequency and dates of use.
     Drug ____ Dose and Frequency ____ Dates/Duration ____
   - ☐ No. Please describe clinical rationale why concurrent therapy is not appropriate for this member.
     ____

2. What is the expected duration of therapy? **Please note:** requests for > six months will require additional clinical rationale for need of further treatment.

3. Does the member have tophaceous gout? ☐ Yes ☐ No
4. For Gloperba, is there a medical necessity for the use of a solution formulation?

   ☐ Yes. Please explain.
   ☐ No
5. For colchicine capsule, please provide clinical rationale for the use instead of colchicine tablet.

Section II. Please complete for prophylactic use of colchicine capsule or Gloperba (colchicine solution) for gout without urate lowering therapy.*

1. Has the member tried allopurinol and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please document dose and frequency, dates of use, and outcome.

   Dose and Frequency Dates/Duration Outcome
   ☐ No. Please document if there is a contraindication to allopurinol therapy.
2. Has the member tried febuxostat and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please document dose and frequency, dates of use, and outcome.

   Dose and Frequency Dates/Duration Outcome

   ☐ No. Please document if there is a contraindication to febuxostat therapy.
3. For Gloperba, is there a medical necessity for the use of a solution formulation?

   ☐ Yes. Please explain.
   ☐ No
4. For colchicine capsule, please provide clinical rationale for the use instead of colchicine tablet.

Section III. Please complete for treatment of gout with Krystexxa (pegloticase).*

1. Has the member tried allopurinol and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please document dose and frequency, dates of use, and outcome.

   Dose and Frequency Dates/Duration Outcome
   ☐ No. Please document if there is a contraindication to allopurinol therapy.
2. Has the member tried febuxostat and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please document dose and frequency, dates of use, and outcome.

   Dose and Frequency Dates/Duration Outcome
   ☐ No. Please document if there is a contraindication to febuxostat therapy.

over

3. Has the member tried a uricosuric agent in combination with allopurinol or febuxostat and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please document drug names with dose and frequency, dates of use, and outcome.
   Drug | Dose and Frequency
   Dates/Duration | Outcome
   Drug | Dose and Frequency
   Dates/Duration | Outcome
   ☐ No. Please document if there is a contraindication to uricosuric agent therapy.

Section IV. Please complete for treatment of gout with febuxostat.*

1. Has the member tried allopurinol and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please document dose and frequency, dates of use, and outcome.
   Dose and Frequency | Dates/Duration | Outcome
   ☐ No. Please document if there is a contraindication to allopurinol therapy.
2. For requests exceeding quantity limits, please provide medical necessity for dosing.

Section V. Please complete for treatment of gout with allopurinol 200 mg tablet.*

1. Please attach medical records documenting an inadequate response or adverse reaction to allopurinol two-100 mg tablets.
2. Please describe the medical necessity for use of allopurinol 200 mg tablet instead of two 100 mg tablets.

**Please attach a letter documenting additional trials as necessary.*

Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

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3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details. _____
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

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Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Growth Hormone and Increlex
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested (check one)

- ☐ Genotropin
- ☐ Genotropin Miniquick
- ☐ Humatrope
- ☐ Increlex
- ☐ Ngenla
- ☐ Norditropin Flexpro
- ☐ Nutropin AQ Nuspin
- ☐ Omnitrope
- ☐ Saizen
- ☐ Saizen Click.easy
- ☐ Serostim
- ☐ Skytrofa
- ☐ Sogroya
- ☐ Zomacton

Dose and frequency of medication requested

Duration of therapy

Cartridge/vial strength

Indication for Growth Hormone agent (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Growth hormone deficiency (Section I or III)
- ☐ Growth deficiency due to chronic renal failure (Section I & II)
- ☐ Hypoglycemia due to growth hormone deficiency (Section I)
- ☐ Human Immunodeficiency Virus-related wasting (Section IV)
- ☐ Noonan syndrome (provide documentation of genetic testing) (Section I)
- ☐ Prader Willi syndrome (provide documentation of genetic testing) (Section I)
- ☐ Small for gestational age with failed catch-up growth between age two to four (Section I)
- ☐ Turner syndrome (provide documentation of genetic testing) (Section I)
- ☐ Other (Section VI or any section that may apply)

Indication for Increlex (Check all that apply.)

- ☐ Growth failure with severe primary IGF-1 deficiency
- ☐ Growth hormone gene deletion with neutralizing antibodies to growth hormone
- ☐ Other (Section VI or any section that may apply)

Section I. Please complete for growth hormone for pediatric indications and attach supporting documentation (e.g., copies of medical records, office notes, growth charts, diagnostic studies, laboratory tests).

Pre-treatment height ____ cm ____ percentile ____ SD below mean. Please attach most recent growth chart.

Current height ____ Current weight ____ Date ____ Growth velocity in past year ____ cm

Please provide information regarding diagnostic tests and assessments including type of growth hormone stimulation test performed, date, and results.

Stimulation Test _____ Peak Result _____ Date _____

Stimulation Test _____ Peak Result _____ Date _____

IGF-1 level _____ Reference Range _____ Date _____

IGFBP-3 level _____ Reference Range _____ Date _____

1. Is the member under the care of a Pediatric Endocrinologist? ☐ Yes ☐ No
   If no, have other causes of short stature (hypothyroidism, malnutrition, chronic illness, skeletal disorders, pituitary tumor) been excluded? ☐ Yes ☐ No
2. Does the member have open epiphyses? ☐ Yes (Please attach most recent bone age, if available.) ☐ No
   (Please attach clinical rationale for continued treatment and/or refer to Section III.)
3. Has pituitary imaging revealed abnormalities?
   ☐ Yes Please attach medical records documenting abnormality. ☐ No
4. Does the member have hypoglycemia-symptoms and low glucose level?
   ☐ Yes. Please provide glucose level _____ Date _____ ☐ No

Section II. Please complete for growth hormone requests for the diagnosis of pediatric-growth deficiency due to chronic renal failure.

1. Have other etiologies for chronic renal failure been excluded including: acidosis, secondary hyperparathyroidism, malnutrition, or zinc deficiency? ☐ Yes ☐ No
2. Is the member under the care of a renal specialist? ☐ Yes ☐ No

Section III. Please complete for growth hormone requests for growth hormone deficiency in adult members.

Please provide information regarding diagnostic tests and assessments including type of growth hormone stimulation test performed, date, and results.

Stimulation Test _____ Peak Result _____ Date _____

Stimulation Test _____ Peak Result _____ Date _____

IGF-1 level _____ Reference Range _____ Date _____

IGFBP-3 level _____ Reference Range _____ Date _____

1. Has pituitary imaging revealed abnormalities?
   ☐ Yes (Please attach medical records documenting abnormality.) ☐ No
2. Has the member experienced a symptom consistent with growth hormone deficiency? ☐ Yes ☐ No
   If yes, please describe. _____

Section IV. Please complete for growth hormone requests for HIV-related wasting.

Current height _____ Current weight _____ Date _____ Premorbid weight _____ Date _____

1. Is decreased caloric intake the etiology of the cachexia or wasting? ☐ Yes ☐ No

If yes, has member attempted therapy with dronabinol or megestrol acetate? If so, provide dates and duration. If not, please explain why.

_____

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2. Have other causes of weight loss been excluded including: gastrointestinal tract opportunistic infections, decrease in food intake due to oral, pharyngeal, esophageal lesions or candidiasis, gonadal dysfunction, adverse effects due to medications, or psychosocial factors. ☐ Yes ☐ No
3. Is the member under the care of an Infectious Disease specialist? ☐ Yes ☐ No
4. Is the member receiving concurrent antiretroviral therapy? ☐ Yes ☐ No

Section V. Please complete for Increlex requests.

Height ____ cm Date ____ SD below mean for age ____

IGF-1 level ____ Reference Range ____ Date ____

Peak growth hormone level ____ Provocative Agent ____ Date ____

1. Is the member under the care of a Pediatric Endocrinologist or other specialist trained to diagnose and treat growth disorders?
   ☐ Yes. Please specify. ____
   ☐ No. Please indicate why not. ____
2. Does the member have open epiphyses?
   ☐ Yes. Please attach most recent bone age, if available.
   ☐ No. Please indicate clinical rationale for continued treatment.
   ____
3. Have other secondary forms of IGF-1 deficiency such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids been ruled out?
   ☐ Yes.
   ☐ No. Please indicate clinical rationale for Increlex (mecasermin) in the presence of any of these conditions.
   ____

Section VI. Please complete for requests for any indication not listed above.

Please describe the medical necessity for the use of growth hormone or Increlex in this member including trials and outcomes of any alternative treatments (if appropriate).

____

____

Section VII. Please complete for Humatrope, Norditropin Flexpro, Nutropin AQ Nuspin, Omnitrope, Saizen, Saizen Click.easy, Serostim, Skytrofa, Sogroya, and Zomacton requests.

Please provide clinical rationale for use of the requested agent instead of Genotropin.

____

____

Section VIII. Please complete for Ngenla requests.

Please provide clinical rationale for use of the requested agent instead of Skytrofa and Sogroya.

____

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Section IX. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

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Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Headache Therapy (Butalbital Combination Agents) Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ butalbital/acetaminophen (50 mg/300 mg)
- ☐ butalbital/acetaminophen (50 mg/325 mg)
- ☐ butalbital/acetaminophen/caffeine (50 mg/ 300 mg/40 mg)
- ☐ butalbital/acetaminophen/caffeine capsule (50 mg/325 mg/40 mg)
- ☐ butalbital/acetaminophen/caffeine tablet (50 mg/325 mg/40 mg) > 20 units/30 days, < 18 years of age
- ☐ butalbital/acetaminophen/caffeine/codeine (50 mg/300 mg/40 mg/30 mg)
- ☐ butalbital/acetaminophen/caffeine/codeine (50 mg/325 mg/40 mg/30 mg) > 20 units/30 days, < 18 years of age
- ☐ butalbital/aspirin/caffeine capsule (50 mg/325 mg/40 mg) > 20 units/30 days, < 18 years of age
- ☐ butalbital/aspirin/caffeine tablet (50 mg/325 mg/40 mg)
- ☐ butalbital/aspirin/caffeine/codeine (50 mg/325 mg/40 mg/30 mg)
- ☐ Other butalbital agent

Quantity requested per month

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Cluster headache. Frequency of headaches (number/month)
- ☐ Migraine headache. Frequency of migraine attacks (number/month)
- ☐ Tension headache. Frequency of headaches (number/month)
- ☐ Other. Specify pertinent medical history, diagnostic studies, and/or laboratory tests.

Section I. Please complete for requests for butalbital agents that require PA for members < 18 years of age or with a diagnosis of migraine headache, or for requests exceeding quantity limits.

1. For migraine headache requests, has the member tried two triptans?
   ☐ Yes. Please list the drug names and outcomes below.

   Drug name ☐ Adverse reaction ☐ Inadequate response

   Briefly describe the details of adverse reaction or inadequate response.

Drug name ☐ Adverse reaction ☐ Inadequate response

Briefly describe the details of adverse reaction or inadequate response.

☐ No. Explain why triptans are not appropriate in this member.

2. For migraine headache requests, has the member tried an oral calcitonin gene-related peptide (CGRP) inhibitor?

☐ Yes. Please list the drug name and outcome below.

Drug name ☐ Adverse reaction ☐ Inadequate response

Briefly describe the details of adverse reaction or inadequate response.

☐ No. Explain why oral CGRP inhibitors are not appropriate in this member.

3. For both migraine and tension headache requests in members exceeding quantity limits or < 18 years of age, is the member currently receiving prophylaxis?

☐ Yes. Please specify.

Drug name Dose and frequency

Drug name Dose and frequency

☐ No. Explain why prophylaxis is not appropriate in this member.

4. Is the member under the care of a neurologist? ☐ Yes ☐ No
5. Please list any other prior headache therapy trials. Please list the drug names and outcomes below.

Drug name ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

over

Section II. Please also complete for requests for butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg capsule.

Has the member tried butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg tablet?

☐ Yes. Please list the dates/duration of use and outcome below.

Dates/duration of use ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Explain why butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg tablet is not appropriate in this member.

Section III. Please also complete for requests for butalbital 50 mg/aspirin 325 mg/caffeine 40 mg tablet.

Has the member tried butalbital 50 mg/aspirin 325 mg/caffeine 40 mg capsule?

☐ Yes. Please list the dates/duration of use and outcome below.

Dates/duration of use ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Explain why butalbital 50 mg/aspirin 325 mg/caffeine 40 mg capsule is not appropriate in this member.

Section IV. Please also complete for requests for all other butalbital agents that require PA for the diagnosis of tension-type headache and requests for codeine-containing products for members < 12 years of age.

Please provide medical necessity for the requested agent. Please address the need for the requested agent instead of formulations available without PA, requested dosage formulation instead of conventional dosage forms, or use in the requested age group as appropriate.

Section V. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

over

If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Headache Therapy (Calcitonin Gene-Related Peptide [CGRP] Inhibitors) Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Aimovig (erenumab-aooe)
- ☐ Ajovy (fremanezumab-vfrm)
- ☐ Emgality (galcanezumab-gnlm)
- ☐ Nurtec (rimegepant)
- ☐ Qulipta (atogepant)
- ☐ Ubrelvy (ubrogepant)
- ☐ Vyepti (eptinezumab-jjmr)[MB]
- ☐ Zavzpret (zavegepant)

Dose, frequency, and duration of medication requested

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Cluster headache
- ☐ Migraine headache
  - ☐ Prophylaxis. Frequency of migraine attacks (days/month)
  - ☐ Acute treatment. Frequency of migraine attacks (number/month)
- ☐ Other

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Section I. Please complete for Aimovig, Ajovy, Emgality, Nurtec, Qulipta, and Vyepti requests for migraine prophylaxis.

1. For all requests except Nurtec, has the member had a trial with a beta-blocker (atenolol, metoprolol, nadolol, propranolol, timolol)?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcomes below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not.

2. For Aimovig, Ajovy, and Emgality requests, please document a trial of topiramate, a tricyclic antidepressant, valproic acid, or venlafaxine. For Qulipta and Vyepti requests, please document a trial of Botox, topiramate, a tricyclic antidepressant, valproic acid, or venlafaxine. Alternatively, provide clinical rationale for use of Aimovig, Ajovy, Emgality, Qulipta, or Vyepti instead of these agents.
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain why not.
3. For Nurtec, Qulipta, and Vyepti requests, please document a trial of Aimovig, Ajovy, or Emgality. Alternatively, provide clinical rationale for use of Nurtec, Qulipta, or Vyepti instead of these agents.
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain why not.

Section II. Please complete for Nurtec and Ubrelvy requests for acute treatment of migraine.

1. Has the member had a trial with two triptans?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain why not.

   For requests for quantities above 16 units/30 days for Nurtec and Ubrelvy, is the member currently receiving prophylaxis?
   ☐ Yes. Please specify.

   Drug name Dose and frequency

   Drug name Dose and frequency

over

☐ No. Please explain why prophylaxis is not appropriate for this member.

**Attach a letter with additional information regarding medication trials as applicable.*

Section III. Please complete for recertification requests for Emgality for cluster headache.

1. Is the member still actively having a cluster headache? ☐ Yes. ☐ No.
2. Has the member been initiated on prophylactic therapy for the cluster headache?
   ☐ Yes. Please specify.

   Drug name Dose and frequency

   Drug name Dose and frequency

   ☐ No. Please explain why prophylaxis is not appropriate for this member.

Section IV. Please complete for Zavzpret requests for acute treatment of migraine.

1. Has the member had a trial with two triptan nasal sprays?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes below.*

   Drug name Dose and frequency

   Drug name Dose and frequency

   ☐ No. Please explain why triptan nasal sprays are not appropriate for this member.
2. Please describe medical necessity for the use of the requested dosage formulation.

Section V. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

over

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

   _____

   _____

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details. _____

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
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☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Headache Therapy (Ergot Alkaloids and Serotonin Receptor Agents) Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Ergot Alkaloids

- ☐ dihydroergotamine injection
- ☐ dihydroergotamine nasal spray
- ☐ ergotamine/caffeine suppository

Serotonin Receptor Agents

- ☐ almotriptan
- ☐ eletriptan
- ☐ frovatriptan
- ☐ naratriptan > quantity limits
- ☐ Reyvow (lasmiditan)
- ☐ rizatriptan orally disintegrating tablet > quantity limits
- ☐ rizatriptan tablet > quantity limits
- ☐ sumatriptan injection
- ☐ sumatriptan 5 mg, 20 mg nasal spray > quantity limits
- ☐ sumatriptan 5 mg, 20 mg nasal spray < 6 years of age
- ☐ sumatriptan tablet > quantity limits
- ☐ sumatriptan/naproxen
- ☐ Tosymra (sumatriptan 10 mg nasal spray)
- ☐ Zembrace (sumatriptan injection)
- ☐ zolmitriptan nasal spray
- ☐ zolmitriptan orally disintegrating tablet
- ☐ zolmitriptan tablet > quantity limits

☐ Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Quantity requested per 30 days _____

Dose, frequency, and duration of requested drug _____

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Cluster headache. Frequency of headaches (number/30 days) _____

☐ Migraine headache. Frequency of migraine attacks (number/30 days) _____

☐ Other. Specify pertinent medical history, diagnostic studies, and/or laboratory tests. _____

_____

Section I. Please complete for all serotonin receptor agent requests, excluding generic naratriptan, rizatriptan orally disintegrating tablet, rizatriptan tablets, sumatriptan 5 mg, 20 mg nasal spray, sumatriptan tablets, and zolmitriptan tablets. Please note, this section must be completed for brand name Imitrex tablet, Maxalt MLT, Maxalt tablet, or Zomig tablet requests.

1. Has the member tried sumatriptan tablets?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why sumatriptan tablets are not appropriate for this member.
2. Has the member tried rizatriptan?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why rizatriptan is not appropriate for this member.
3. Has the member tried zolmitriptan tablets?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why zolmitriptan tablets are not appropriate for this member.
4. Has the member tried naratriptan tablets?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why naratriptan tablets are not appropriate for this member.

Section II. Please complete for all requests for quantities above quantity limits.

1. Is the member under the care of a neurologist? ☐ Yes ☐ No
2. Is the member currently receiving prophylaxis?
   ☐ Yes. Please specify.
   Drug Dose and frequency
   Drug Dose and frequency
   ☐ No. Explain why prophylaxis is not appropriate for this member.

Section III. Please complete for requests for sumatriptan 5 mg, 20 mg nasal spray for members < 6 years of age

1. Is the member under the care of a neurologist? ☐ Yes ☐ No

over

2. Has the member tried acetaminophen?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why acetaminophen is not appropriate for this member.
3. Has the member tried a nonsteroidal anti-inflammatory drug?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why a nonsteroidal anti-inflammatory drug is not appropriate for this member.

Section IV. Please complete for requests for sumatriptan injection, Tosymra, Zembrace, zolmitriptan nasal spray and zolmitriptan orally disintegrating tablets.

1. Please describe medical necessity for the use of the requested dosage formulation instead of tablet formulation.
2. For Tosymra requests, has the member had a trial with zolmitriptan or sumatriptan 5 mg, 20 mg nasal spray?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why zolmitriptan or sumatriptan 5 mg, 20 mg nasal spray is not appropriate for this member.
3. For Zembrace requests, has the member had a trial with sumatriptan injection?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why sumatriptan injection is not appropriate for this member.

Section V. Please complete for requests for sumatriptan/naproxen.

Please describe medical necessity for the use of the combination product (sumatriptan/naproxen) instead of the commercially-available separate agents.

Section VI. Please complete for requests for Reyvow.

1. Is the member under the care of a neurologist? ☐ Yes ☐ No
2. Has the member had a trial with two different triptan agents?
   ☐ Yes. Please describe the drug names and outcomes.
   Drug name ☐ Adverse reaction ☐ Inadequate response

over

Briefly describe the details of adverse reaction or inadequate response.

Drug name ☐ Adverse reaction ☐ Inadequate response

Briefly describe the details of adverse reaction or inadequate response.

☐ No. Explain why triptan agents are not appropriate for this member.

Section VII. Please complete for dihydroergotamine nasal spray requests.

1. Has the member tried sumatriptan nasal spray?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why sumatriptan nasal spray is not appropriate in this member.
2. Has the member tried zolmitriptan nasal spray?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why zolmitriptan nasal spray is not appropriate in this member.

Section VIII. Please complete for dihydroergotamine injection and ergotamine/caffeine suppository requests.

1. Please describe medical necessity for the use of the requested dosage formulation.
2. For dihydroergotamine injection requests, has the member tried sumatriptan injection?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why sumatriptan injection is not appropriate in this member.
3. For ergotamine/caffeine suppository requests, has the member tried sumatriptan nasal spray?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why sumatriptan nasal spray is not appropriate in this member.

Section IX. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

over

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Health Safety Net Prior Authorization Request Administrative Information

Patient information

Last name _____ First name _____ MI _____

Patient ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

Health Safety Net does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please fax or submit this completed and signed form according to the Plan's contact information below.

Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318

over

Health Safety Net Formulary Exceptions
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current patient eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and patient of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication Requested

☐ Wegovy (semaglutide injection)
☐ Zepbound (tirzepatide)
☐ Other

Dose and frequency of medication requested

Is the patient stabilized on the requested medication? ☐ Yes. Please provide start date. ☐ No

Indication* or ICD-10 code, if applicable

☐ Moderate to severe obstructive sleep apnea in obesity
☐ Risk reduction of major adverse cardiovascular events with established cardiovascular disease and obesity or overweight
☐ Other

**Please note, anti-obesity agents and/or drugs used for the treatment of obesity are not payable for Health Safety Net patients for weight loss.*

Section I. Please complete for all requests for moderate to severe obstructive sleep apnea (OSA) in patients with obesity, and risk reduction of major adverse cardiovascular events with established cardiovascular disease and obesity or overweight.

1. Patient's baseline weight ____ kg Date ____
2. Patient's current weight ____ kg Date ____
3. Patient's current height ____ cm Date ____
4. Patient's baseline BMI ____ kg/m^2 Date ____
5. Patient's current BMI ____ kg/m^2 Date ____
6. Has the patient been counseled to continue reduced-calorie diet and increased physical activity?
   ☐ Yes ☐ No
7. Will the requested agent be used in combination with a GLP-1 receptor agonist?
   ☐ Yes ☐ No
   If yes, please provide clinical rationale for concurrent use with a GLP-1 receptor agonist.

Section II. Please complete for indication of moderate to severe OSA for Zepbound requests.

1. Does the patient have any of the following conditions?
   Central or mixed sleep apnea ☐ Yes ☐ No

Major craniofacial abnormalities ☐ Yes ☐ No
Obesity hypoventilation syndrome or daytime hypercapnia ☐ Yes ☐ No
Planned procedure for sleep apnea or obesity ☐ Yes ☐ No
Type 1 diabetes mellitus ☐ Yes ☐ No
Type 2 diabetes mellitus ☐ Yes ☐ No
Other comorbidity _____ ☐ Yes ☐ No

2. Has the patient had a sleep study (polysomnogram) that diagnosed obstructive sleep apnea?
   ☐ Yes. Please include medical records with submission. ☐ No
3. Please attach medical records documenting the patient's apnea-hypopnea index (AHI).

Section III. Please also complete for indication of risk reduction of major adverse cardiovascular events for Wegovy requests.

1. Please indicate if the patient has any of the following cardiovascular conditions. Check all that apply and please provide medical records documenting cardiovascular condition(s).
   ☐ History of myocardial infarction
      Please include medical records documenting the patient is receiving or has an adverse reaction or contraindication to the following: antiplatelet, ACE-I or ARB, beta blocker, statin.
   ☐ History of stroke (hemorrhagic)
      Please include medical records documenting the patient is receiving or has an adverse reaction or contraindication to the following: blood pressure management regimen (e.g., ACE-I, ARB, beta blocker, calcium channel blocker).
   ☐ History of stroke (ischemic)
      Please include medical records documenting the patient is receiving or has an adverse reaction or contraindication to the following: antiplatelet or anticoagulant, blood pressure management regimen (e.g., ACE-I, ARB, beta blocker, calcium channel blocker), statin.
   ☐ Symptomatic peripheral arterial disease (e.g., intermittent claudication with ankle–brachial index <0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease)
      Please include medical records documenting the patient is receiving or has an adverse reaction or contraindication to the following: antiplatelet, blood pressure management regimen (e.g., ACE-I, ARB, beta blocker, calcium channel blocker), statin.
2. Does the patient have any of the following chronic medical conditions?
   Type 1 diabetes mellitus ☐ Yes ☐ No
   Type 2 diabetes mellitus ☐ Yes ☐ No
   New York Heart Association Class IV Heart Failure ☐ Yes ☐ No

---

Section IV. Please complete for recertification requests.

1. Patient's current weight _____ Date _____
2. Has the patient been counseled to continue with reduced calorie diet and increased physical activity?
   ☐ Yes ☐ No
3. For Wegovy recertification requests, does the patient require use of Wegovy for cardiovascular protection, and the benefit of cardiovascular protection outweighs the risk associated with use of GLP-1 agents?
   ☐ Yes. Please explain and provide medical records documenting cardiovascular condition(s).
   _____
   ☐ No
4. For Wegovy recertification requests, does the patient continue to receive appropriate therapies for management of cardiovascular disease?

over

☐ Yes. Please document all current medications below.

☐ No. Please document adverse reaction or contraindication to clinically appropriate therapies for management of cardiovascular disease.

5. For Zepbound recertification requests, does the patient have improvement in OSA symptoms, such as less daytime sleepiness, fewer sleep arousals, or fewer partner-reported snoring episodes or pauses in breathing?
☐ Yes ☐ No

If yes, please describe.

Section V. Please complete for GLP-1 and GIP/GLP-1 agonist polypharmacy requests.

Please complete information for medications requested and select the reason for polypharmacy.

1. Drug name Dates/duration of use
2. Drug name Dates/duration of use

☐ Patient is transitioning from one GLP-1 or GIP/GLP-1 agonist to another and prior GLP-1 or GIP/GLP-1 agonist use will be discontinued.

☐ Other. Please explain.

Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the patient? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of patient and alternative drug regimen.
3. Has the patient previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action; and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the patient experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

over

4. Is the patient stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the patient?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

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Printed legal name and title of signatory above

Date

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Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Heart Failure Agents
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ digoxin 62.5 mcg tablet
☐ digoxin solution ≥ 13 years
☐ Entresto (sacubitril/valsartan)
☐ ivabradine
☐ Verquvo (vericiguat)

Dose, frequency, and duration of medication requested

Is the member stabilized on the requested medication? ☐ Yes. Please provide start date. ☐ No

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Chronic heart failure with reduced left ventricular ejection fraction (LVEF)

LVEF ☐ ≤ 35% ☐ ≤ 40% ☐ < 45% ☐ Other

New York Heart Association (NYHA) ☐ Class I ☐ Class II ☐ Class III ☐ Class IV

☐ Heart failure

☐ Other (please specify)

Please indicate prescriber specialty below.

☐ Cardiology ☐ Other

☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

Name(s) of the specialist(s)

Date(s) of last visit or consult

Contact information

Section I. Please complete for all ivabradine requests.

For ivabradine in pediatric members, please complete questions 2 through 4. For ivabradine in adult members, please complete questions 1 through 3. For all ivabradine solution requests, please also complete question 5.

1. For ivabradine requests in adult members, is the member's resting heart rate ≥ 70 beats per minute? ☐ Yes ☐ No
2. Has the member tried a beta-blocker (e.g., carvedilol, metoprolol succinate, or bisoprolol) at maximally tolerated doses?
   ☐ Yes. Please list the specific drug name, dose, dates/duration of use, and outcomes below.

   Drug name/dose

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe the details of adverse reaction or inadequate response.

☐ No. Please explain why oral beta-blockers are not appropriate for this member.

3. Has the member tried an angiotensin-converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB) or angiotensin receptor neprilysin inhibitor (ARNI)?
   ☐ Yes. Please list the specific drug name(s), dates/duration of use, and outcomes below.

   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe the details of adverse reaction or inadequate response.

   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe the details of adverse reaction or inadequate response.

   ☐ No. Please explain why an ACE-I, ARB, or ARNI is not appropriate for this member.
4. For ivabradine requests in pediatric members, does the member have normal sinus rhythm with an elevated heart rate? ☐ Yes ☐ No
5. For ivabradine solution requests, is there a medical necessity for the solution formulation?
   ☐ Yes. Please explain.
   ☐ No

Section II. Please complete for Verquvo requests in adult members.

1. Has the member tried an ACE-I, ARB, or ARNI in combination with a beta blocker?
   ☐ Yes. Please list the specific drug name(s), dates/duration of use, and outcomes below.

   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe the details of adverse reaction or inadequate response.

   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe the details of adverse reaction or inadequate response.

   ☐ No. Please explain contraindication to the use of an ACE-I, ARB, or ARNI in combination with a beta blocker for this member.
2. Has the member had a heart failure hospitalization within six months?
   ☐ Yes. Date ☐ No

over

3. Has the member had outpatient IV diuretic therapy for heart failure within three months?

☐ Yes. Date ☐ No

Section III. Please complete for all digoxin requests.

1. For digoxin 62.5 mcg tablet, please provide medical necessity for use instead of digoxin formulations available without prior authorization
2. For digoxin oral solution for members ≥ 13 years, please provide medical necessity for requested formulation (e.g., member utilizes a feeding tube, has a swallowing disorder or condition affecting ability to swallow)

Section IV. Please complete for all Entresto pellet requests.

Has the member tried sacubitril/valsartan tablets?

☐ Yes. Please describe the dates/duration of use and outcome.

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe the details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please provide medical necessity for requested formulation (e.g., member utilizes a feeding tube, has a swallowing disorder or condition affecting ability to swallow).

Section V. Please include any other pertinent information (if needed).

Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

over

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details. _____
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

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Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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over

Hepatitis Antiviral Agents
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Diagnosis

☐ Hepatitis C

☐ Acute ☐ Chronic

☐ HIV-coinfection ☐ Renal impairment. Creatinine clearance _____ ☐ Status post-liver transplant

HCV Genotype ☐ 1a ☐ 1b ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ Other _____

☐ Treatment-experienced (Please complete the section for Prior Hepatitis Treatment.) ☐ Treatment-naïve

☐ Treatment initiation Anticipated start date _____ Anticipated end date _____

☐ Continuation of therapy, current week _____

☐ Chronic Hepatitis B

Fibrosis Staging

Please indicate below and attach documentation including medical records and results of diagnostic tests assessing liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4). Staging information must clearly demonstrate early stage (Metavir Score F0 to F2) or advance liver disease (Metavir Score F3 to F4). If results are inconclusive or if imaging studies are performed and are not suggestive of cirrhosis, further diagnostic testing may be required.

☐ Metavir Score F0 to F2 ☐ Metavir Score F3 to F4 ☐ Other _____

Does the member have cirrhosis? ☐ Yes ☐ No

If yes, please indicate Child-Turcotte-Pugh (CTP) class. (Please attach calculations.) ☐ A ☐ B ☐ C

Lab Values

Baseline HCV RNA lab value _____ Date drawn _____

Prior Hepatitis Treatment

Drug name _____ Dates/duration of use _____

Please indicate treatment outcome. ☐ Adverse reaction ☐ Null responder ☐ Partial responder ☐ Relapser ☐ Other

Briefly describe details. _____

Drug name _____ Dates/duration of use _____

Please indicate treatment outcome. ☐ Adverse reaction ☐ Null responder ☐ Partial responder ☐ Relapser ☐ Other

Briefly describe details. _____

Drug name _____ Dates/duration of use _____

Please indicate treatment outcome. ☐ Adverse reaction ☐ Null responder ☐ Partial responder ☐ Relapser ☐ Other

Briefly describe details. _____

Complete Treatment Regimen (Check All that Apply)

HCV Combination Agents

☐ ledipasvir/sofosbuvir
☐ Mavyret (glecaprevir/pibrentasvir)
☐ sofosbuvir/velpatasvir
☐ Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
☐ Zepatier (elbasvir/grazoprevir)

Dose/frequency _____ Duration of therapy _____

For sofosbuvir/velpatasvir requests only, for members with HCV genotype 3 who are treatment-experienced without cirrhosis, please indicate if NS5A resistance-associated substitution Y93H is present. (Please attach laboratory testing results.) ☐ Yes ☐ No

For Zepatier requests only, for members with HCV genotype 1a, please indicate if baseline NS5A polymorphisms at amino acid positions 28, 30, 31 or 93 are present. (Please attach laboratory testing results.) ☐ Yes ☐ No

HCV Single Agents

☐ Sovaldi (sofosbuvir)

Dose/frequency _____ Duration of therapy _____

Pegylated Interferon

☐ Pegasys (peginterferon alfa-2a)

Dose/frequency _____ Duration of therapy _____

Ribavirin

☐ ribavirin 200 mg capsule
☐ None. Please explain the clinical rationale for not using ribavirin below.

Dose/frequency _____ Duration of therapy _____

Please indicate if using ribavirin 200 mg tablets. ☐ Yes ☐ No

Please describe medical necessity for use of the other products instead of the 200 mg tablet.

_____

If applicable, please explain the clinical rationale for not using ribavirin. _____

_____

Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

over

If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
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4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

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Printed legal name and title of signatory above

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Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Hereditary Angioedema Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Diagnosis

Is the member diagnosed with hereditary angioedema? ☐ Yes ☐ No

Please provide any lab tests that confirm the diagnosis.

Test _____ Lab value _____ Lab reference range _____ Date obtained _____

Test _____ Lab value _____ Lab reference range _____ Date obtained _____

Test _____ Lab value _____ Lab reference range _____ Date obtained _____

Please document the baseline frequency of hereditary angioedema attacks: _____ attacks/month

Medication information

Medication requested

☐ Berinert (c1 esterase inhibitor, human)
☐ Cinryze (c1 esterase inhibitor, human)
☐ Haegarda (c1 esterase inhibitor, human)
☐ icatibant
☐ Kalbitor (ecallantide)[MB]
☐ Orladeyo (berotralstat)
☐ Ruconest (c1 esterase inhibitor, recombinant)
☐ Takhzyro (lanadelumab-flyo)

Instructions for use _____

[MB] *This drug is available through the healthcare professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other healthcare professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

☐ Prophylaxis therapy ☐ Treatment of acute attacks

Place of administration ☐ Clinician's office ☐ Home

Has the member been instructed to self-administer the medication? ☐ Yes ☐ No

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code _____

Is the member under the care of an allergist or immunologist? ☐ Yes ☐ No

If yes, and the requesting provider is not the allergist or immunologist, please provide consult notes regarding the member's diagnosis.

Section I. For Cinryze, Haegarda, Orladeyo, and Takhzyro requests, please complete the following.

1. Is the member experiencing more than one HAE attack per month? ☐ Yes ☐ No
2. Does the member have a history of recurrent laryngeal attacks? ☐ Yes ☐ No

Section II. For recertification requests for Berinert, icatibant, Kalbitor, or Ruconest, please complete the following.

1. Has the member used the previously approved product?

   ☐ Yes. Please indicate the quantity used.
   ☐ No
2. Has the previously approved product expired?

   ☐ Yes. Please indicate the quantity expired.
   ☐ No
3. Does the member have sufficient medication available to treat one attack? ☐ Yes ☐ No

Section III. For recertification requests for Takhzyro, please complete the following.

1. Please indicate requested dosing frequency. ☐ Every four weeks ☐ Every two weeks
2. For requested dosing every two weeks, please indicate the number of HAE attacks in the last six months.
   ☐ Member has had ≥ one HAE attack in the last six months.
   ☐ Member has been HAE attack free for ≥ six months. Please provide clinical rationale for every two-week dosing instead of every four-week dosing.

Section IV. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

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3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details. _____
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Hyaluronan Injections
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Device information

Device requested

- ☐ Durolane (hyaluronate) [MB]
- ☐ Euflexxa (hyaluronate) [MB]
- ☐ Gel-One (cross-linked hyaluronate) [MB]
- ☐ Gelsyn (hyaluronate) [MB]
- ☐ Genvisc (hyaluronate) [MB]
- ☐ Hyalgan (hyaluronate) [MB]
- ☐ Hymovis (hyaluronate modified) [MB]
- ☐ Monovisc (hyaluronate) [MB]
- ☐ Orthovisc (high molecular weight hyaluronan) [MB]
- ☐ Supartz (hyaluronate) [MB]
- ☐ Synojoynt (hyaluronate) [MB]
- ☐ Synvisc (hylan G-F 20) [MB]
- ☐ Synvisc-One (hylan G-F 20) [MB]
- ☐ Triluron (hyaluronate) [MB]
- ☐ Trivisc (hyaluronate) [MB]
- ☐ Visco-3 (hyaluronate) [MB]

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above,this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency and duration of device requested

Device NDC (if known) or service code

Indication (Check all that apply, or ICD-10 code, if applicable.)

☐ Osteoarthritis of the knee ☐ Left knee ☐ Right knee ☐ Both knees

☐ Other (Please indicate.)

Is the request for retreatment of the same knee(s)? ☐ Yes ☐ No

Section I. Please complete the following for all requests.

1. Please indicate billing preference. ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.
2. Has the member tried acetaminophen?

   ☐ Yes. Please provide the following information.* Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

☐ No. Does the member have a contraindication to acetaminophen? Please explain.

3. Has the member tried an intra-articular corticosteroid injection?
   ☐ Yes. Please provide the following information.*

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Does the member have a contraindication to all intra-articular corticosteroid injections? Please explain.

4. Has the member tried a non-steroidal anti-inflammatory drug (NSAID)?
   ☐ Yes. Please provide the following information.*

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Does the member have a contraindication to all NSAIDs? Please explain.

** Please attach a letter documenting additional trials as necessary.*

Section II. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

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4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

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Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Hypnotic Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about hypnotic agents and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form.**

Medication information

Hypnotic requested	Qty/month	Hypnotic requested	Qty/month
☐ Belsomra (suvorexant)		☐ zaleplon > 1 unit/day	
☐ Dayvigo (lemborexant)		☐ zolpidem 1.75 mg, 3.5 mg sublingual	
☐ doxepin tablet		☐ zolpidem extended-release tablet > 1 unit/day	
☐ Edluar (zolpidem 5 mg, 10 mg sublingual)		☐ zolpidem tablet > quantity limits	
☐ eszopiclone > 1 unit/day		☐ zolpidem 7.5 mg capsule	
☐ Quviviq (daridorexant)			
☐ ramelteon > 1 unit/day			

Dose and frequency _____ **Intended duration** _____

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Insomnia
- ☐ Acute ☐ Chronic

☐ Insomnia characterized by middle of the night awakenings with difficulty falling back asleep

☐ Other _____

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for all requests exceeding the quantity limit.

Please provide medical necessity for exceeding the quantity limit.

Section II. Hypnotic Polypharmacy for all members. Please complete information for medications requested and select the reason for polypharmacy with hypnotics (two or more hypnotics, including benzodiazepine hypnotics [estazolam, flurazepam, quazepam, temazepam, and triazolam] and non-benzodiazepine hypnotics, for ≥ 60 days within a 90-day period).

Please document complete treatment plan (include all hypnotic agents [benzodiazepine and/or non-benzodiazepine] and indication or ICD-10 code, if applicable).

1. Hypnotic name/dose/frequency _____ Indication _____
2. Hypnotic name/dose/frequency _____ Indication _____
3. Hypnotic name/dose/frequency _____ Indication _____
4. Please indicate prescriber specialty below.

   ☐ Psychiatry ☐ Neurology ☐ Sleep Medicine ☐ Other _____

   If prescriber is not a specialist, please attach consult notes from specialist.

   For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable. _____
5. Please describe the severity of sleep diagnosis (e.g., symptoms, recent hospitalizations, risk of harm to self or others, etc.) _____

   Has the member had a trial with all alternative hypnotics indicated for diagnosis?

   ☐ Yes. Please list the drug names, dose and frequency, dates/durations, and outcomes in Section VIII below.*

   ☐ No. If these trials are contraindicated, please describe.

Section III. Please complete for all requests for Belsomra, Dayvigo, and Quviviq.

1. Has the member had a trial with two of the following: eszopiclone, ramelteon, zaleplon, or zolpidem (immediate-release or extended-release)?

   ☐ Yes. Please list the drug names, dose and frequency, dates/durations, and outcomes in Section VIII below.*

   ☐ No. If these trials are contraindicated, please describe.

   For Dayvigo, has the member had a trial with Belsomra?

   ☐ Yes. Please list the drug names, dose and frequency, dates/durations, and outcomes in Section VIII below.*

   ☐ No. If these trials are contraindicated, please describe.

   For Quviviq, has the member had a trial with Belsomra and Dayvigo?

   ☐ Yes. Please list the drug names, dose and frequency, dates/durations, and outcomes in Section VIII below.*

   ☐ No. If these trials are contraindicated, please describe.

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Section IV. Please complete for all requests for Edluar.

Please provide medical necessity for sublingual formulation.

Section V. Please complete for all requests for doxepin tablet.

1. Has the member had a trial with doxepin oral concentrate at an equivalent dose to the requested tablet or doxepin capsule?
   ☐ Yes. Please list the drug name, dose and frequency, dates/duration, and outcome in Section VIII below.*
   ☐ No. If these trials are contraindicated, please describe.

2. Has the member had a trial with two of the following: eszopiclone, ramelteon, Belsomra or Dayvigo or Quviviq, zaleplon, or zolpidem (immediate-release or extended-release)?
   ☐ Yes. Please list the drug name, dose and frequency, dates/duration, and outcome in Section VIII below.*
   ☐ No. If these trials are contraindicated, please describe.

Section VI. Please complete for all requests for zolpidem 1.75 mg, and 3.5 mg sublingual.

Has the member had a trial with three of the following: eszopiclone, zaleplon, zolpidem extended-release, zolpidem immediate-release?
☐ Yes. Please list the drug names, dose and frequency, dates/durations, and outcomes in Section VIII below.*
☐ No. If there is a medical necessity for sublingual formulation, please describe.

Section VII. Please complete for all requests for zolpidem 7.5 mg capsule.

Has the member had a trial with both of the following: zolpidem 5 mg tablet and zolpidem 10 mg tablet?
☐ Yes. Please list the drug names, dose and frequency, dates/durations, and outcomes in Section VIII below.*

Please provide medical necessity for 7.5 mg capsule instead of formulations available without prior authorization.

Section VIII. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

Drug name Dose and frequency Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dose and frequency Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

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Drug name Dose and frequency Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dose and frequency Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

Section IX. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

MassHealth Pediatric Behavioral Health Medication Initiative

Please fill out all the sections below, as applicable, for pediatric members only. You may also use the Pediatric Behavioral Health Medication Initiative PA Request Form if the member is prescribed other behavioral health medications.

over

Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name Dose/frequency Indication
2. Medication name Dose/frequency Indication
3. Medication name Dose/frequency Indication
4. Medication name Dose/frequency Indication
5. Medication name Dose/frequency Indication
6. Medication name Dose/frequency Indication
7. Other(s)

Is the member currently in an acute care setting?

☐ Yes (Inpatient) ☐ Yes (Community Based Acute Treatment)
☐ Yes (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.

Prescriber name Contact information

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months.
☐ No

On the current regimen, is the member considered to be a severe risk of harm to self or others?

☐ Yes. Please provide details. ☐ No

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g. weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain.

Has informed consent from a parent or legal guardian been obtained?* ☐ Yes ☐ No

Please indicate prescriber specialty below.

☐ Psychiatry ☐ Neurology ☐ Other
☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

Name(s) of the specialist(s) Date(s) of last visit or consult

Contact information

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility ☐ Uncertain
☐ Other

over

Please document agency involvement.

☐ DCF ☐ Department of Mental Health (DMH) ☐ Department of Developmental Services (DDS)
☐ Department of Youth Services (DYS)

Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions below, if applicable. ☐ No

Psychiatric care provided is coordinated with other psychotherapeutic and community based services.

☐ Yes ☐ No

* *Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information go to:* https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information

Please complete for members who have been on one of the following for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation): a polypharmacy regimen, members < six years of age who have been on an applicable behavioral health medication, and members < ten years of age who have been on an antipsychotic.

Have previous efforts to reduce or simplify the regimen in the past 24 months resulted in symptom exacerbation? ☐ Yes ☐ No

The family or caregiver does not support the regimen change at this time due to risk of exacerbation.

☐ Yes ☐ No

Is there another significant barrier for therapy discontinuation? ☐ Yes ☐ No

If yes, please explain.

Section II. Hypnotic Requests for Members < six years of age.

Please document if member has other behavioral health comorbidities (e.g., anxiety, depression, ADHD).

Please document medication trials with melatonin and/or clonidine, if clinically appropriate. Include drug name, dates/duration of use, and outcome.*

Please document clinical rationale for the use of a hypnotic agent in this member < six years of age.

Has the member been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

* *Attach a letter with additional information regarding medication trials as applicable.*

Section III. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.*

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Please document clinical rationale for use of multiple behavioral health medications for this member < 18 years of age.

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

** Attach a letter with additional information regarding medication trials as applicable.*

Please continue to next page and complete Prescriber and Provider Information section.

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Imcivree
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Dose, frequency, and duration of medication requested

Indication or ICD-10 code, if applicable

☐ Obesity due to Bardet-Biedl syndrome

☐ Obesity due to genetic deficiency (Specify type of deficiency below.)

☐ Leptin receptor (LEPR) ☐ Proprotein convertase subtilisin/kexin type 1 (PCSK1)

☐ Proopiomelanocortin (POMC)

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Is the prescriber an endocrinologist? ☐ Yes ☐ No

Section I. Please complete for all requests.

Current height Baseline weight Baseline body mass index (BMI) Date

For adult members, BMI, height, and weight are required. For pediatric members, BMI and most recent growth chart are required.

Section II. Please complete for obesity due to genetic deficiency.

1. Please attach a copy of genetic test(s) confirming obesity due to a homozygous or presumed homozygous variant in at least one of the following genes: LEPR, PCSK1, or POMC.
2. Please specify interpretation of the variant(s) in LEPR, PCSK1, or POMC genes as confirmed by genetic testing:

   ☐ Pathogenic ☐ Likely pathogenic ☐ Of uncertain significance (VUS) ☐ Other

Section III. Please complete for recertification requests.

Current height Current weight Current BMI Date

For adult members, weight is required. For pediatric members, BMI is required.

1. For pediatric members, does the member have continued growth potential? ☐ Yes ☐ No
2. Has the member been adherent to Imcivree?
   ☐ Yes. Please note: Continued approval of the requested agent will be contingent upon MassHealth pharmacy claims history or additional documentation addressing adherence.
   ☐ No

Section IV. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Immune Globulin
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ Alyglo	☐ Flebogamma	☐ Gammaplex	☐ Panzyga
☐ Asceniv	☐ Gamastan S/D	☐ Gamunex-C	☐ Privigen
☐ Bivigam	☐ Gammagard	☐ Hizentra	☐ Xembify
☐ Cutaquig	☐ Gammagard S/D	☐ Hyqvia	
☐ Cuvitru	☐ Gammaked	☐ Octagam	

Dose of medication requested _____ mg per kg = _____ g

Frequency and duration of medication requested _____

Please specify dosing schedule. ☐ Scheduled ☐ Intermittent

Member's current actual body weight (ABW) _____ Date _____

Member's current height _____ Date _____

Member's current Body Mass Index (BMI) _____ Date _____

For initiation of intravenous immune globulin (IVIG), if a member's BMI is ≥ 30 kg/m^2 or ABW is > 120% of ideal body weight (IBW), dosing calculated using adjusted body weight has been demonstrated to have similar clinical effect as using ABW. MassHealth suggests the use of this dosing strategy to promote cost effective care. This is not meant to replace clinical decision making when initiating medication therapy. Please complete the below question.

If member meets the criteria noted above (BMI ≥ 30 kg/m^2 or ABW > 120% of IBW), is the member a candidate for adjusted body weight dosing? If criteria are not applicable, this may be left blank.

☐ Yes. MassHealth to calculate total dose based on adjusted body weight* (may round dose to vial size).

☐ No. Please explain why adjusted body weight* dosing is not appropriate for this member. _____

_____

** Adjusted Body Weight = IBW + 0.4 (ABW - IBW)*

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code _____

Indication or ICD-10 code, if applicable _____

Is the member stabilized on the requested medication?

☐ Yes. Please provide start date. _____ ☐ No

Section I. Please specify the indication for all requests except for a diagnosis of dermatomyositis (DM). For Asceniv requests, please also complete Section III as appropriate.

☐ Primary immunodeficiency disorders (PID)

Please attach laboratory documentation supporting diagnosis.

Provide date and results of most recent serum immunoglobulin levels (including laboratory reference ranges).

☐ Immune thrombocytopenia (ITP)

Provide date and results of most recent platelet count (including laboratory reference ranges).

Does the member have clinically significant bleeding? ☐ Yes. Please describe below. ☐ No

Does the member have a history of or risk of significant bleeding? ☐ Yes. Please describe below. ☐ No

Does the member have a medical necessity to raise platelet count within 12 to 24 hours?
☐ Yes. Please describe below. ☐ No

☐ Kawasaki disease (mucocutaneous lymph node syndrome)

Provide date of onset.

Does the member have an unexplained persistent fever? ☐ Yes ☐ No

Does the member have evidence of aneurysm? ☐ Yes ☐ No

Does the member exhibit signs of persistent inflammation? ☐ Yes ☐ No

☐ B-cell chronic lymphocytic leukemia (CLL)

☐ Chronic inflammatory demyelinating polyneuropathy (CIDP)

☐ Multifocal motor neuropathy (MMN)

☐ Other

Please describe the medical necessity for the use of immune globulin including previous trials and outcomes.

Section II. Please complete for treatment of dermatomyositis (DM). For Asceniv requests, please also complete Section III as appropriate.

1. Has the member had a trial with one systemic corticosteroid?

   ☐ Yes. Please list the dates/duration of trials and outcomes.* Dates/duration of trial

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain if there is a contraindication.
2. Does the member have severe disease? ☐ Yes ☐ No
3. Has the member had a trial with one of the following: azathioprine, chloroquine, hydroxychloroquine, methotrexate, mycophenolate mofetil, or rituximab?

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☐ Yes. Please list the drug names, dates/duration of trials and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to these trials.

Section III. Please also complete for requests for Asceniv. Please complete Section I or II above as appropriate.

Please provide clinical rationale for the use of this product instead of other available IVIG products.

Section IV. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details.

   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Inhaled Respiratory Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested (Check one or all that apply. Where applicable, the brand name is provided in brackets for reference.)

Anticholinergics

- ☐ Yupelri (revefenacin)

Combination Products

- ☐ Airduo Digihaler (fluticasone/salmeterol)
- ☐ Airsupra (albuterol/budesonide)
- ☐ Bevespi (glycopyrrolate/formoterol)
- ☐ Breztri (budesonide/glycopyrrolate/formoterol)
- ☐ Duaklir (aclidinium/formoterol)
- ☐ fluticasone/salmeterol [Airduo Respiclick]
- ☐ Stiolto (tiotropium/olodaterol)
- ☐ Trelegy (fluticasone furoate/umeclidinium/ vilanterol)

Corticosteroids

- ☐ Alvesco (ciclesonide inhaler)
- ☐ Armonair Digihaler (fluticasone propionate inhalation powder)
- ☐ budesonide inhalation suspension ≥ 13 years
- ☐ fluticasone propionate inhalation aerosol ≥ 12 years
- ☐ fluticasone propionate inhalation powder
- ☐ Qvar Redihaler (beclomethasone inhaler)

Long-acting Beta Agonists

- ☐ arformoterol
- ☐ formoterol
- ☐ Striverdi (olodaterol)

Short-acting Beta Agonists

- ☐ albuterol inhaler ‡
- ☐ levalbuterol inhalation solution
- ☐ Proair Digihaler (albuterol inhalation powder)

‡Brand name Ventolin is available without prior authorization.

Phosphodiesterase 3/phosphodiesterase 4 inhibitor

- ☐ Ohtuvayre (ensifentrine)

Other Medication

- ☐ Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Dose and frequency of medication requested _____

Number of inhalers/month _____

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Asthma (Specify severity below.)
  - ☐ Intermittent ☐ Mild Persistent ☐ Moderate Persistent ☐ Severe Persistent
- ☐ Chronic Obstructive Pulmonary Disease (COPD) (Specify severity and subtype below.)
  - Severity ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe
  - Subtype ☐ Chronic bronchitis ☐ Emphysema

☐ Exercise-induced bronchospasm

☐ Reactive airway disease ☐ Other

Please list all other medications currently prescribed for the member for this indication.

Is this member a referral candidate for care coordination? ☐ Yes ☐ No
If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for albuterol inhaler and Proair Digihaler requests.

1. For requests for albuterol inhaler, please attach medical records documenting an inadequate response or adverse reaction to an albuterol product available without prior authorization. *
2. For requests for Proair Digihaler, has the member had a trial with brand name Proair Respiclick, or Ventolin?
   ☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.
   ☐ No. Please describe the clinical rationale why an albuterol inhaler is not appropriate for this member.

** Brand name Ventolin does not require prior authorization*.

Section II. Please complete for all arformoterol, budesonide inhalation suspension, formoterol, levalbuterol inhalation solution, and Yupelri requests.

1. Please describe the medical necessity for a nebulized formulation.
2. For levalbuterol inhalation solution, has the member had a trial with albuterol solution?
   ☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.
   ☐ No. Please describe the clinical rationale why albuterol solution is not appropriate for this member.
3. For Yupelri, has the member had a trial with ipratropium inhalation nebulizer solution?
   ☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.
   ☐ No. Please describe the clinical rationale why ipratropium inhalation nebulizer solution is not appropriate for this member.

Section III. Please complete for Airduo Digihaler, and fluticasone/salmeterol (generic Airduo Respiclick) requests.

1. Has the member had a trial with fluticasone/salmeterol inhalation aerosol, powder (generic Advair)?
   ☐ Yes. Please list the dates/duration of trials and the outcomes in Section X.
   ☐ No. Please describe the clinical rationale for use of the requested agent in this member.
2. For Airduo Digihaler, has the member had a trial with fluticasone/salmeterol (generic Airduo Respiclick)?
   ☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.
   ☐ No. Please describe the clinical rationale for use of the requested agent in this member.

over

Section IV. Please complete for Alvesco, Armonair Digihaler, fluticasone propionate inhalation aerosol for members ≥ 12 years of age, fluticasone propionate inhalation powder, and Qvar Redihaler requests.

Has the member had a trial with two inhaled corticosteroids?

☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.

☐ No. Please document if there is a contraindication to all other inhaled corticosteroids.

Section V. Please complete for Bevespi and Duaklir requests.

Has the member had a trial with Stiolto or umeclidinium/vilanterol?

☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.

☐ No. Please describe the clinical rationale for use of the requested agent in this member.

Section VI. Please complete for Trelegy requests.

Has the member had a trial with fluticasone/vilanterol and Incruse or Arnuity and umeclidinium/vilanterol?

☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.

☐ No. Please describe the clinical rationale for use of the requested agent in this member.

Section VII. Please complete for Breztri requests.

Has the member had a trial with the following combination of the separate agents: Bevespi and Pulmicort inhalation powder?

☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.

☐ No. Please describe the clinical rationale for use of the requested agent in this member.

Section VIII. Please complete for Airsupra requests.

Has the member had a trial with budesonide/formoterol or albuterol and Pulmicort inhalation powder?

☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.

☐ No. Please describe the clinical rationale for use of the requested agent in this member.

Section IX. Please complete for Ohtuvayre requests.

1. Has the member had a trial with Bevespi, Duaklir, Stiolto, or umeclidinium/vilanterol?

   ☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.

   ☐ No. Please describe the clinical rationale why Bevespi, Duaklir, Stiolto, and umeclidinium/vilanterol is not appropriate for this member.

2. Has the member had a trial with Breztri or Trelegy?

   ☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.

   ☐ No. Please describe the clinical rationale why Breztri and Trelegy is not appropriate for this member.

over

Section X. Please complete as instructed in sections above.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

** Please attach a letter documenting additional trials as necessary.*

Section XI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

over

4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Injectable Antibiotic
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Avycaz (ceftazidime/avibactam)
- ☐ Baxdela (delafloxacin injection)
- ☐ Dalvance (dalbavancin)
- ☐ Defencath (taurolidine/heparin) [MB]
- ☐ Fetroja (cefiderocol)
- ☐ Kimyrsa (oritavancin)
- ☐ linezolid injection
- ☐ Nuzyra (omadacycline injection)
- ☐ Orbactiv (oritavancin)
- ☐ Recarbrio (imipenem/cilastatin/relebactam)
- ☐ Sivextro (tedizolid injection)
- ☐ tigecycline
- ☐ Vabomere (meropenem/vaborbactam)
- ☐ Vibativ (telavancin)
- ☐ Xerava (eravacycline)
- ☐ Zemdri (plazomicin)
- ☐ Zerbaxa (ceftolozane/tazobactam)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

☐ Initial request ☐ Recertification request ☐ Naïve to therapy ☐ Continuation of therapy

Is the member stabilized on the requested medication? ☐ Yes. Dates of use ☐ No

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Bacteremia
- ☐ Bone or joint infection:
- ☐ Central nervous system (CNS) infection:
- ☐ Community-acquired bacterial pneumonia (CABP)
- ☐ Complicated intra-abdominal infection (cIAI)
- ☐ Complicated urinary tract infection (cUTI)
- ☐ Endocarditis
- ☐ Hospital-acquired (nosocomial) bacterial pneumonia (HABP)
- ☐ Prevention of catheter-related bloodstream infections (CRBSI) with kidney failure
- ☐ Skin and soft tissue infection (SSTI):
  ☐ Acute ☐ Complicated ☐ Uncomplicated
- ☐ Ventilator-associated bacterial pneumonia
- ☐ Other infection:

Please indicate the infecting organism.

- ☐ Methicillin-resistant Staphylococcus aureus (MRSA)
  ☐ Confirmed ☐ Suspected
- ☐ Vancomycin-resistant Enterococcus (VRE)
- ☐ Non-MRSA/non-VRE:
  ☐ Confirmed ☐ Suspected

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Section I. Please complete for all requests, excluding Defencath.

1. Were cultures and susceptibility testing performed?
   ☐ Yes. Please attach a copy of the culture and sensitivity report with submission.
   ☐ No. Please provide clinical rationale why cultures and susceptibility testing were not performed.
2. Please list previous antibiotic trials for the requested indication including outcomes.*
   Drug Outcome Dates of use
   Drug Outcome Dates of use
   Drug Outcome Dates of use
3. Is the member ≥ 18 years of age? ☐ Yes ☐ No
4. For Avycaz and Zerbaxa requests for a diagnosis of complicated intra-abdominal infection (cIAI), will the member be using the requested medication concurrently with metronidazole?
   ☐ Yes
   ☐ No. Please explain.
5. For requests for Kimyrsa, please provide clinical rationale for use instead of Orbactiv.

**Attach a letter with additional information regarding medication trials as applicable.*

Section II. Please complete for requests for Defencath.

1. Is the member ≥ 18 years of age? ☐ Yes ☐ No
2. Does the member have a history of CRBSIs? ☐ Yes ☐ No
3. Is the member a nasal carrier of Staphylococcus aureus? ☐ Yes ☐ No
4. Is the member receiving chronic hemodialysis through a central venous catheter? ☐ Yes ☐ No
5. Has the member had a trial with two antibiotic agents used in combination with heparin?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.
   Drug Outcome Dates of use
   Drug Outcome Dates of use
   Drug Outcome Dates of use
   Drug Outcome Dates of use
   ☐ No. Please document if there is a contraindication to all antibiotic agent alternatives.

Section III. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

over

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

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Date

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Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
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over

Intranasal Corticosteroids
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested

- ☐ flunisolide nasal spray
- ☐ fluticasone propionate 50 mcg nasal spray > 1 inhaler/30 days
- ☐ mometasone nasal spray
- ☐ Omnaris (ciclesonide 50 mcg nasal spray) > 1 inhaler/30 days
- ☐ Qnasl (beclomethasone nasal aerosol)
- ☐ Ryaltris (olopatadine/mometasone)
- ☐ Sinuva (mometasone sinus implant)
- ☐ Xhance (fluticasone propionate 93 mcg nasal spray)
- ☐ Zetonna (ciclesonide 37 mcg nasal aerosol) > 1 inhaler/30 days

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Allergic rhinitis
- ☐ Nasal polyps
- ☐ Nasal polyps with a history of ethmoid sinus surgery
- ☐ Non-allergic rhinitis
- ☐ Seasonal allergic rhinitis
- ☐ Other (please indicate)

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Section I. Please complete for requests for flunisolide nasal spray, mometasone nasal spray, and Qnasl.

For members ≥ 6 years of age, please complete questions 1 through 3. For members 4 to 5 years of age, please complete questions 1 and 3. For members < 4 years of age, please complete question 3.

1. Has the member had a trial with fluticasone propionate 50 mcg nasal spray?

   ☐ Yes. Please list the dates/duration of trials, and outcomes.* Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe clinical rationale for not using fluticasone propionate 50 mcg nasal spray.

2. Has the member had a trial with budesonide over-the-counter (OTC) nasal spray?

☐ Yes. Please list the dates/duration of trials, and outcomes.* Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using budesonide OTC nasal spray.

3. Has the member had a trial with triamcinolone OTC nasal spray?

☐ Yes. Please list the dates/duration of trials, and outcomes.* Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using triamcinolone OTC nasal spray.

Section II. Please complete for any agent at a quantity > one inhaler per 30 days. Please complete Section I above as appropriate.

1. Has the member had a trial with two intranasal or second-generation oral antihistamines?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using intranasal or second-generation oral antihistamines.

2. For requests for any agent at a quantity > one inhaler per month, please attach medical records documenting an inadequate response to the manufacturer's recommended dosing.

Section III. Please complete for requests for Ryaltris.

1. Has the member had a trial with one intranasal corticosteroid agent used in combination with one intranasal antihistamine agent?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

over

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using intranasal corticosteroids in combination with intranasal antihistamines.

2. Has the member had a trial with azelastine/fluticasone propionate nasal spray?

☐ Yes. Please list the dates/duration of trials and outcomes below.*

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using azelastine/fluticasone propionate nasal spray.

Section IV. Please complete for requests for Sinuva.

1. Please indicate prescriber specialty below.

☐ Otolaryngologist ☐ Other

2. Has the member had a trial with two intranasal corticosteroids?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using intranasal corticosteroids.

3. Has the member had a trial with an oral corticosteroid?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

over

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using an oral corticosteroid.

**Please attach a letter documenting additional trials as necessary.*

Section V. Please complete for requests for Xhance.

Please describe medical necessity for use of the requested agent instead of all other intranasal corticosteroids.

Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Lipid-Lowering Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Statins

- ☐ Altoprev (lovastatin extended-release)
- ☐ Atorvaliq (atorvastatin suspension)
- ☐ atorvastatin > quantity limits
- ☐ atorvastatin/amlodipine
- ☐ Ezallor (rosuvastatin sprinkle capsule)
- ☐ Flolipid (simvastatin suspension)
- ☐ fluvastatin
- ☐ fluvastatin extended-release
- ☐ Leqvio (inclisiran)
- ☐ lovastatin > quantity limits
- ☐ pitavastatin calcium
- ☐ pravastatin > quantity limits
- ☐ rosuvastatin > quantity limits
- ☐ simvastatin > quantity limits
- ☐ simvastatin/ezetimibe > quantity limits
- ☐ Zypitamag (pitavastatin magnesium)

Fibric Acids

- ☐ fenofibrate tablet 40 mg, 120 mg
- ☐ fenofibrate 90 mg capsule

Miscellaneous Agents

- ☐ Evkeeza (evinacumab-dgnb) [MB]
- ☐ icosapent ethyl
- ☐ Juxtapid (lomitapide)
- ☐ Nexletol (bempedoic acid)
- ☐ Nexlizet (bempedoic acid/ezetimibe)

PCSK9 Inhibitors

- ☐ Praluent (alirocumab)
- ☐ Repatha (evolocumab)

Other Lipid-Lowering Agents

Other* ☐

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of requested medication ☐ **Quantity requested per month** ☐

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Atherosclerotic cardiovascular (CV) disease
- ☐ CV risk reduction
- ☐ Heterozygous familial hypercholesterolemia
- ☐ Homozygous familial hypercholesterolemia
- ☐ Hypercholesterolemia
- ☐ Hypercholesterolemia with previous history of any cardiovascular event
- ☐ Hypertriglyceridemia
- ☐ Mixed dyslipidemia
- ☐ Primary hyperlipidemia

☐ Other. Specify pertinent medical history, diagnostic studies, and/or laboratory results.

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Please indicate prescriber specialty.

☐ Cardiology ☐ Other

☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

Name(s) of the specialist(s)

Date(s) of last visit or consult

Contact Information

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Lab Values and Treatment Plan: Please complete for all requests.

1. Is this a request for treatment initiation?
   ☐ Yes. Please provide the current baseline laboratory values.
   Date
   Total cholesterol mg/dl LDL/LDL-C mg/dl
   HDL mg/dl Triglycerides mg/dl
   ☐ No
2. Is this a request for continuation of treatment?
   ☐ Yes. Please provide the current laboratory values following treatment demonstrating efficacy of the requested agent.
   Date
   Total cholesterol mg/dl LDL/LDL-C mg/dl
   HDL mg/dl Triglycerides mg/dl
   ☐ No
3. Please summarize treatment goals including target cholesterol levels.

Please note: High-intensity statin therapy is defined as atorvastatin 40 mg, 80 mg, and rosuvastatin 20 mg, 40 mg.

Section I. Please complete for Altoprev, fluvastatin, fluvastatin extended-release, pitavastatin calcium, and Zypitamag requests.

1. Has the member had an inadequate response to a high-intensity statin for at least three months?
   ☐ Yes ☐ No

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2. Has the member tried a high-intensity statin and had an adverse reaction or does the member have a contraindication to all high-intensity statins?

☐ Yes. Please explain.

☐ No. Please provide clinical rationale for not trying a high intensity statin.

Section II. Please complete for requests for quantities above quantity limits.

Please attach documentation of the clinical rationale for the requested dose, quantity, and frequency, including a detailed treatment plan. Specify pertinent medical history, diagnostic studies, and/or lab results.

Section III. Please complete for fenofibrate tablet 40 mg, 120 mg and fenofibrate 90 mg capsule requests.

Please attach medical records documenting failure with a therapeutically equivalent fenofibrate formulation available without prior authorization.

Section IV. Please complete for atorvastatin/amlodipine requests.

Please describe medical necessity for use of the combination product instead of the commercially available separate agents.

Section V. Please complete for icosapent ethyl for hypertriglyceridemia (not inclusive of those with established cardiovascular disease (CVD) or diabetes mellitus and CV risk factors) requests.

Has the member had a trial with a fibric acid derivative?

☐ Yes. Please list the drug name, dose and frequency, dates/duration of trials, and outcomes below.

Drug name Dose and frequency Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please document if there is a contraindication to all fibric acid derivatives.

Section VI. Please complete for icosapent ethyl for cardiovascular risk reduction requests.

1. Does the member have established cardiovascular disease (CVD)?

   ☐ Yes. Please describe.

   ☐ No
2. Does the member have diabetes mellitus with at least one risk factor for CVD?

   ☐ Yes. Please describe.

   ☐ No
3. Will icosapent ethyl will be used in combination with a statin?

   ☐ Yes

   ☐ No. Please provide clinical rationale why member cannot take a statin.

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Section VII. Please complete for Nexletol, Nexlizet, Praluent, and Repatha requests.

1. Has the member had an inadequate response to a high-intensity statin in combination with ezetimibe for at least the last three months?
   - ☐ Yes
     - ☐ Name of statin _____ Dose and frequency _____
     - Dates of use _____ Outcome _____
     - ☐ ezetimibe
       - Dose and frequency _____ Dates of use _____ Outcome _____
   - ☐ No
2. Has the member tried a high-intensity statin and had an adverse reaction or does the member have a contraindication to all high-intensity statins?
   - ☐ Yes. Please explain. _____ ☐ No
3. Has the member tried ezetimibe and had an adverse reaction or does the member have a contraindication to this agent?
   - ☐ Yes. Please explain. _____ ☐ No
4. For Praluent and Repatha, has the member had an inadequate response to a maximally tolerated statin dose for at least the last three months?
   - ☐ Yes
     - ☐ Name of statin _____ Dose and frequency _____
     - Dates of use _____ Outcome _____
   - ☐ No
5. For Nexletol and Nexlizet, does the member have a previous history of cardiovascular event?
   - ☐ Yes
   - ☐ No. If no, does the member have any of the following risk factors? (Check all that apply.)
     - ☐ Type 1 diabetes mellitus
     - ☐ Type 2 diabetes mellitus
     - ☐ Reynolds risk score > 30% or SCORE risk score > 7.5% over 10 years
     - ☐ Coronary artery calcium score > 400 Agatston units

Section VIII. Please complete for Leqvio requests.

1. Has the member had an inadequate response to a high-intensity statin in combination with ezetimibe for at least the last three months?
   - ☐ Yes
     - ☐ Name of statin _____
     - Dose and frequency _____ Dates of use _____ Outcome _____
     - ☐ ezetimibe
       - Dose and frequency _____ Dates of use _____ Outcome _____
   - ☐ No
2. Has the member tried a high-intensity statin and had an adverse reaction or does the member have a contraindication to all high-intensity statins?
   - ☐ Yes. Please explain. _____ ☐ No

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3. Has the member tried ezetimibe and had an adverse reaction or does the member have a contraindication to this agent?

   ☐ Yes. Please explain. _____ ☐ No

4. Has the member had an inadequate response to Praluent or Repatha for at least the last three months?

   ☐ Yes. Please note: Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to this agent.

   Drug name _____

   Dose and frequency _____ Dates of use _____ Outcome _____

   ☐ No

5. Has the member tried Praluent and had an adverse reaction or does the member have a contraindication to this agent?

   ☐ Yes. Please explain. _____ ☐ No

6. Has the member tried Repatha and had an adverse reaction or does the member have a contraindication to this agent?

   ☐ Yes. Please explain. _____ ☐ No

7. Does the member have a previous history of cardiovascular event?

   ☐ Yes

   ☐ No. If no, does the member have any of the following risk factors? (Check all that apply.)

   ☐ Type 2 diabetes mellitus

   ☐ Member has ≥ 20% 10-year risk of a cardiovascular event based on Framingham Risk Score for cardiovascular disease or equivalent

8. If this is a request for continuation of treatment, has the member been adherent to the lipid-lowering regimen?

   ☐ Yes. Please note: Continued approval of the requested agent will be contingent upon MassHealth pharmacy claims history or additional documentation addressing adherence to the entire lipid-lowering regimen.

   ☐ No

Section IX. Please complete for Atorvaliq, Ezallor, and Flolipid requests.

1. Please provide medical necessity for use of the requested formulation.

   _____

2. For Atorvaliq, please provide clinical rationale for use instead of Ezallor.

   _____

Section X. Please complete for Juxtapid requests.

1. Does the member have laboratory testing results confirming genetic mutation associated with homozygous familial hypercholesterolemia including low density lipoprotein receptor mutations, PCSK9 mutations, and familial defective apoB mutations? ☐ Yes. Please attach laboratory testing results. ☐ No
2. Please provide the following laboratory values:

   Baseline LDL/LDL-C _____ mg/dl Date _____

   Current LDL/LDL-C _____ mg/dl Date _____

3. Did the member have evidence of xanthoma before 10 years of age? ☐ Yes ☐ No
4. Does the member have evidence of heterozygous familial hypercholesterolemia in both parents?

   ☐ Yes ☐ No

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5. Has the member had an inadequate response to a high-intensity statin for at least three months?
   ☐ Yes. Drug name _____ Dose and frequency _____ Dates/duration of use _____
   ☐ No
6. Has the member tried a high-intensity statin and had an adverse reaction or does the member have a contraindication to all high-intensity statins?
   ☐ Yes. Please explain. _____
   ☐ No
7. Has the member had a trial with an additional non-statin lipid-lowering agent?
   ☐ Yes. Please list the drug name, dose and frequency, dates/duration of trials, and outcomes below.
   Drug name _____ Dose and frequency _____ Dates/duration of use _____
   Did the member experience any of the following?
   ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   _____
   ☐ No. Please document if there is a contraindication to all non-statin lipid-lowering agents.
   _____
8. Will the requested agent be used in combination with a high-intensity statin?
   ☐ Yes. Please list the drug name and dose and frequency below.
   Drug name _____ Dose and frequency _____
   ☐ No. Please explain. _____

Section XI. Please complete for Evkeeza requests.

1. Does the member have laboratory testing results confirming genetic mutation associated with homozygous familial hypercholesterolemia including low density lipoprotein receptor mutations, PCSK9 mutations, and familial defective apoB mutations? ☐ Yes. Please attach laboratory testing results. ☐ No
2. Please provide the following laboratory values:
   Baseline LDL/LDL-C _____ mg/dl Date _____
   Current LDL/LDL-C _____ mg/dl Date _____
3. Did the member have evidence of xanthoma before 10 years of age? ☐ Yes ☐ No
4. Does the member have evidence of heterozygous familial hypercholesterolemia in both parents?
   ☐ Yes ☐ No
5. Please provide member's current weight _____ Date _____
6. Will the requested agent be used in combination with a high-intensity statin, ezetimibe, and a PCSK9 inhibitor?
   ☐ Yes. Please list the drug name(s) and dose and frequency below.
   Drug name _____ Dose and frequency _____
   Drug name _____ Dose and frequency _____
   Drug name _____ Dose and frequency _____
   ☐ No. Please explain. _____

over

Section XII. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen? ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details. ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Lung Cancer Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested

- ☐ Alecensa (alectinib)
- ☐ Alunbrig (brigatinib)
- ☐ Augtyro (repotrectinib)
- ☐ erlotinib
- ☐ gefitinib
- ☐ Gilotrif (afatinib)
- ☐ Krazati (adagrasib)
- ☐ Lazcluze (lazertinib)
- ☐ Lorbrena (lorlatinib)
- ☐ Lumakras (sotorasib)
- ☐ Portrazza (necitumumab) [MB]
- ☐ Rybrevant (amivantamab-vmjw) [MB]
- ☐ Tabrecta (capmatinib)
- ☐ Tagrisso (osimertinib)
- ☐ Tepmetko (tepotinib)
- ☐ Vizimpro (dacomitinib)
- ☐ Xalkori (crizotinib)
- ☐ Zepzelca (lurbinectedin) [MB]
- ☐ Zykadia (ceritinib)

[MB] *This drug is available through the healthcare professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other healthcare professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Height Weight Date

Please indicate prescriber specialty below.

☐ Oncology ☐ Other

Will the requested agent be used as monotherapy for this indication? ☐ Yes ☐ No

If no, please list all other medications currently prescribed for the member that will be used concomitantly for this indication.

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ **Lung cancer**

- ☐ Non-small cell lung cancer (NSCLC)
  - ☐ Adjuvant treatment for stage IB to IIIA
  - ☐ Advanced or metastatic
- ☐ Small-cell lung cancer (SCLC)
  - ☐ Advanced or metastatic

☐ **Other Oncologic Indication**

- ☐ Colorectal cancer
  - ☐ Advanced or metastatic
- ☐ Inflammatory myofibroblastic tumors (IMT)
- ☐ Pancreatic cancer
  - ☐ Advanced or metastatic
- ☐ Solid tumors
- ☐ Systemic anaplastic large cell lymphoma
- ☐ Other ______

Please describe pertinent mutations.

☐ ALK-positive ☐ EGFR ☐ KRAS G12C ☐ MET exon 14 skipping ☐ ROS1 ☐ T790M resistance

Please describe details of pertinent mutations including exon deletions or mutations below.

______

Please describe the cell histology, if applicable.

______

Please describe the stage and severity of disease.

______

Has the member had persistent or recurring disease following surgery and/or radiation therapy? ☐ Yes ☐ No

Is the member a candidate for surgery and/or radiation?

☐ Yes ☐ No. Please describe. ______

Section I. Please complete for all requests.

Please list any other prior trials. Please list the drug names, dates/duration of use and outcomes below.*

Drug name ______ Dates/duration of use ______

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

______

Drug name ______ Dates/duration of use ______

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

______

Drug name ______ Dates/duration of use ______

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

______

Drug name ______ Dates/duration of use ______

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

______

* *Please attach a letter documenting additional trials as necessary.*

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Section II. Please complete for Portrazza requests.

Please describe medical necessity for the requested agent instead of all other clinically appropriate alternatives.

Section III. Please complete for Xalkori pellet requests.

Does the member have a medical condition in which they are unable to swallow tablets/capsules?

☐ Yes. Please provide details.

☐ No. Please provide clinical rationale why conventional dosage forms cannot be used.

Section IV. Please complete for requests for agents with a preferred alternative.

Please describe clinical rationale for use of the requested agent instead of the preferred alternative.

Section V. Please complete for requests for quantities above quantity limits.

Please describe the clinical rationale for exceeding the quantity limit, including a detailed treatment plan.

Section VI. Please include any other pertinent information (if needed).

Section VII. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

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If yes, please provide details for the previous trial.

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

_____

_____

4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details. _____

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Multiple Myeloma Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested

- ☐ Blenrep (belantamab mafodotin-blmf)
- ☐ Darzalex (daratumumab) [MB]
- ☐ Darzalex Faspro (daratumumab-hyaluronidase-fihj) [MB]
- ☐ Empliciti (elotuzumab) [MB]
- ☐ Kyprolis (carfilzomib) [MB]
- ☐ Ninlaro (ixazomib)
- ☐ Pomalyst (pomalidomide)
- ☐ Sarclisa (isatuximab-irfc) [MB]
- ☐ Xpovio (selinexor)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Height Weight Date

Please indicate prescriber specialty: ☐ Hematology ☐ Oncology ☐ Other

Will the requested agent be used as monotherapy for this indication? ☐ Yes ☐ No

If no, please list all other medications currently prescribed for the member that will be used concomitantly for this indication.

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ **Multiple myeloma**

Other Oncologic Indications

- ☐ Diffuse large B-cell lymphoma (DLBCL)
- ☐ Light chain amyloidosis
- ☐ Kaposi sarcoma
  - ☐ Acquired Immunodeficiency Syndrome (AIDS) and failed highly active antiretroviral therapy
  - ☐ Negative for Human Immunodeficiency Virus (HIV)

Please describe the stage and severity of disease.

Is the cancer metastatic? ☐ Yes ☐ No

Has the member had persistent or recurring disease following surgery and/or radiation therapy? ☐ Yes ☐ No

Is the member a candidate for surgery and/or radiation?

☐ Yes ☐ No. Please describe.

Section I. Please complete for all requests.

Please list any other prior trials. Please list the drug names, dates/duration of use and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

** Please attach a letter documenting additional trials as necessary.*

Section II. Please complete for Blenrep, and Xpovio for monotherapy requests.

1. Has the member received at least four prior chemotherapy regimens? ☐ Yes. Complete Section I. ☐ No
2. Is the member's disease refractory to at least one proteasome inhibitor (for Blenrep requests) or two proteasome inhibitors (for Xpovio requests), or does the member have a contraindication to proteasome inhibitors? ☐ Yes. Complete Section I. ☐ No
3. Is the member's disease refractory to at least one immunomodulatory agent (for Blenrep requests) or two immunomodulatory agents (for Xpovio requests), or does the member have a contraindication to immunomodulatory agents? ☐ Yes. Complete Section I. ☐ No
4. Is the member's disease refractory to at least one anti-CD38 monoclonal antibody, or does the member have a contraindication to anti-CD38 monoclonal antibodies? ☐ Yes. Complete Section I. ☐ No

over

Section III. Please complete for requests for agents with a preferred alternative.

Please describe clinical rationale for use of the requested agent instead of the preferred alternative.

Section IV. Please complete for requests for quantities above quantity limits.

Please describe the clinical rationale for exceeding the quantity limit, including a detailed treatment plan.

Section V. Please include any other pertinent information (if needed).

Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

over

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Multiple Sclerosis Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Bafiertam (monomethyl fumarate)
- ☐ Briumvi (ublituximab-xiiy)
- ☐ dalfampridine > 2 units/day
- ☐ dimethyl fumarate > 2 units/day
- ☐ fingolimod capsule > 1 unit/day
- ☐ Kesimpta (ofatumumab prefilled syringe)
- ☐ Lemtrada (alemtuzumab)[MB]
- ☐ Mavenclad (cladribine tablet)
- ☐ Mayzent (siponimod)
- ☐ Ocrevus (ocrelizumab)
- ☐ Ocrevus Zunovo (ocrelizumab-ocsq)
- ☐ Plegridy (peginterferon beta-1a)
- ☐ Ponvory (ponesimod)
- ☐ Tascenso ODT (fingolimod orally disintegrating tablet)
- ☐ teriflunomide > 1 unit/day
- ☐ Vumerity (diroximel fumarate)
- ☐ Zeposia (ozanimod)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Clinically Isolated Syndrome (CIS)
- ☐ Multiple Sclerosis (MS)
  - Subtype ☐ relapsing-remitting (RR) ☐ primary progressive (PP) ☐ non-active secondary progressive (SP)
    ☐ active SP (member has had a relapse in the past two years)
- ☐ Other (Please indicate.)

Is the prescriber a neurologist?

- ☐ Yes
- ☐ No. Please attach consultation notes from a neurologist addressing the use of the requested agent.

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Is this member a referral candidate for care coordination? ☐ Yes ☐ No
If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for requests for Lemtrada.

Has the member had trials with two of the following agents: Briumvi or Ocrevus or Ocrevus Zunovo, dimethyl fumarate or Vumerity, fingolimod capsule, glatiramer, interferon formulations, teriflunomide, or Tysabri?

☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XIII below.*

☐ No. Please describe why the member is not a candidate for these agents.

Section II. Please complete for requests for Ocrevus and Ocrevus Zunovo for CIS, RRMS, and active SPMS.

Has the member had a trial with Briumvi?

☐ Yes. Please list the drug name, dates/duration of use, and outcomes in Section XIII below.*

☐ No. Please describe why the member is not a candidate for Briumvi.

Section III. Please complete for requests for dalfampridine.

Is the medication requested to improve walking distance in a member with multiple sclerosis?

☐ Yes

☐ No. Please describe the clinical rationale for using the requested medication below.

Section IV. Please complete for requests for Mayzent, Ponvory and Zeposia.

1. Please provide medical necessity for use instead of fingolimod capsule.
2. Has the member had a trial with one of the following agents: Briumvi or Ocrevus or Ocrevus Zunovo, dimethyl fumarate or Vumerity, glatiramer, interferon formulations, or teriflunomide?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XIII below.*
   ☐ No. Please describe why the member is not a candidate for these agents.
3. For requests for Mayzent, please indicate CYP2C9 genotype.

   ☐ *1/*1 ☐ *1/*2 ☐ *1/*3 ☐ *2/*2 ☐ *2/*3 ☐ *3/*3 ☐ Other

Section V. Please complete for requests for Kesimpta.

Has the member had trials with two of the following agents: Briumvi or Ocrevus or Ocrevus Zunovo, dimethyl fumarate or Vumerity, fingolimod capsule, glatiramer, interferon formulations, teriflunomide, or Tysabri?

☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XIII below.*

☐ No. Please describe why the member is not a candidate for these agents.

Section VI. Please complete for requests for Plegridy.

1. Please provide medical necessity for use instead of interferon beta-1a (Avonex, Rebif).

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2. Has the member had a trial with one of the following agents: Briumvi or Ocrevus or Ocrevus Zunovo, dimethyl fumarate or Vumerity, fingolimod capsule, glatiramer, Lemtrada, teriflunomide, or Tysabri?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcomes in Section XIII below.*
   ☐ No. Please describe why the member is not a candidate for these agents.

Section VII. Please complete for requests for fingolimod capsule.

Please indicate: Member's current weight _____ Date _____

Section VIII. Please complete for requests for Mavenclad.

Has the member had trials with three of the following agents: Briumvi or Ocrevus or Ocrevus Zunovo, dimethyl fumarate or Vumerity, fingolimod capsule or Mayzent, glatiramer, interferon formulations, teriflunomide, or Tysabri?

☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XIII below.*
☐ No. Please describe why the member is not a candidate for these agents.

Section IX. Please complete for requests for Bafiertam and Vumerity.

1. Please provide medical necessity for use instead of dimethyl fumarate.
2. For requests for Bafiertam, please provide medical necessity for use instead of Vumerity.

Section X. Please complete for requests for Tascenso ODT.

1. Please indicate: Member's current weight _____ Date _____
2. Please provide medical necessity for use instead of fingolimod capsule.

Section XI. Please complete for all requests exceeding quantity limits.

Please describe the medical necessity for using the requested agent above the quantity limit.

Section XII. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

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Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

_____

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

_____

* *Please attach a letter documenting additional trials as necessary*

Section XIII. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

   _____

   _____

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

   _____

   _____

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

   _____

   _____

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details. _____

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Narcolepsy and Miscellaneous Sleep Disorder Therapy Agents Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ armodafinil > 1 unit/day
- ☐ modafinil 100 mg > 1.5 unit/day
- ☐ modafinil 200 mg > 2 units/day
- ☐ sodium oxybate
- ☐ Sunosi (solriamfetol)
- ☐ tasimelteon
- ☐ Wakix (pitolisant)
- ☐ Xywav (calcium oxybate/ magnesium oxybate/potassium oxybate/sodium oxybate)

Dose and frequency of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Cataplexy associated with narcolepsy
- ☐ Idiopathic hypersomnia
- ☐ Excessive daytime sleepiness (EDS) associated with narcolepsy
- ☐ EDS associated with obstructive sleep apnea (OSA)
- ☐ Non-24-hour sleep-wake disorder
- ☐ Smith-Magenis Syndrome (SMS)
- ☐ Other (Please specify.)

Please indicate prescriber specialty below.

☐ Neurology ☐ Sleep ☐ Other (Please specify.)

If prescriber is not a specialist, please attach consult notes from a specialist.

Section I. Please complete for sodium oxybate, Sunosi, Wakix, and Xywav for the diagnosis of narcolepsy. Please also complete Section IV or V below as appropriate.

Has the member had a sleep study (polysomnogram or multiple sleep latency test) that diagnosed narcolepsy?

☐ Yes. Please include medical records with submission.

☐ No. Please explain why this member has not had a sleep study or why treatment is required when sleep study did not document narcolepsy.

Section II. Please complete for Sunosi for the diagnosis of EDS associated with OSA.

1. Has the member had a sleep study (polysomnogram) that diagnosed obstructive sleep apnea?
   ☐ Yes. Please include medical records with submission. ☐ No
2. Is the member utilizing CPAP/BiPAP, an oral appliance, or has undergone successful surgical treatment for OSA?
   ☐ Yes. Please include medical records with submission.
   ☐ No. Please explain why this member is not utilizing CPAP/BiPAP, an oral appliance, or surgical treatment for OSA.

3. For Sunosi, has the member tried modafinil or armodafinil for the treatment of this condition?*
   ☐ Yes. Please list the drug name, dates of trials and outcomes In Section VII below.
   ☐ No. Please describe clinical rationale why modafinil and armodafinil are not appropriate for this member.

Section III. Please complete for requests for the diagnosis of non-24-hour sleep-wake disorder and SMS.

For the diagnosis of non-24-hour sleep-wake disorder, please complete questions 1 and 2. For SMS, complete questions 1 and 3.

1. Has the member tried melatonin for the treatment of this condition?*
   ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   ☐ No. Please describe clinical rationale why melatonin is not appropriate for this member.
2. Is the member totally blind? ☐ Yes ☐ No
3. For tasimelteon suspension, please provide medical necessity for use instead of the capsule formulation.

Section IV. Please also complete for requests for sodium oxybate, Sunosi, Wakix, and Xywav for a diagnosis of EDS associated with narcolepsy. Please complete Section I above as appropriate.

1. Has the member tried modafinil or armodafinil for the treatment of this condition?*
   ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   ☐ No. Please describe clinical rationale why modafinil and armodafinil are not appropriate for this member.
2. Has the member tried a cerebral stimulant for the treatment of this condition?*
   ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   ☐ No. Please describe clinical rationale why cerebral stimulants are not appropriate for this member.
3. For Sunosi, will the requested medication be used in combination with other stimulants or stimulant-like agents?
   ☐ Yes. Please describe clinical rationale for combination therapy with other stimulants or stimulant-like agents.
   ☐ No.
4. For Wakix, has the member tried Sunosi for the treatment of this condition?*
   ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   ☐ No. Please describe the clinical rationale why Sunosi is not appropriate for this member.
5. For Wakix, has the member tried sodium oxybate for the treatment of this condition?*
   ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   ☐ No. Please describe the clinical rationale why sodium oxybate is not appropriate for this member.
6. For Xywav, please describe clinical rationale why sodium oxybate is not appropriate for this member.
   ☐ Yes. Please explain.
   ☐ No

over

Section V. Please also complete for requests for sodium oxybate, Wakix, and Xywav for a diagnosis of cataplexy associated with narcolepsy. Please complete Section I above as appropriate.

1. Has the member tried atomoxetine, a selective serotonin reuptake inhibitor (SSRI), tricyclic antidepressant (TCA), or venlafaxine for the treatment of this condition?*
   - ☐ Yes. Please list the drug name, dates of trials and outcomes In Section VII below.
   - ☐ No. Please describe clinical rationale why SSRIs, TCAs, and venlafaxine are not appropriate for this member.
2. For Wakix, has the member tried sodium oxybate or Xywav for the treatment of this condition?*
   - ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   - ☐ No. Please describe the clinical rationale why sodium oxybate and Xywav are not appropriate for this member.
3. For Xywav, is there clinical rationale for use instead of sodium oxybate for the treatment of this condition?*
   - ☐ Yes. Please explain.
   - ☐ No

Section VI. Please also complete for requests for sodium oxybate and Xywav for a diagnosis of idiopathic hypersomnia.

1. Has the member had a polysomnogram ruling out other causes of hypersomnia?
   - ☐ Yes. Please include medical records with submission.
   - ☐ No. Please explain why not.
2. Has the member had a multiple sleep latency test?
   - ☐ Yes. Please include medical records with submission.
   - ☐ No. Please explain why not.
3. Does the member have hypersomnia due to another medical, behavioral, or psychiatric disorder?
   - ☐ Yes. Please explain.
   - ☐ No.
4. Please attach a current medication list. Is the member currently utilizing a drug that can cause excessive daytime sleepiness?
   - ☐ Yes. Please explain.
   - ☐ No.
5. Has the member tried a cerebral stimulant for the treatment of this condition?*
   - ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   - ☐ No. Please describe clinical rationale why cerebral stimulants are not appropriate for this member.
6. Has the member tried modafinil or armodafinil for the treatment of this condition?*
   - ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   - ☐ No. Please describe clinical rationale why modafinil and armodafinil are not appropriate for this member.
7. For Xywav, is there clinical rationale for use instead of sodium oxybate for the treatment of this condition?*
   - ☐ Yes. Please explain.
   - ☐ No

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Section VII. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

Drug _____ Dates of use _____

☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

_____

Drug _____ Dates of use _____

☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

_____

Drug _____ Dates of use _____

☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

_____

Section VIII. Please complete for requests for quantities above quantity limits.

Please describe medical necessity for exceeding the quantity limits.

_____

_____

Section IX. Please complete for requests for concomitant use of modafinil and armodafinil.

Please describe medical necessity for concomitant use of modafinil and armodafinil.

_____

_____

Section X. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

   _____

   _____

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

   _____

   _____

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

over

If yes, please provide details for the previous trial.

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

_____

_____

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details. _____

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Neuromuscular Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ Amondys 45 (casimersen)
☐ Duvyzat (givinostat)
☐ Evrysdi (risdiplam)
☐ Exondys 51 (eteplirsen)
☐ Spinraza (nusinersen) [MB]
☐ Viltepso (viltolarsen)
☐ Vyondys 53 (golodirsen)

[MB] *This drug is available through the healthcare professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other healthcare professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Duchenne muscular dystrophy (DMD)

☐ Other

☐ Spinal muscular atrophy (SMA)
☐ pre-symptomatic ☐ symptomatic
Type

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Member's current weight Date

Is the member stabilized on the requested medication? ☐ Yes. Please provide start date. ☐ No

Section I. Please complete for Amondys 45, Duvyzat, Exondys 51, Viltepso, and Vyondys 53 requests.

For initial requests, please complete questions 1 through 12 as applicable. For recertification requests, please complete questions 3, 7, 9, 10, 11, and 12 as applicable.

1. Please attach laboratory testing results of a confirmed out-of-frame deletion in the DMD gene that is amenable to either exon 45 skipping (for Amondys 45 requests), exon 51 skipping (for Exondys 51 requests) or exon 53 skipping (for Viltepso and Vyondys 53 requests). For Duvyzat, attach a copy of genetic test showing mutation in the DMD gene confirming the diagnosis.
2. Is the prescriber a neuromuscular neurologist? ☐ Yes ☐ No. If no, please attach consultation notes from a neuromuscular neurologist addressing the use of the requested agent.

3. Is the member ambulatory as defined by a current six-minute walk test (6MWT-distance walked in six minutes in meters) of ≥ 200 meters?
   Please note, the test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.

   ☐ Yes. Distance _____ meters ☐ No

   Date of performance _____ Treatment at the time of test _____
4. For Amondys 45, Exondys 51 and Vyondys 53 requests, has the member received a corticosteroid for at least six months prior to use with the requested agent?
   ☐ Yes. Please list the drug name, dose and frequency, and dates of use below.

   Drug name _____ Dose and frequency _____ Dates of use _____

   ☐ No. Please explain. _____
5. For Viltepso requests, has the member received a corticosteroid for at least three months prior to use with the requested agent?
   ☐ Yes. Please list the drug name, dose and frequency, and dates of use below.

   Drug name _____ Dose and frequency _____ Dates of use _____

   ☐ No. Please explain. _____
6. For Duvyzat requests, is the member on a stable dose of corticosteroid?
   ☐ Yes. Please list the drug name, dose and frequency, and dates of use below.

   Drug name _____ Dose and frequency _____ Dates of use _____

   ☐ No
7. Will the member be taking the requested agent concurrently with a corticosteroid?
   ☐ Yes. Please document drug name with dose and frequency below.

   Drug name _____ Dose and frequency _____

   ☐ No. Please explain. _____
8. Please provide dates and measurements and attach medical records of baseline measurements for each of the following five timed function tests: timed 10-meter walk/run, timed floor (supine) to stand, timed four-step descend, timed four-step climb, timed sit to stand. Medical records must include the times in seconds, dates of performances, and treatment at the time of tests. Please note, the test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.

   Timed 10-meter walk/run (time in seconds) _____

   Date of performance _____ Treatment at the time of test _____

   Timed floor (supine) to stand (time in seconds) _____

   Date of performance _____ Treatment at the time of test _____

   Timed four-step descend (time in seconds) _____

   Date of performance _____ Treatment at the time of test _____

   Timed four-step climb (time in seconds) _____

   Date of performance _____ Treatment at the time of test _____

   Timed sit to stand (time in seconds) _____

   Date of performance _____ Treatment at the time of test _____

over

9. Please provide dates and measurements and attach medical records of all previous and current six-minute walk tests (6MWTs). Please note, the current test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.
   Baseline 6MWT
   Distance _____ meters
   Date of performance _____ Treatment at the time of test _____
   Current 6MWT
   Distance _____ meters
   Date of performance _____ Treatment at the time of test _____
   Additional 6MWT(s)
   Date(s) of performance _____
10. Please provide dates and measurements and attach medical records of current measurements for each of the following five timed function tests: timed 10-meter walk/run, timed floor (supine) to stand, timed four-step descend, timed four-step climb, timed sit to stand. Medical records must include the times in seconds, dates of performances, and treatment at the time of tests. Please note, the test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.
    Timed 10-meter walk/run (time in seconds) _____
    Date of performance _____ Treatment at the time of test _____
    Timed floor (supine) to stand (time in seconds) _____
    Date of performance _____ Treatment at the time of test _____
    Timed four-step descend (time in seconds) _____
    Date of performance _____ Treatment at the time of test _____
    Timed four-step climb (time in seconds) _____
    Date of performance _____ Treatment at the time of test _____
    Timed sit to stand (time in seconds) _____
    Date of performance _____ Treatment at the time of test _____
11. Has the member previously received treatment with a gene therapy for DMD? ☐ Yes ☐ No
12. For Duvyzat requests, will the requested agent be used in combination with other disease-modifying therapies for DMD (e.g., exon-skipping therapies)? ☐ Yes ☐ No

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Section II. Please complete for Evrysdi and Spinraza requests.

1. Please attach a copy of genetic test(s) confirming the diagnosis of SMA and SMN2 copy number.
2. Is the member symptomatic? ☐ Yes ☐ No
3. Is the member a pre-symptomatic infant diagnosed via newborn screening? ☐ Yes ☐ No
4. Is the prescriber a neurologist? ☐ Yes ☐ No. If no, please attach consultation notes from a neurologist addressing the use of the requested agent.
5. Please attach documentation of current motor function test.
6. Will the requested agent be used in combination with other agents for SMA?
   ☐ Yes. Please provide drug name(s). _____
   ☐ No

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7. For initial and recertification requests, does the member have evidence of permanent ventilator, defined as any of the following?
   Member has an endotracheal tube ☐ Yes ☐ No
   Member has a tracheotomy tube ☐ Yes ☐ No
   Member has at least 14 days of continuous respiratory assistance for at least 16 hours per day
   ☐ Yes ☐ No
8. Has the member been previously treated with any other SMA agent? ☐ Yes ☐ No
   If yes, please list the drug names and outcomes below.
   Drug name _____ ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   _____
9. For members previously treated with another SMA agent, please attach documentation of pre-treatment baseline motor function tests and post-treatment motor function tests.
10. For members previously treated with Zolgensma, please attach pre-Zolgensma baseline motor function test (if different than the pre-treatment tests) and post-treatment motor function tests.
11. For recertification requests, please attach medical records documenting positive response to therapy (e.g., follow up information on motor function tests and/or member's improvement or stability of function).

Section III. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
   _____
   _____
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
   _____
   _____
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details. _____
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Nonsteroidal Anti-Inflammatory Drugs (NSAID) Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested (Check one or all that apply. Where applicable, the brand name is provided in brackets for reference.)

- ☐ diclofenac 25 mg capsule
- ☐ diclofenac/misoprostol < 60 years of age
- ☐ diclofenac potassium 25 mg tablet
- ☐ diclofenac powder for solution
- ☐ diclofenac topical patch
- ☐ Elyxyb (celecoxib oral solution)
- ☐ etodolac extended-release
- ☐ fenoprofen
- ☐ ibuprofen/famotidine < 60 years of age
- ☐ indomethacin suppository
- ☐ indomethacin suspension
- ☐ ketoprofen extended-release
- ☐ ketorolac > 20 units/30 days
- ☐ ketorolac nasal spray
- ☐ meclofenamate
- ☐ meloxicam capsule
- ☐ naproxen controlled-release
- ☐ naproxen suspension < 13 years of age
- ☐ naproxen/esomeprazole < 60 years of age
- ☐ Relafen DS (nabumetone 1000 mg)
- ☐ salsalate
- ☐ tolmetin
- ☐ Other*

Dose, frequency, and duration of medication requested

Indication or ICD-10 code, if applicable

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Section I. Please complete for topical product requests.

Has the member tried diclofenac 1% gel?

- ☐ Yes. Please complete Section IV.
- ☐ No. Please indicate why not.

Section II. Please complete for controlled-release products, extended-release products, solution products, orally disintegrating products, suspension products, and suppositories.

1. Please provide medical necessity for the use of the requested formulation.
2. For indomethacin suspension and naproxen suspension products, has the member tried ibuprofen suspension?
   - ☐ Yes. Please complete Section IV.
   - ☐ No. Please indicate why not.

3. For diclofenac powder for solution, has the member tried naproxen suspension?
   ☐ Yes. Please complete Section IV.
   ☐ No. Please indicate why not.
4. For Elyxyb, has the member tried celecoxib capsules?
   ☐ Yes. Please complete Section IV.
   ☐ No. Please indicate why not.
5. For indomethacin suppositories, has the member tried ibuprofen suppositories?
   ☐ Yes. Please complete Section IV.
   ☐ No. Please indicate why not.

Section III. Please complete for diclofenac/misoprostol, ibuprofen/famotidine, ketorolac nasal spray, naproxen/esomeprazole, and Relafen DS requests.

Please attach medical records/office notes documenting medical necessity. A trial with concurrent therapy of diclofenac and misoprostol is required for diclofenac/misoprostol requests. A trial of ketorolac tablets or injection is required for ketorolac nasal spray requests. A trial with concurrent therapy of ibuprofen and famotidine is required for ibuprofen/famotidine requests. A trial with concurrent therapy of naproxen and omeprazole is required for naproxen/esomeprazole requests. A trial of an equivalent dose of nabumetone 500 mg or 750 mg is required for Relafen DS requests.

Section IV. Please complete for all requests as needed.

Please provide the following information regarding previous NSAID trials.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Details of adverse reaction, inadequate response, or other.

** Please attach a letter documenting additional trials as necessary.*

Section V. Please complete for ketorolac requests exceeding the quantity limit.

Please describe the medical necessity for exceeding the quantity limit.

over

Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Oncology Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Please note: Chimeric Antigen Receptor (CAR)-T Immunotherapies and Prostate Cancer Agents have specific PA Request forms that contain information pertinent to these medication classes. For these agents, please see more drug-specific PA forms within the MassHealth Drug List at **www.mass.gov/druglist.**

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Drug name

Dose and frequency

Height Weight Date

Indication or ICD-10 code, if applicable **Duration of therapy**

Please indicate prescriber specialty below.

☐ Hematology ☐ Oncology ☐ Other

Please list all other medications currently prescribed for the member for this indication.

Section I. Please complete for all requests.

1. Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.
   Drug NDC (if known) or service code
2. Please describe the cancer type, histology, and any pertinent mutations as applicable.
3. Please describe the stage and severity of disease, including status of metastases as applicable.
4. Please list any other prior trials. Please list the drug names, dates/duration of use and outcomes below.*
   Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

Drug _____ Dates/duration _____ ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug _____ Dates/duration _____ ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

5. For requests for agents with a preferred alternative, please describe clinical rationale for use of the requested agent instead of the preferred alternative.
6. Has the member had persistent or recurring disease following surgery and/or radiation therapy? ☐ Yes ☐ No
7. Is the member a candidate for surgery and/or radiation?

   ☐ Yes ☐ No. Please describe.

** Please attach a letter documenting additional trials as necessary.*

Section II. Please complete for requests for quantities above quantity limits.

Please describe the clinical rationale for exceeding the quantity limit, including a detailed treatment plan.

Section III. Please complete for requests for solution and suspension dosage formulations.

Please provide medical necessity for the use of the requested dosage formulation.

Section IV. Please include any other pertinent information (if needed).

Section V. Please complete for all requests for non-preferred drug products if one or more preferred drug products have been designated for this class of drugs.

If one or more preferred drug products have been designated for this class of drugs, and if you are requesting PA for a non-preferred drug product, please provide medical necessity for prescribing the non-preferred drug product rather than the preferred drug product.

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Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details.

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

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Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

One-Time Cell and Gene Therapies Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please note: One-time cell and gene therapies (CGT) are listed on the Acute Hospital Carve-Out Drugs List. They are subject to additional monitoring and billing requirements. They are part of the ACPP and MCO unified pharmacy policy. PA requests for one-time CGT for members with ACPP and MCO plans are reviewed by the MassHealth Drug Utilization Review (DUR) Program.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, Health Safety Net Plan, and all one-time CGT requests
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
Note: One-time CGT requests must be submitted to the MassHealth Drug Utilization Review Program

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One-Time Cell and Gene Therapies Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested	Requested indication
Beta thalassemia and sickle cell disease agents (See Section VII, XI, or XV as applicable.)	
☐ Casgevy (exagamglogene autotemcel) ☐ Lyfgenia (lovotibeglogene autotemcel) ☐ Zynteglo (betibeglogene autotemcel)	☐ Beta Thalassemia (provide documentation of genetic testing) ☐ Sickle Cell Disease (SCD)
Enzyme and Metabolic Disorder Therapies	
☐ Kebilidi (eladocagene exuparvovec-tneq)	☐ Aromatic L-amino acid decarboxylase (AADC) deficiency
Hemophilia gene therapies (See Section IV, V, and VI as applicable.)	
☐ Beqvez (fidanacogene elaparvovec-dzkt) ☐ Hemgenix (etranacogene dezparvovec-drlb) ☐ Roctavian (valoctocogene roxaparvovec-rvox)	☐ Moderately severe to severe hemophilia B ☐ Severe hemophilia A
Neuromuscular agents (See Section VIII or XIV as applicable.)	
☐ Elevidys (delandistrogene moxeparvovec-rokl) ☐ Zolgensma (onasemnogene abeparvovec-xioi)	☐ Duchenne muscular dystrophy (DMD) ☐ Spinal muscular atrophy (SMA) ☐ Pre-symptomatic ☐ Symptomatic Type
T-cell immunotherapies (See Section I, II, and III as applicable.)	
☐ Abecma (idecabtagene vicleucel) ☐ Amtagvi (lifileucel) ☐ Aucatzyl (obecabtagene autoleucel) ☐ Breyanzi (lisocabtagene maraleucel) ☐ Carvykti (ciltacabtagene autoleucel) ☐ Kymriah (tisagenlecleucel) ☐ Tecartus (brexucabtagene autoleucel) ☐ Tecelra (afamitresgene autoleucel) ☐ Yescarta (axicabtagene ciloleucel)	☐ B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse ☐ Large B-cell lymphoma that is refractory to firstline chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy ☐ Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) ☐ Relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy ☐ Relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), high grade B-cell lymphoma, and DLBCL arising from FL ☐ Relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL NOS, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from FL ☐ Relapsed or refractory mantle cell lymphoma (MCL)

	☐ Relapsed or refractory multiple myeloma (RRMM) ☐ Unresectable or metastatic melanoma ☐ Unresectable or metastatic synovial sarcoma
Miscellaneous agents (See Section IX, X, XII or XIII as applicable.)	
☐ Lenmeldy (atidarsagene autotemcel) ☐ Luxturna (voretigene neparvovec-rzyl) ☐ Omisirge (omidubicel-onlv) ☐ Skysona (elivaldogene autotemcel)	☐ Biallelic RPE65 mutation-associated retinal dystrophy ☐ Cerebral adrenoleukodystrophy (CALD) ☐ Hematologic malignancy ☐ Metachromatic leukodystrophy ☐ Presymptomatic late infantile ☐ Presymptomatic early juvenile ☐ Early symptomatic early juvenile

Please specify if indication is none of the above.

Dose, frequency, and duration of medication requested

Please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Please indicate prescriber specialty below.

☐ Geneticist ☐ Hematologist ☐ Neurologist ☐ Oncologist ☐ Ophthalmologist ☐ Retinal specialist

☐ Other

Member's current weight Date

Section I. Please complete for all T-cell immunotherapy agent requests.

1. Please describe pertinent mutations if applicable.
   ☐ BRAF V600 ☐ HLA-A*02:01P ☐ HLA-A*02:02P ☐ HLA-A*02:03P ☐ HLA-A*02:06P ☐ Ph+
   Please describe the cell histology, if applicable.
2. Please provide anticipated dates for the following as applicable.
   Treatment date Leukapheresis Admission Infusion Discharge
3. Please provide the infusion setting. ☐ Inpatient ☐ Outpatient
4. Will the infusion take place in a qualified treatment facility or, as applicable, a health care facility that has been certified pursuant to the Risk Evaluation and Mitigation Strategy (REMS) program specific to the treatment being provided? ☐ Yes ☐ No
5. Please list any other prior trials including the drug names, dates/duration of use, and outcomes below. Please note, Abecma is FDA-approved for use after two or more lines of therapy, and Carvykti after at least one prior line of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. *
   Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

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Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

Section II. Please also complete for Kymriah requests for a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.

1. Please indicate Philadelphia chromosome type. ☐ Positive ☐ Negative
   If positive, has the member failed two kinase inhibitors? ☐ Yes. Please provide details below.* ☐ No
   Drug Dates/duration Outcome
   Drug Dates/duration Outcome
2. Does the member have refractory disease? ☐ Yes ☐ No
3. Please provide the number of relapses.

Section III. Please also complete for Aucatzyl and Tecartus requests for a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

1. Please indicate Philadelphia chromosome type. ☐ Positive ☐ Negative
   If positive, has the member failed one tyrosine kinase inhibitor? ☐ Yes. Please provide details below.* ☐ No
   Drug Dates/duration Outcome
2. Does the member have primary refractory disease? ☐ Yes ☐ No
3. Please provide the number of relapses. Dates/duration
4. Did the member receive an allogeneic stem cell transplant? ☐ Yes ☐ No Date

Section IV. Please complete for all hemophilia gene therapy requests.

1. Please provide anticipated dates and dosing for the following as applicable.
   Admission Infusion Dose Discharge
2. Will the member be screened for acute infection prior to administration? ☐ Yes ☐ No
3. Baseline weight Date
4. Baseline annualized bleeding rate (ABR) Date
5. Has the member received any prior gene therapy for the requested diagnosis? ☐ Yes ☐ No
6. Does the member have active human immunodeficiency virus (HIV)? ☐ Yes ☐ No
7. Does the member have active hepatitis B (HBV)? ☐ Yes ☐ No
8. Does the member have active hepatitis C (HCV)? ☐ Yes ☐ No

Section V. Please also complete for requests for Beqvez and Hemgenix.

1. Does the member currently have a life-threatening hemorrhage? ☐ Yes ☐ No
2. Does the member have a history of life-threatening hemorrhage? ☐ Yes ☐ No
3. Has the member had repeated, serious spontaneous bleeding episodes? ☐ Yes ☐ No

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4. Does the member currently use FIX prophylaxis therapy?

   ☐ Yes. Please provide details. _____ ☐ No

5. FIX activity level _____ Date _____
6. Does the member have factor IX inhibitor? (Please attach a copy of test.) ☐ Yes ☐ No
7. For Beqvez, does the member have any of the following?

Hepatic fibrosis	☐ Yes ☐ No
Cirrhosis	☐ Yes ☐ No
Liver-related coagulopathy	☐ Yes ☐ No
Hypoalbuminemia	☐ Yes ☐ No
Persistent jaundice	☐ Yes ☐ No
Portal hypertension	☐ Yes ☐ No
Splenomegaly	☐ Yes ☐ No
Hepatic encephalopathy	☐ Yes ☐ No

8. For Beqvez, does the member have AAVRh74var Nab? (Please attach a copy of FDA-approved test.)
   ☐ Yes ☐ No
9. For Beqvez, will the infusion take place in a qualified treatment center? ☐ Yes _____ ☐ No
10. For Hemgenix, does the member have NAb titer (AAV5)? (Please attach a copy of CLIA-validated test.)
    _____ Date _____

Section VI. Please also complete for requests for Roctavian.

1. Does the member currently use FVIII prophylaxis therapy?

   ☐ Yes. Please provide details. _____

   ☐ No. If no, does the member currently use Hemlibra (emicizumab)? ☐ Yes ☐ No

2. FVIII activity level _____ Date _____
3. Does the member have preexisting immunity to AAV5? (Please attach a copy of FDA-approved test.)
   ☐ Yes ☐ No
4. Does the member have factor VIII inhibitor? (Please attach a copy of test.) ☐ Yes ☐ No
5. Does the member have hepatic fibrosis? ☐ Yes ☐ No
6. Does the member have cirrhosis? ☐ Yes ☐ No

Section VII. Please complete for Casgevy requests.

For a diagnosis of transfusion dependent beta thalassemia, please complete questions 1-9. For a diagnosis of sickle cell disease, please complete questions 1-8 and 10-11.

1. Please attach a copy of genetic test confirming diagnosis.
2. Please provide anticipated dates and dosing for the following as applicable.

   Apheresis _____ Admission _____ Infusion _____ Dose _____ Discharge _____

3. Will the infusion take place in a qualified treatment center? ☐ Yes _____ ☐ No
4. Will the member receive pre-infusion conditioning with busulfan? ☐ Yes ☐ No
5. Is the member clinically stable and eligible for hematopoietic stem cell transplantation (HSCT)?
   ☐ Yes ☐ No
6. Does the member have active human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) infection? ☐ Yes. Please describe. _____ ☐ No

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7. Has the member received any prior gene therapy for the requested diagnosis?
   ☐ Yes. Please describe. ☐ No
8. Outreach for both short- and long-term monitoring for efficacy and durability of response will be conducted by MassHealth. The applicable information (including, but not limited to, medical records, dates of procedures, hospital admissions, emergency department visits, and adverse reactions experienced [e.g., occurrence of VOC event]) will be provided to MassHealth upon request.
   ☐ Yes ☐ No
9. For beta thalassemia, has the member required ≥100 mL/kg/year of pRBC or ≥ ten units per year within the previous two years? ☐ Yes. Please describe. ☐ No
10. For sickle cell disease, has the member experienced at least two sickle cell crises per year in the last two years? ☐ Yes. Please describe. ☐ No
11. For sickle cell disease, has the member had an inadequate response to hydroxyurea for at least three months? Please note: Trial will be evaluated to ensure titration to maximally tolerated dose.*
    ☐ Yes. Please note: Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to this agent.
    Dose and frequency Dates of use Outcome
    Please attach hematologic laboratory data (e.g., absolute neutrophil count [ANC], platelet count, hemoglobin, reticulocyte count) supporting dosing regimen.
    ☐ No

Section VIII. Please complete for Elevidys requests.

1. Please attach a copy of genetic test with a confirmed mutation in the DMD gene.
2. Please attach a copy of baseline anti-AAVrh74 total binding antibody titers < 1:400.
3. Will the infusion take place in a qualified treatment center? ☐ Yes ☐ No
4. Please provide anticipated date of administration.
5. Is the prescriber a neuromuscular specialist? ☐ Yes ☐ No
6. Does the member have any deletion in exon 8 or exon 9 of the DMD gene? ☐ Yes ☐ No
7. Is the member on a stable dose of corticosteroid? ☐ Yes ☐ No
8. Will the member continue to utilize chronic corticosteroids after Elevidys infusion? ☐ Yes ☐ No
9. Does the member have a contraindication to corticosteroids? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication.
10. Has the member been previously treated with a gene therapy for DMD? ☐ Yes ☐ No
11. Is the member currently utilizing antisense oligonucleotides? ☐ Yes ☐ No
12. Has the member had a baseline measurement for the North Star Ambulatory Assessment (NSAA)?
    ☐ Yes. Please attach medical records of NSAA, including scores and times on individual items. ☐ No
13. Is the member ambulatory as defined by a current 6MWT of ≥ 200 meters?
    Please note, the test must have been observed or completed by the treating provider or ordered by the treating provider and completed by a qualified medical practitioner.
    ☐ Yes. Distance meters ☐ No
    Date of performance Treatment at the time of test

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14. Please provide dates and measurements and attach medical records of all previous and current six-minute walk tests (6MWTs). Please note, the current test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.
    Baseline 6MWT
    Distance ☐ meters
    Date of performance ☐ Treatment at the time of test ☐
    Current 6MWT
    Distance ☐ meters
    Date of performance ☐ Treatment at the time of test ☐
    Additional 6MWT(s)
    Date(s) of performance ☐

Section IX. Please complete for Lenmeldy requests.

1. Does the member have deficient arylsulfatase A (ARSA) enzyme activity in leukocytes? ☐ Yes ☐ No
2. Please describe ARSA mutation(s).
   ☐
3. Does the member have elevated sulfatides on 24-hour urine collection? ☐ Yes ☐ No
4. Does the member have neurological signs and symptoms of MLD? ☐ Yes ☐ No
   If yes, are the signs and symptoms limited to the following? ☐ Yes. Please indicate. ☐ No
   ☐ Absence of neurological signs and symptoms of MLD with the exception of abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia).
   ☐ Absence of neurological signs and symptoms of MLD or physical exam findings limited to abnormal reflexes and/or clonus with the exception of abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia).
5. Does the member have peripheral neuropathy as determined by electroneurographic study? ☐ Yes ☐ No
6. For early symptomatic early juvenile MLD, please provide the following:
   Age of MLD disease onset. ☐
   Intelligence quotient score on age-appropriate neurodevelopmental testing. ☐
   Gross Motor Function Classification score in metachromatic leukodystrophy (GMFC-MLD). ☐
7. Please provide results for the following serology tests.

Human immunodeficiency virus (HIV)-1/2	☐ Positive	☐ Negative	☐ Not completed
Human T-lymphotrophic virus (HTLV)-1/2	☐ Positive	☐ Negative	☐ Not completed
Hepatitis B virus (HBV)	☐ Positive	☐ Negative	☐ Not completed
Hepatitis C virus (HCV)	☐ Positive	☐ Negative	☐ Not completed
Mycoplasma	☐ Positive	☐ Negative	☐ Not completed

8. Has the member received any prior MLD gene therapy? ☐ Yes. Please describe. ☐ No
   ☐
9. Will the infusion take place in a qualified treatment center? ☐ Yes. Please indicate. ☐ No
   ☐

over

Section X. Please complete for Luxturna requests.

1. Please provide anticipated dates for retinal surgery.

   Initial treatment date _____ Subsequent treatment date _____
2. Please provide medical records documenting the results from genetic testing showing mutations in the RPE65 gene.
3. Please provide documentation of baseline full-field light sensitivity threshold (FST) scores. _____

   _____
4. Does the member have viable retinal cells (e.g., retinal thickness >100 microns)? ☐ Yes ☐ No
5. Has the member had ocular surgery within the past six months? ☐ Yes ☐ No
6. Has the member discontinued retinoid compounds for at least the past 18 months? ☐ Yes ☐ No
7. Will the treatment procedure be performed at a specialized treatment center? ☐ Yes ☐ No
8. Outreach for both short- and long-term monitoring for efficacy and durability of response will be conducted by MassHealth. The applicable information [including but not limited to medical records confirming the dates of surgery and documenting the initial response to therapy (e.g. FST scores)] will be provided to MassHealth upon request. ☐ Yes ☐ No
9. Has the member received any prior gene therapy for biallelic RPE65 mutation-associated retinal dystrophy?
   ☐ Yes. Please describe. ☐ No

   _____

Section XI. Please complete for Lyfgenia requests.

1. Please attach a copy of genetic test confirming diagnosis of SCD.
2. Has the member experienced at least two sickle cell crises per year in the last two years? ☐ Yes ☐ No

   If yes, please provide dates. _____
3. Has the member had an inadequate response to hydroxyurea for at least three months? Please note: Trial will be evaluated to ensure titration to maximally tolerated dose.*
   ☐ Yes. Please note: Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to this agent.

   Dose and frequency _____ Dates of use _____ Outcome _____

   Please attach hematologic laboratory data (e.g., absolute neutrophil count [ANC], platelet count, hemoglobin, reticulocyte count) supporting dosing regimen.
   ☐ No
4. Please provide anticipated dates and dosing for the following as applicable.

   Apheresis _____ Admission _____ Infusion _____ Dose _____ Discharge _____
5. Will the infusion take place in a qualified treatment center? ☐ Yes _____ ☐ No
6. Is the member clinically stable and eligible for hematopoietic stem cell transplantation (HSCT)? ☐ Yes ☐ No
7. Please provide human immunodeficiency virus (HIV) serology test results.
   ☐ Positive ☐ Negative ☐ Not completed
8. Does the member have α-thalassemia trait (-α3.7/-α3.7)? ☐ Yes. Please describe. ☐ No

   _____
9. Please provide medical necessity for use of requested agent instead of Casgevy.

   _____
10. Has the member received any prior SCD gene therapy? ☐ Yes. Please describe. ☐ No

    _____

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11. Outreach for both short- and long-term monitoring for efficacy and durability of response will be conducted by MassHealth. The applicable information (including, but not limited to, medical records, dates of procedures, hospital admissions, emergency department visits and adverse reactions experienced [e.g., occurrence of VOC event]) will be provided to MassHealth upon request.
☐ Yes ☐ No

Section XII. Please complete for Omisirge requests.

Is the member planned for umbilical cord blood transplantation following myeloablative conditioning? ☐ Yes ☐ No

Section XIII. Please complete for Skysona requests.

1. Please provide anticipated dates and dosing for the following as applicable.
   Apheresis _____ Admission _____ Infusion _____ Dose _____ Discharge _____
2. Does the member have elevated very long chain fatty acids (VLCFAs)? ☐ Yes ☐ No
3. Please provide medical records documenting the results from genetic testing showing mutations in the ABCD1 gene.
4. Please provide the following scores.
   Neurologic Function Score (NFS) _____
   Loes score _____
5. Did the member have gadolinium enhancement on brain magnetic resonance imaging (MRI)? ☐ Yes ☐ No
6. Has the member had previous allogeneic transplant or gene therapy for CALD? ☐ Yes. Please describe. ☐ No
   _____
7. Please provide results for the following serology tests.
   Human immunodeficiency virus (HIV)-1/2 ☐ Positive ☐ Negative ☐ Not completed
8. Will the infusion take place in a qualified treatment center?
   ☐ Yes. Please indicate. _____ ☐ No
9. Outreach for both short- and long-term monitoring for efficacy and durability of response will be conducted by MassHealth. The applicable information [including but not limited to medical records confirming the dates of treatment and documenting the initial response to therapy] will be provided to MassHealth upon request.
   ☐ Yes ☐ No

Section XIV. Please complete for Zolgensma requests.

Please note, questions 7, 8, and 9 will not impact the outcome of review for approval of Zolgensma.

1. Please attach a copy of the genetic test confirming diagnosis of SMA and number of copies of SMN2 gene.
2. Is the prescriber a neuromuscular specialist? ☐ Yes ☐ No. If no, please attach the consultation notes from a neuromuscular specialist addressing the use of the requested agent.
3. Please attach a copy of baseline AAV9 antibody test.
4. Pre-treatment baseline Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) score. _____
5. Does the member have evidence of complete paralysis of limbs? ☐ Yes ☐ No
6. At the time Zolgensma is to be administered, does the member have evidence of permanent ventilator dependence, defined as any of the following?
   Member has an endotracheal tube. ☐ Yes ☐ No
   Member has a tracheotomy tube. ☐ Yes ☐ No
   Member has at least 14 days of continuous respiratory assistance for at least 16 hours per day. ☐ Yes ☐ No

over

7. Has the member had a trial with Spinraza? ☐ Yes ☐ No
   If yes, please list the dose and frequency, dates of use, outcome, and treatment plan below.
   Dose and frequency _____ Dates of use _____
   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   _____
   Will the member continue Spinraza after Zolgensma? ☐ Yes ☐ No
   Has the member had a trial with Evrysdi? ☐ Yes ☐ No
   If yes, please list the dose and frequency, dates of use, outcome, and treatment plan below.
   Dose and frequency _____ Dates of use _____
   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   _____
   Will the member continue Evrysdi after Zolgensma? ☐ Yes ☐ No
8. Please describe the functional tests that will be used to monitor this member and attach medical records with baseline functional test scores.
   _____
9. Has the member previously received treatment with a gene therapy for DMD? ☐ Yes ☐ No
10. Does the member have an active viral infection, including human immunodeficiency virus (HIV) or positive serology for hepatitis B or C, or Zika virus? ☐ Yes ☐ No

Section XV. Please complete for Zynteglo requests.

1. Please attach a copy of genetic test confirming diagnosis of beta thalassemia.
2. Is the member transfusion-dependent?
   ☐ Yes. Please attach medical records supporting regular blood transfusions. ☐ No
3. Please provide anticipated dates and dosing for the following as applicable.
   Apheresis _____ Admission _____ Infusion _____ Dose _____ Discharge _____
4. Please provide medical necessity for the requested agent instead of Casgevy.
   _____
5. Please provide human immunodeficiency virus (HIV) serology test results.
   ☐ Positive ☐ Negative ☐ Not completed
6. Has the member required ≥100 mL/kg/year of pRBC or ≥ eight transfusions within the last 12 months?
   ☐ Yes. Please describe. _____ ☐ No
7. Will the infusion take place in a qualified treatment center? ☐ Yes _____ ☐ No
8. Is the member clinically stable and eligible for hematopoietic stem cell transplantation (HSCT)? ☐ Yes ☐ No
9. Has the member received any prior TDT gene therapy? ☐ Yes. Please describe. ☐ No
   _____
10. Outreach for both short- and long-term monitoring for efficacy and durability of response will be conducted by MassHealth. The applicable information (including, but not limited to, medical records, dates of procedures, infusions, admissions, adverse reactions experienced, agents used to treat adverse reactions, and response to therapy [e.g., necessity of pRBC transfusions, including date, frequency, volume, reason for transfusion (e.g., planned procedure, accident, low hemoglobin level, etc.)]) will be provided to MassHealth upon request.
    ☐ Yes ☐ No

over

Section XVI. Please complete for Kebilidi requests.

1. Please attach a copy of genetic test confirming diagnosis.
2. Please attach laboratory test results documenting decreased AADC enzyme activity in plasma or cerebrospinal fluid showing decreased levels of 5-HIAA, HV, and MHPG and increased levels of 3-OMD, L-Dopa, and 5-HTP.
3. Please attach medical records documenting member is unable to ambulate independently and is experiencing neurological defects despite treatment with a dopamine agonist, monoamine oxidase inhibitor and/or vitamin B6.
4. Has the member achieved skull maturity required for stereotactic surgical administration? ☐ Yes ☐ No
5. Please provide anticipated dates and dosing for the following as applicable.

   Admission Infusion Dose Discharge

6. Will the infusion take place in a qualified treatment center? ☐ Yes ☐ No
7. Has the member received any prior gene therapy for the requested diagnosis?

   ☐ Yes. Please describe. ☐ No

Section XVII. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen? ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details.

   ☐ No

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Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Ophthalmic Anti-Allergy and Anti-Inflammatory Agents Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Ophthalmic Anti-Allergy Agents (Section I)

- ☐ Zerviate (cetirizine ophthalmic solution)

Ophthalmic Corticosteroids (Section III)

- ☐ Eysuvis (loteprednol 0.25% suspension)
- ☐ Inveltys (loteprednol 1% suspension)
- ☐ Lotemax SM (loteprednol 0.38% gel)

Ophthalmic Non-Steroidal Anti-Inflammatory Agents (Section II)

- ☐ bromfenac 0.075%
- ☐ bromfenac 0.09%
- ☐ Ilevro (nepafenac 0.3% ophthalmic solution)
- ☐ Cequa (cyclosporine 0.09% ophthalmic solution) (Section IV)

Miscellaneous

- ☐ Miebo (perfluorohexyloctane) (Section IV)
- ☐ Restasis Multidose (cyclosporine multidose 0.05% ophthalmic emulsion) (Section IV)
- ☐ Tyrvaya (varenicline nasal spray) (Section IV)
- ☐ Verkazia (cyclosporine 0.1% ophthalmic emulsion) (Section V)
- ☐ Vevye (cyclosporine 0.1% ophthalmic solution) (Section VI)
- ☐ Xdemvy (lotilaner)
- ☐ Xiidra (lifitegrast) (Section IV)

Other Medication

- ☐ Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Dose, frequency, and duration of medication requested _____

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Allergic conjunctivitis (seasonal or perennial)
- ☐ Demodex Blepharitis
- ☐ Keratoconjunctivitis sicca
- ☐ Post-operative pain and/or inflammation following ocular surgery
- ☐ Vernal conjunctivitis and/or vernal keratitis
- ☐ Other (Please indicate.) _____

Symptoms and symptom frequency _____

Section I. Please complete for Zerviate requests.

For members ≥ two to < three years of age, please complete question 1. For members ≥ three years of age, please complete question 2. For members with diagnosis of vernal keratoconjunctivitis or atopic keratoconjunctivitis please complete question 3 if member is ≥ two to < three years of age, and question 4 if member is ≥ three years of age.

1. Has the member had a trial with two of the following: alcaftadine, Alomide, bepotastine, epinastine, or olopatadine ophthalmic solution?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to these trials.

2. Has the member had a trial with two of the following: Alomide, azelastine ophthalmic solution, bepotastine, epinastine, ketotifen, or olopatadine ophthalmic solution?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to these trials.

3. Has the member had a trial with one of the following: bepotastine, epinastine, or olopatadine ophthalmic solution?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to these trials.

4. Has the member had a trial with one of the following: azelastine ophthalmic solution, epinastine, ketotifen, or olopatadine ophthalmic solution?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to these trials.

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Section II. Please complete for all requests for ophthalmic non-steroidal anti-inflammatory agents.

Has the member had a trial with ophthalmic diclofenac, flurbiprofen, ketorolac, or nepafenac 0.1%?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name _____ Dates/duration of trial _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

_____

☐ No. Please explain if there is a contraindication to these trials. _____

Section III. Please complete for all requests for ophthalmic corticosteroids.

1. For Eysuvis, has the member had a trial with a topical corticosteroid for ophthalmic use that is available without prior authorization?

   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name _____ Dates/duration of trial _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   _____

   ☐ No. Please explain if there is a contraindication to this trial. _____

2. For Eysuvis, has the member had a trial with cyclosporine 0.05% ophthalmic emulsion?

   ☐ Yes. Please list the dates/duration of trials and outcomes.* Dates/duration of trial _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   _____

   ☐ No. Please explain if there is a contraindication to this trial. _____

   For Inveltys and Lotemax SM, has the member had a trial with loteprednol 0.5% suspension, gel or ointment?

   ☐ Yes. Please list the dates/duration of trials and outcomes.* Dates/duration of trial _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   _____

   ☐ No. Please explain if there is a contraindication to this trial. _____

Section IV. Please complete for all requests for Cequa, Miebo, Restasis Multidose, Tyrvaya, and Xiidra.

1. Has the member had a trial with cyclosporine 0.05% ophthalmic emulsion?

   ☐ Yes. Please list the dates/duration of trials and outcomes.* Dates/duration of trial _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   _____

   ☐ No. Please explain if there is a contraindication to this trial. _____

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2. For Restasis Multidose, please provide medical necessity for the use of the requested formulation instead of cyclosporine 0.05% ophthalmic emulsion (single use vial formulation).

3. For Miebo and Tyrvaya, has the member had a trial with Xiidra?

☐ Yes. Please list the dates/duration of trials and outcomes.* Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to this trial.

Section V. Please complete for all requests for Verkazia.

1. Has the member had a trial with ophthalmic azelastine, epinastine, ketotifen, or olopatadine?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to these trials.

2. Has the member had a trial with a topical corticosteroid for ophthalmic use?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to this trial.

* Please attach a letter with additional information regarding medication trials as applicable.

Section VI. Please complete for all requests for Vevye.

1. Has the member had a trial with ophthalmic cyclosporine 0.05% emulsion?

☐ Yes. Please list dates/duration of use and outcomes below.*

Dates/duration of trial Outcome

☐ No. Please document if there is a contraindication to ophthalmic cyclosporine 0.05% emulsion.

2. Has the member had a trial with ophthalmic cyclosporine 0.09% emulsion?

☐ Yes. Please list dates/duration of use and outcomes below.*

Dates/duration of trial Outcome

☐ No. Please document if there is a contraindication to ophthalmic cyclosporine 0.09% emulsion.

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3. Has the member had a trial with Tyrvaya?
   ☐ Yes. Please list dates/duration of use and outcomes below.*
   Dates/duration of trial ____ Outcome ____
   ☐ No. Please document if there is a contraindication to Tyrvaya.
   ____
4. Has the member had a trial with Xiidra?
   ☐ Yes. Please list dates/duration of use and outcomes below.*
   Dates/duration of trial ____ Outcome ____
   ☐ No. Please document if there is a contraindication to Xiidra.
   ____

* Please attach a letter with additional information regarding medication trials as applicable.

Section VII. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
   ____
   ____
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
   ____
   ____
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name ____ Dates/duration of use ____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   ____
   ____
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details. ____
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

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Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Opioid Dependence and Reversal Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ buprenorphine sublingual tablet ☐ 2 mg ☐ 8 mg
- ☐ buprenorphine/naloxone film ☐ 2 mg/0.5 mg ☐ 4 mg/1 mg ☐ 8 mg/2 mg ☐ 12 mg/3 mg
- ☐ buprenorphine/naloxone sublingual tablet ☐ 2 mg/0.5 mg ☐ 8 mg/2 mg
- ☐ Lifems (naloxone syringe kit)
- ☐ lofexidine
- ☐ Opvee (nalmefene nasal spray)
- ☐ Zubsolv (buprenorphine/naloxone sublingual tablet) ☐ 0.7 mg/0.18 mg ☐ 1.4 mg/0.36 mg ☐ 2.9 mg/0.71 mg ☐ 5.7 mg/1.4 mg ☐ 8.6 mg/2.1 mg ☐ 11.4 mg/2.9 mg

Dose, frequency, and duration of medication requested

For all requests for medications containing buprenorphine, is the member maintained on the lowest effective dose?

☐ Yes ☐ No. If no, please provide complete treatment plan.

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Management of opioid withdrawal symptoms
- ☐ Opioid overdose prevention/reversal
- ☐ Opioid dependence
- ☐ Other

Section I. Please complete for all requests.

1. Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.
2. Drug NDC (if known) or service code
3. Has the prescriber evaluated the Massachusetts Prescription Awareness Tool (MassPAT) data? ☐ Yes ☐ No
4. Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section II. Please complete for buprenorphine tablet requests.

1. Is the member pregnant? ☐ Yes. Anticipated date of delivery ☐ No
2. Is the member breastfeeding? ☐ Yes ☐ No

3. Does the member have a documented allergy to naloxone? ☐ Yes ☐ No
   If yes, please provide medical records documenting the allergic reaction.
4. If you answered "No" to the three questions above, please provide medical necessity for prescribing buprenorphine rather than buprenorphine/naloxone. (Please explain below and provide medical records.)

Section III. Please complete for buprenorphine, buprenorphine/naloxone film, and buprenorphine/naloxone tablet doses exceeding 24 mg/day, and Zubsolv doses exceeding 17.2 mg/day.

Please document medical necessity for high dose of buprenorphine/naloxone and buprenorphine below and submit medical records supporting the medical necessity provided.

Section IV. Please complete for Zubsolv requests.

Has the member had an allergic reaction to buprenorphine/naloxone film?

☐ Yes. (Specify and provide medical records.)

☐ No. Please explain.

Section V. Please complete for lofexidine requests.

Has the member had a trial with oral clonidine?

☐ Yes. Please list the dose and frequency, dates/durations of use, and outcomes below.

Dose and frequency Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please describe clinical rationale why the member is not a candidate for oral clonidine.

Section VI. Please complete for Lifems requests.

Please document medical necessity for the convenience kit formulation, as it pertains to the caregiver.

Section VII. Please complete for Opvee requests.

Please provide medical necessity for use of a long-acting formulation for overdose reversal.

Section VIII. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

over

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
☐ Yes ☐ No
If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
If yes, please provide details for the previous trial.
Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
☐ Yes. Please provide details.
☐ No

Please continue to next page and complete Prescriber and Provider Information section.

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Opioids/Acetaminophen Analgesic Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about opioid and acetaminophen analgesic agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Drug name **Dose and frequency** **Duration of therapy**

Indication or ICD-10 code, if applicable

Has the prescriber evaluated Massachusetts Prescription Awareness Tool (MassPAT) data, risk factors, and potential risk factors for abuse/misuse in their assessment of this member? ☐ Yes ☐ No

Has the member been offered and/or given a prescription for naloxone treatment?

☐ Yes ☐ No. Please provide details.

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician.

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health service would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for oxycodone extended-release (ER) tablet (Oxycontin) requests.*

Has the member tried a morphine extended-release product or a fentanyl transdermal product?

☐ Yes. Drug Dose and frequency

Dates of use Outcome

☐ No. If morphine and fentanyl transdermal are contraindicated in this member, please describe.

Section II. Please complete for methadone (Methadose) requests.*

1. Has the member tried a morphine extended-release product?

   ☐ Yes. Dose and frequency Dates of use Outcome

   ☐ No. If morphine is contraindicated in this member, please describe.

2. Has the member tried a fentanyl transdermal product?

   ☐ Yes. Dose and frequency Dates of use Outcome

☐ No. If fentanyl transdermal is contraindicated in this member, please describe.

3. If the answer to questions 1 and 2 is no, please provide clinical rationale for the use of methadone instead of other long-acting opioids.
4. Is the member opioid naive? ☐ Yes ☐ No
5. Has the member had a baseline ECG showing a normal QTc interval? ☐ Yes ☐ No

Section III. Please complete for requests for fentanyl transmucosal system, fentanyl buccal tablet (Fentora), and oxymorphone immediate-release (IR).*

1. Is the member currently maintained on a long-acting opioid regimen?

   ☐ Yes. Drug Dose and frequency Dates of use

   ☐ No
2. Has the member tried the following agents? ☐ Yes. Please describe below.

   hydromorphone IR Dose and frequency Dates of use Outcome

   morphine IR Dose and frequency Dates of use Outcome

   oxycodone IR Dose and frequency Dates of use Outcome

   ☐ No. If hydromorphone, morphine, and oxycodone are contraindicated in this member, please describe.
3. If the request is for fentanyl buccal tablet, has the member tried fentanyl transmucosal system?

   ☐ Yes. Dose and frequency Dates of use Outcome

   ☐ No. If fentanyl transmucosal system is contraindicated in this member, please describe.

Section IV. Please complete for requests for hydrocodone ER (Hysingla ER), hydrocodone ER capsule, hydromorphone ER, levorphanol tablet, and oxymorphone ER.*

1. Has the member tried the following agents? ☐ Yes. Please describe below.

   fentanyl transdermal Dose and frequency Dates of use Outcome

   morphine ER Dose and frequency Dates of use Outcome

   oxycodone ER Dose and frequency Dates of use Outcome

   ☐ No. If fentanyl transdermal, morphine ER, and oxycodone ER are contraindicated in this member, please describe.
2. For levorphanol tablet requests, please provide clinical rationale for the use of levorphanol instead of other long-acting opioids.

Section V. Please complete for hydromorphone suppository requests.*

Has the member tried morphine suppositories?

☐ Yes. Dose and frequency Dates of use Outcome

☐ No. If morphine suppositories are contraindicated in this member or there is medical necessity for the requested formulation, please describe.

over

Section VI. Please complete for morphine ER capsule requests.*

1. Has the member tried morphine extended-release tablets?

   ☐ Yes. Dose and frequency _____ Dates of use _____ Outcome _____

   ☐ No. If morphine extended-release tablets are contraindicated in this member or there is medical necessity for the requested formulation, please describe. _____

2. Please provide medical necessity for once daily dosing. _____

Section VII. Please complete for meperidine (Demerol) requests.

Please attach documentation describing medical necessity due to allergy to morphine.

Section VIII. Please complete for requests for benzhydrocodone/acetaminophen, dihydrocodeine/acetaminophen/caffeine, hydrocodone 5 mg, 10 mg/ibuprofen, and oxycodone/acetaminophen 300mg.*

Please attach documentation of prior combination analgesic trials including hydrocodone/acetaminophen, oxycodone/acetaminophen, codeine/acetaminophen, and hydrocodone/ibuprofen.

Section IX. Please complete for buprenorphine buccal film (Belbuca) requests.*

For requests for microdosing buprenorphine, please complete question 2.

1. Has the member tried a morphine extended-release product?

   ☐ Yes. Dose and frequency _____ Dates of use _____

   Outcome _____

   ☐ No. If morphine is contraindicated in this member or there is medical necessity for the requested formulation, please describe.

2. Is the treatment plan to microdose buprenorphine with the intent to taper off full agonist opioid therapy?
   ☐ Yes ☐ No

   If yes, please document opioid taper plan, buprenorphine dosing, and tapering schedule. _____

Section X. Please complete for fentanyl transdermal 37.5, 62.5, 87.5 mcg/hr requests.*

Please provide medical necessity for use of requested formulation instead of other strengths. _____

Section XI. Please complete for butorphanol nasal spray requests.

Please attach documentation describing an adverse reaction or contraindication to all other short-acting opioids, or medical necessity for nasal spray formulation in addition to an adverse reaction or contraindication to morphine and oxycodone IR solutions.

Section XII. Please complete for tramadol ER capsule (Conzip) and tramadol ER tablet requests.

1. Please provide medical necessity for use of an extended-release formulation. _____

over

2. Please attach documentation describing an inadequate response or adverse reaction to tramadol IR.

Section XIII. Please complete for Seglentis requests.

Please provide medical necessity for use of the combination product instead of the commercially available separate agents.

Section XIV. Please complete for tramadol 25 mg requests.

Please attach documentation describing an adverse reaction or contraindication to tramadol 50 mg tablet and tramadol/acetaminophen tablet.

Section XV. Please complete for tramadol 100 mg requests.

1. Please provide medical necessity for use of the requested strength.
2. Please attach documentation describing an inadequate response or adverse reaction to tramadol 50 mg at the requested dose.

Section XVI. Please complete for requests for codeine and tramadol products for members < 12 years of age.

Please provide clinical rationale for use of a codeine and tramadol-containing product in a member < 12 years of age.

Section XVII. Please complete for tramadol solution requests.*

Is there a medical necessity for use of an oral solution formulation?

☐ Yes. Please explain.

☐ No. Please attach medical records documenting inadequate response or adverse reaction to a tramadol immediate-release tablet formulation that is available without PA.

Section XVIII. Please complete for Roxybond (oxycodone immediate-release) requests.*

Please provide medical necessity for use of requested formulation instead of oxycodone immediate-release tablets available without prior authorization.

Section XIX. Please complete for requests for duplicate short-acting or long-acting opioids.

Please provide clinical rationale for duplicate therapy including plan to consolidate therapy.

Section XX. Please complete for requests for Journavx above quantity limits (>29 units/60 days).

1. Is the diagnosis for a new acute episode of moderate to severe pain? ☐ Yes ☐ No

over

2. Please provide medical necessity for another 14-day course of therapy with the requested agent.

Section XXI. Please complete for requests above established dose limits.

For all opioids, please provide medical records documenting treatment plan including clinical rationale for high dose and titration of medication up to current dose. In addition, please provide a signed and dated patient-prescriber agreement and a consult from a pain specialist recommending the requested dose for this member. If a current pain consult is not available, please provide the anticipated date of upcoming pain consult. If there are plans to initiate a taper of the requested medication within the next 90 days, please provide medical records documenting treatment plan. For acetaminophen and aspirin products, please provide a clinical rationale for the use above 4 grams per day. For ibuprofen products, please provide a clinical rationale for the use above 3.2 grams per day.

Section XXII. Please complete for requests for high dose short-acting opioids as monotherapy.

Please provide medical records documenting treatment plan including clinical rationale for use of high dose short-acting opioids without a long-acting opioid agent. In addition, please provide clinical rationale for high dose and titration of medication up to current dose, a signed and dated patient-prescriber agreement, and a consult from a pain specialist recommending the requested dose for this member.

Section XXIII. Please complete for requests above established quantity limits (except Journavx).

Can the requested dose be obtained by using products within established quantity limits (i.e., for oxycodone ER 20 mg, 2 tablets twice daily could be consolidated to one oxycodone ER 40 mg tablet twice daily)?

☐ Yes ☐ No. If dose consolidation is not an option, please explain why.

Section XXIV. Please complete for concurrent therapy with opioid dependence agents.

1. Are you the prescriber of both buprenorphine/naloxone or buprenorphine and the opioid? ☐ Yes ☐ No
2. Prior to continuing buprenorphine/naloxone or buprenorphine therapy, will the member be discontinuing the opioid(s)? ☐ Yes ☐ No
3. Please document the medical necessity for concurrent buprenorphine/naloxone or buprenorphine and opioid therapy. Please submit medical records supporting the medical necessity, including the specific pain that the current opioid is being used to treat.
4. Please document the complete treatment plan, including expected duration of therapy for this member in regard to acute pain management with concurrent buprenorphine/naloxone or buprenorphine and opioid therapy.

**Attach a letter with additional information regarding medication trials as applicable. If MassHealth pharmacy claims history of required trials is not available, medical records documenting such trials may be required.*

over

Section XXV. Concomitant Opioid and Benzodiazepine Polypharmacy. Please complete information for medications requested and clinical rationale for polypharmacy with opioids and benzodiazepines [≥ 15 days supply for one or more opioid(s) who are newly starting opioid therapy and one or more benzodiazepine(s), excluding clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations for ≥ 15 days supply within a 45-day period].

Please document the indication or ICD-10 code(s), if applicable, for the agents requested.

1. Opioid

Name/dose/frequency Indication

Name/dose/frequency Indication

Name/dose/frequency Indication

2. Benzodiazepine

Name/dose/frequency Indication

Name/dose/frequency Indication

Name/dose/frequency Indication

Please document clinical rationale for concomitant use of opioids and benzodiazepines for this member.

Please describe the ongoing treatment plan for continued use.

Has the member had trials with three non-opioid therapies?

☐ Yes. Drug name Dates Outcome

Drug name Dates Outcome

Drug name Dates Outcome

Other Dates Outcome

☐ No. Please document clinical rationale for the use of opioids instead of non-opioid alternatives.

Has consideration been given for possible taper of benzodiazepine or opioid?

☐ Yes. Please describe plan for taper and plan to reevaluate in the future.

☐ No. Please describe why taper is not possible at this time and plan to reevaluate in the future.

Has the member been offered and/or given a prescription for naloxone treatment?

☐ Yes ☐ No. Please provide details.

**Attach a letter with additional information regarding medication trials as applicable.*

over

Section XXVI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Oral Antibiotics and Anti-Infectives
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Aemcolo (rifamycin)
- ☐ amoxicillin/clavulanate extended-release
- ☐ Augmentin (amoxicillin/clavulanate 125/31.25 mg/5 mL suspension)
- ☐ azithromycin powder packet
- ☐ Baxdela (delafloxacin tablet)
- ☐ cefaclor extended-release
- ☐ cefaclor suspension
- ☐ cefadroxil tablet
- ☐ cefixime
- ☐ cefpodoxime suspension
- ☐ cephalexin 750 mg capsule
- ☐ ciprofloxacin 100 mg tablet
- ☐ clarithromycin extended-release
- ☐ Coartem (artemether/lumefantrine) > 24 units/365 days
- ☐ Dificid (fidaxomicin)
- ☐ Doryx (doxycycline hyclate delayed-release 60 mg tablet)
- ☐ doxycycline hyclate 50 mg tablet
- ☐ doxycycline hyclate 75 mg, 150 mg tablet
- ☐ doxycycline hyclate delayed-release 50 mg, 75 mg, 80 mg, 100 mg, 150 mg, 200 mg tablet
- ☐ doxycycline monohydrate 40 mg capsule
- ☐ doxycycline monohydrate 75 mg capsule
- ☐ doxycycline monohydrate 150 mg capsule
- ☐ doxycycline monohydrate 150 mg tablet
- ☐ Egaten (triclabendazole)
- ☐ Krintafel (tafenoquine) > 2 units/365 days
- ☐ Lampit (nifurtimox)
- ☐ Likmez (metronidazole oral suspension)
- ☐ linezolid suspension
- ☐ Lymepak (doxycycline 100 mg tablet pack)
- ☐ mebendazole
- ☐ metronidazole 125 mg tablet
- ☐ metronidazole 375 mg capsule
- ☐ minocycline extended-release 45 mg, 90 mg, 135 mg tablet
- ☐ minocycline tablet
- ☐ nitazoxanide tablet
- ☐ nitrofurantoin 25 mg/5 mL suspension
- ☐ nitrofurantoin 50 mg/5 mL suspension
- ☐ Nuzyra (omadacycline tablet)
- ☐ ofloxacin tablet
- ☐ pyrimethamine
- ☐ Sivextro (tedizolid tablet)
- ☐ Solosec (secnidazole)
- ☐ Sovuna (hydroxychloroquine)
- ☐ tetracycline tablet
- ☐ Xifaxan (rifaximin 550 mg)

Dose, frequency, and duration of medication requested

Indication or ICD-10 code, if applicable

Section I. Please complete for all requests.

1. Is the member under the care of an infectious disease specialist? ☐ Yes ☐ No
2. Please list previous trials for the requested indication including outcomes.*

Drug Outcome Dates of use

Drug Outcome Dates of use

Drug Outcome Dates of use

**Attach a letter with additional information regarding medication trials as applicable.*

Section II. Please complete for all requests for antibiotics.

1. Please indicate the infecting organism.
   - ☐ Clostridium difficile
   - ☐ Methicillin-resistant Staphylococcus aureus (MRSA)
   - ☐ Vancomycin-resistant Enterococcus (VRE)
   - ☐ Other
2. Is the infecting organism confirmed or suspected? ☐ Confirmed ☐ Suspected
3. Were cultures and susceptibility testing performed?
   - ☐ Yes. Please attach a copy of the culture and sensitivity report with submission.
   - ☐ No. Please provide clinical rationale why cultures and susceptibility testing were not performed.

Section III. Please also complete for requests for amoxicillin/clavulanate extended-release, cefaclor extended-release, and clarithromycin extended-release.

Please describe the medical necessity for the use of an extended-release dosage formulation instead of immediate-release formulations of the requested agent. Please describe prior trials and outcomes with the immediate-release formulation and additional antibiotics, if applicable, in Section I above.

Section IV. Please also complete for requests for azithromycin powder packet, cefadroxil tablet, cefpodoxime suspension, cephalexin 750 mg capsule, ciprofloxacin 100 mg tablet, metronidazole 375 mg, and tetracycline tablet.

Please describe prior trials and outcomes with formulations of the requested antibiotic that are available without PA in Section I above. Please describe medical necessity for the use of the requested antibiotic instead of alternative strengths available without PA.

Section V. Please also complete for requests for doxycycline agents requiring PA, except for Lymepak.

Please describe prior trials and outcomes with doxycycline formulations that are available without PA in Section I above. Please describe medical necessity for the requested formulation instead of doxycycline formulations available without PA.

Section VI. Please also complete for requests for Lymepak.

Please describe prior trials and outcomes with all doxycycline formulations that are available without PA in Section I above. Please describe medical necessity for the requested formulation instead of doxycycline 100 mg formulations available without PA.

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Section VII. Please also complete for requests for cefixime.

Is the member completing a course of therapy that was initiated in the hospital? ☐ Yes ☐ No

If the answer to the above question is no, has the member had a trial with cefdinir or cefpodoxime?

☐ Yes. Please describe prior trials and outcomes in Section I above.

☐ No. Please explain why not.

Section VIII. Please also complete for requests for Xifaxan 550 mg.

1. For the diagnosis of hepatic encephalopathy, has the member tried lactulose?
   ☐ Yes. Please describe prior trials and outcomes in Section I above.
   ☐ No. Please explain why not.
2. For the diagnosis of irritable bowel syndrome with diarrhea, has the member had a trial with three of the following: loperamide, diphenoxylate/atropine, bile acid sequestrant, bismuth subsalicylate, bulk-forming agent, tricyclic antidepressant (TCA)?
   ☐ Yes. Please describe prior trials and outcomes in Section I above.
   ☐ No. Please explain why not.

Section IX. Please also complete for requests for Sivextro tablet.

1. For Sivextro for the diagnosis of VRE, has the member had a trial with linezolid?
   ☐ Yes. Please describe prior trials and outcomes in Section I above.
   ☐ No. Please explain why not.
2. For the diagnosis of MRSA, has the member had a trial with clindamycin, doxycycline or minocycline, sulfamethoxazole/trimethoprim, or vancomycin IV?
   ☐ Yes. Please describe prior trials and outcomes in Section I above.
   ☐ No. Please explain why not.

Section X. Please also complete for requests for minocycline extended-release 45 mg, 90 mg, 135 mg tablets, and minocycline tablets.

1. For minocycline immediate-release tablet, please describe prior trials and outcomes with minocycline capsules in Section I above. Please describe medical necessity for the dosage formulation instead of immediate-release capsules.
2. For minocycline extended-release tablet and capsule formulations, has the member had a trial with minocycline capsules and Solodyn?
   ☐ Yes. Please describe prior trials and outcomes in Section I above.
   ☐ No. Please explain why not.

Section XI. Please also complete for requests for cefaclor suspension, linezolid suspension, nitrofurantoin 25 mg/5 mL suspension, and nitrofurantoin 50 mg/5 mL suspension.

Please describe medical necessity for use of the suspension formulation instead of the respective capsule or tablet formulation.

over

Section XII. Please also complete for requests for Augmentin 125/31.25 mg/5 mL suspension.

Please provide clinical rationale for not using 250/62.5 mg/5 mL formulation.

Section XIII. Please also complete for requests for Baxdela tablet and Nuzyra tablet.

1. For suspected or confirmed MRSA infections or mixed pathogen infections (including MRSA), has the member had a trial with clindamycin, doxycycline or minocycline, linezolid, sulfamethoxazole/trimethoprim, or vancomycin IV?
   - ☐ Yes. Please describe prior trials and outcomes in Section I above.
   - ☐ No. Please explain why not.
2. For suspected or confirmed mixed pathogen infections (including MRSA), has the member had a trial with at least one other antibiotic with gram-negative coverage available without PA?
   - ☐ Yes. Please describe prior trials and outcomes in Section I above.
   - ☐ No. Please explain why not.

Section XIV. Please also complete for requests for ofloxacin tablet.

Has the member had a trial with ciprofloxacin or levofloxacin?

- ☐ Yes. Please describe prior trials and outcomes in Section I above.
- ☐ No. Please explain why not.

Section XV. Please also complete for requests for Coartem > 24 units/365 days and Krintafel (tafenoquine) > two units/365 days.

1. Please describe the medical necessity for exceeding the quantity limit.
2. For Krintafel, is the member currently receiving chloroquine therapy?
   - ☐ Yes.
   - ☐ No. Please explain why not.

Section XVI. Please also complete for requests for Lampit.

Member's current weight Date

Section XVII. Please also complete for requests for pyrimethamine.

Will the requested agent be used in combination with other agents for the diagnosis?

- ☐ Yes. Please provide drug name(s).
- ☐ No

Section XVIII. Please also complete for requests for Likmez, metronidazole 125 mg tablet, and Sovuna.

1. For Likmez, please describe prior trials and outcomes with metronidazole tablets in Section I above.
2. For metronidazole 125 mg tablet, please describe prior trial and outcome with Likmez in Section I above.

over

3. Please describe medical necessity for the requested formulation instead of formulations available without PA.

Section XIX. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen? ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Oral Respiratory Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested

Leukotrienes

☐ montelukast granules ☐ zafirlukast ☐ zileuton extended-release ☐ Zyflo (zileuton)

Other

☐ roflumilast tablet ☐ Ofev (nintedanib) ☐ pirfenidone

Dose and frequency of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Allergic Rhinitis (montelukast only)
☐ Asthma
☐ Chronic Obstructive Pulmonary Disease (roflumilast tablet only)
☐ Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype
☐ Exercise-Induced Bronchospasm
☐ Idiopathic Pulmonary Fibrosis
☐ Systemic sclerosis-associated interstitial lung disease (SSc-ILD)
☐ Other

Please list all other medications currently prescribed for the member for this indication.

Section I. Please complete for montelukast granule requests.

1. Has the member had a trial with montelukast chewable tablet?.
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*
   ☐ No. Please describe why montelukast chewable tablet is not appropriate for this member.
2. For the diagnosis of allergic rhinitis, has the member had a trial with an intranasal antihistamine or intranasal corticosteroid and one oral second-generation antihistamines (e.g., cetirizine, loratadine)?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*
   ☐ No. Please describe why intranasal antihistamines and corticosteroids, and oral second-generation antihistamines are not appropriate for this member.
3. For the diagnosis of exercise-induced bronchospasm, has the member had a trial with inhaled albuterol, levalbuterol, or low dose inhaled corticosteroid-formoterol (e.g., budesonide/formoterol or Dulera [mometasone/formoterol])?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*
   ☐ No. Please describe why inhaled albuterol, levalbuterol, or low dose inhaled corticosteroid-formoterol is not appropriate for this member.

Please provide details for the previous trials.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Section II. Please complete for roflumilast tablet requests.

1. Has the member had a trial with Bevespi, Duaklir, Stiolto, or umeclidinium/vilanterol within the past four months?

   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why Bevespi, Duaklir, Stiolto, and umeclidinium/vilanterol are not appropriate for this member.

2. Has the member had a trial with Breztri or Trelegy within the past four months?

   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why Breztri and Trelegy are not appropriate for this member.

Section III. Please complete for zileuton extended-release and Zyflo requests.

1. Has the member had a trial with montelukast or zafirlukast?

   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why montelukast and zafirlukast are not appropriate for this member.

over

2. For requests for zileuton extended-release, has the member had a trial with Zyflo?
   ☐ Yes. Please describe the dates/duration of trial and outcomes below*.
   Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Please describe why Zyflo is not appropriate for this member.

Section IV. Please complete for Ofev requests for a diagnosis of SSc-ILD.

Has the member had a trial with cyclophosphamide or mycophenolate?
☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.
☐ No. Please describe why cyclophosphamide and mycophenolate are not appropriate for this member.

**Please attach a letter documenting additional trials as necessary*

Section V. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

over

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
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☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Oral/Injectable Antifungal Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Brexafemme (ibrexafungerp)
- ☐ Cresemba (isavuconazonium)*
- ☐ Noxafil (posaconazole powder for oral suspension)
- ☐ Oravig (miconazole buccal tablet)
- ☐ posaconazole injection*
- ☐ posaconazole suspension
- ☐ Rezzayo (rezafungin)
- ☐ Tolsura (itraconazole 65 mg capsule)
- ☐ Vivjoa (oteseconazole)
- ☐ voriconazole suspension
- ☐ Other** _____

*For posaconazole IV and Cresemba IV, Section VII is also required.

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).

Dose and frequency of medication requested _____

Indication (check all that apply or include ICD-10 code, if applicable)

***voriconazole requests only **Cresemba and posaconazole**

- ☐ *Aspergillus* endophthalmitis*
- ☐ *Aspergillus* keratitis*
- ☐ *Scedosporium* infection*
- ☐ *Aspergillus* infection
- ☐ *Fusarium* infection*
- ☐ *Zygomycosis* (mucormycosis)**

Please note: For posaconazole or voriconazole for the above indications, Sections I through VIII are not required.

For all indications checked below, please complete sections in parentheses

- ☐ Blastomycosis (Section V)
- ☐ Candidemia (Section II) †
- ☐ Disseminated candidiasis (Section II)
- ☐ Esophageal candidiasis (Section III)
- ☐ Histoplasmosis (Section V)
- ☐ Invasive candidiasis (Section X)
- ☐ Onychomycosis (Section V)
- ☐ Oropharyngeal candidiasis (Section IV)
- ☐ Prevention of *Aspergillus* and *Candida* infections (Section I)
- ☐ Vulvovaginal candidiasis (Section IX)
- ☐ Other _____

(Please attach a letter regarding medical necessity.)

† For Rezzayo, please complete Section X

Section I. Please complete for posaconazole and voriconazole for prevention of Aspergillus and Candida infections.

1. For posaconazole requests, is the member's age within the FDA-approved range for use (posaconazole suspension ≥ 13 years; posaconazole powder for oral suspension ≥ 2 years to < 18 years; posaconazole IV ≥ 2 years)?
   ☐ Yes ☐ No. Please provide clinical rationale for use in non-FDA-approved age.
2. For both posaconazole and voriconazole requests, does the member have one of the following?
   ☐ Hematologic malignancy with neutropenia ☐ Graft-versus-host disease
   ☐ Hematopoietic stem cell transplantation
   ☐ No. Please describe why the member requires antifungal prophylaxis.
3. For posaconazole request, please provide clinical rationale for use of requested formulation instead of tablet formulation.
4. For posaconazole powder for oral suspension, is the member's weight ≤ 40 kg?
   ☐ Yes ☐ No. Please provide clinical rationale for use in non-FDA-approved weight.

Section II. Please complete for voriconazole for candidemia and disseminated candidiasis.

Has the member had a trial of oral fluconazole?

☐ Yes. Dates/durations of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for oral fluconazole.

Section III. Please complete for posaconazole suspension and voriconazole for esophageal candidiasis.

1. For posaconazole requests, is the member 13 years of age or older?
   ☐ ☐
2. For posaconazole requests, has the member had a trial of voriconazole?
   ☐ Yes. Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   ☐ No. Please describe why the member is not a candidate for voriconazole.

over

3. For both posaconazole and voriconazole requests, has the member had a trial of fluconazole?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for fluconazole.

4. For both posaconazole and voriconazole requests, has the member had a trial of itraconazole?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for itraconazole.

5. For posaconazole requests, please provide clinical rationale for use of requested formulation.

Section IV. Please complete for Oravig, posaconazole suspension, and voriconazole for oropharyngeal candidiasis.

1. For posaconazole requests, is the member 13 years of age or older?

☐ Yes ☐ No. Please provide clinical rationale for use in non-FDA-approved age.

2. For voriconazole requests, has the member had a trial of posaconazole?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for posaconazole.

3. For both posaconazole and voriconazole requests, has the member had a trial of oral fluconazole?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for oral fluconazole.

4. For both posaconazole and voriconazole requests, has the member had a trial of itraconazole?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

over

☐ No. Please describe why the member is not a candidate for itraconazole.

5. For Oravig requests, has the member had a trial of clotrimazole troches?

   ☐ Yes. Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Please describe why the member is not a candidate for clotrimazole troches.

6. For Oravig requests, has the member had a trial of nystatin suspension or tablet?

   ☐ Yes. Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Please describe why the member is not a candidate for nystatin suspension and tablet.

7. For Oravig requests, has the member had a trial of fluconazole suspension or tablet?

   ☐ Yes. Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Please describe why the member is not a candidate for fluconazole suspension and tablet.

Section V. Please complete for Tolsura.

Please provide medical necessity for the requested formulation instead of itraconazole 100 mg capsules and itraconazole oral suspension.

Section VI. Please complete for Cresemba for the treatment of Aspergillus infection.

1. Member's current weight Date
2. Has the member had a trial of voriconazole?

   ☐ Yes. Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Please describe why the member is not a candidate for voriconazole.

3. Has the member had a trial of posaconazole?

   ☐ Yes. Dates/duration of use

over

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for posaconazole.

Section VII. Please complete for Cresemba IV, posaconazole IV, and posaconazole suspension.

1. For Cresemba IV, please provide medical necessity for use of IV formulation instead of oral formulations.
2. For posaconazole requests, please provide medical necessity for requested formulation instead of the tablet formulation.

Section VIII. Please complete for Cresemba for Zygomycosis (mucormycosis).

1. Member's current weight Date
2. Has the member had a trial of posaconazole?

☐ Yes. Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for posaconazole.

Section IX. Please complete for Brexafemme and Vivjoa for vulvovaginal candidiasis (VVC).

For Brexafemme requests for a diagnosis of acute VVC, please complete questions 1 and 2. For Brexafemme requests for a diagnosis of recurrent VVC, please complete questions 1 through 5. For Vivjoa requests, please complete questions 1 through 6.

1. Has the member had a trial of oral fluconazole?

☐ Yes. Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for oral fluconazole.

2. Is the member post-menarchal? ☐ Yes ☐ No
3. Please attach results from a diagnostic test to confirm diagnosis (e.g, KOH, nucleic acid probe-based test system, nucleic acid amplification, etc.).
4. Has the member had ≥ three acute VVC episodes within past 12 months? ☐ Yes ☐ No
5. Is the member not of reproductive potential? ☐ Yes ☐ No
6. Is the member post-menopausal? ☐ Yes ☐ No

over

Section X. Please complete for Rezzayo.

1. Has the member had a trial of Eraxis?

   ☐ Yes. Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Please describe why the member is not a candidate for Eraxis.

2. Has the member had a trial of caspofungin?

   ☐ Yes. Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Please describe why the member is not a candidate for caspofungin.

3. Has the member had a trial of micafungin?

   ☐ Yes. Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Please describe why the member is not a candidate for micafungin.

Section XI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use

over

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Osteoporosis Agents and Calcium Regulators
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Bisphosphonates

- ☐ alendronate solution
- ☐ Binosto (alendronate effervescent tablet)
- ☐ Fosamax Plus D (alendronate/cholecalciferol)
- ☐ ibandronate IV [MB]
- ☐ risedronate
- ☐ risedronate delayed-release

Miscellaneous Agents

- ☐ calcitonin salmon injection
- ☐ Evenity (romosozumab-aqqg)
- ☐ Duavee (conjugated estrogens/bazedoxifene)
- ☐ Prolia (denosumab)
- ☐ teriparatide 620 mcg/2.48 mL
- ☐ teriparatide 600 mcg/2.4 mL
- ☐ Tymlos (abaloparatide)
- ☐ Xgeva (denosumab)
- ☐ Yorvipath (palopegteriparatide)

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Giant cell tumor of the bone (Xgeva) (Section VIII)
- ☐ Glucocorticoid-Induced Osteoporosis (GIO) (Section II)
- ☐ Hypercalcemia
- ☐ Hypercalcemia of malignancy (Xgeva) (Section VII)
- ☐ Hypoparathyroidism
- ☐ Osteopenia
- ☐ Paget's Disease
- ☐ Postmenopausal Osteoporosis (PMO)
- ☐ Prevention of postmenopausal osteoporosis
- ☐ Prevention of bone loss in men receiving androgen deprivation therapy for prostate cancer
- ☐ Prevention of bone loss in women receiving aromatase inhibitors for breast cancer
- ☐ Prevention of skeletal-related events secondary to bone metastases in cancer related to solid tumors (Xgeva) (Section VII)
- ☐ Prevention of skeletal-related events secondary to multiple myeloma (Xgeva) (Section VII)
- ☐ Primary/Hypogonadal Osteoporosis
- ☐ Treatment of moderate-severe vasomotor symptoms associated with menopause
- ☐ Other

[MB] This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Section I. Please complete for bisphosphonates, calcitonin salmon injection, Evenity, Prolia, teriparatide 600 mcg/2.4 mL, and teriparatide 620 mcg/2.48 mL as indicated above.
For calcitonin salmon injection requests for the diagnosis of Paget's disease, please complete questions 4 and 5. For calcitonin salmon injection requests for the diagnosis of hypercalcemia, please complete question 7.

1. Please provide results of bone mineral density (BMD) measurements (T-scores of total hip and lumbar vertebrae).
2. Has the member had a radiographically confirmed fracture?
   ☐ Yes. Please provide site and date below.
   Site Date
   ☐ No
3. Please list all non-modifiable risk factors for fracture in this member.
4. Has the member tried an oral bisphosphonate and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please list the dates/duration of oral bisphosphonate trial and outcomes in Section X below.*
   ☐ No. Please document if there is a contraindication to oral bisphosphonates.
5. If the request is for calcitonin salmon injection, Evenity, teriparatide 600 mcg/2.4 mL, teriparatide 620 mcg/2.48 mL, or Tymlos, has the member tried Prolia, if applicable, or an intravenous bisphosphonate and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section X below.*
   ☐ No. Please document if there is a contraindication to Prolia and intravenous bisphosphonates.
6. If the request is for calcitonin salmon injection, Evenity, or Tymlos, has the member tried teriparatide 600 mcg/2.4 mL and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section X below.*
   ☐ No. Please document if there is a contraindication to teriparatide 600 mcg/2.4 mL.
7. If the request is for calcitonin salmon injection, has the member tried calcitonin nasal spray and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section X below.*
   ☐ No. Please document if there is a contraindication to Prolia and intravenous bisphosphonates.

Section II. Please complete for all agents being requested for the treatment or prevention of Glucocorticoid-Induced Osteoporosis (GIO).

Please provide specifics of the member's chronic glucocorticoid use.

Drug Dose and Frequency Dates/Duration

over

Section III. Please complete for Yorvipath requests.

1. Please indicate prescriber specialty below.

   ☐ Endocrinologist ☐ Nephrologist ☐ Surgeon ☐ Other
   If prescriber is not a specialist, please attach consult notes from specialist.
2. Has the member had a trial with calcium in conjunction with active vitamin D (e.g., calcitriol) supplementation?
   ☐ Yes. Please list the dates/duration of menopausal hormonal agent trial and outcomes in Section X below.*
   ☐ No. Please document if there is a contraindication to calcium and active vitamin D supplements.
3. Has the member tried teriparatide 600 mcg/2.4 mL and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section X below.*
   ☐ No. Please document if there is a contraindication to teriparatide 600 mcg/2.4 mL.

Section IV. Please complete for teriparatide 620 mcg/2.48 mL requests.

Please provide medical necessity for the use of teriparatide 620 mcg/2.48 mL instead of teriparatide 600 mcg/2.4 mL.

Section V. Please complete for Fosamax Plus D requests.

Please provide medical necessity for the combination product instead of the individual agents.

Section VI. Please complete for Xgeva requests for a diagnosis of prevention of skeletal-related events secondary to bone metastases in cancer related to solid tumors, prevention of skeletal-related events secondary to multiple myeloma, and hypercalcemia of malignancy.

Please indicate prescriber specialty below.

☐ Hematology ☐ Oncology ☐ Orthopedic Specialist ☐ Other
If prescriber is not a specialist, please attach consult notes from specialist.

Section VII. Please complete for Xgeva requests for a diagnosis of giant cell tumor of the bone.

Please describe surgical history and/or prognosis. If surgery is not appropriate for this member, please explain.

Section VIII. Please complete for alendronate solution and Binosto requests.

Does the member have a medical condition in which they are unable to swallow tablets/capsules?

☐ Yes. Please list reason.
☐ No. Please provide clinical rationale why conventional dosage forms cannot be used.

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Section IX. Please complete for Duavee requests.

For the diagnosis of moderate- severe vasomotor symptoms associated with menopause, please complete question 1. For indication of prevention of postmenopausal osteoporosis, please complete questions 1 – 3.

1. Has the member had a trial with one menopausal hormonal agent available without prior authorization?
   ☐ Yes. Please list the dates/duration of menopausal hormonal agent trial and outcomes in Section X below.*
   ☐ No. Please document if there is a contraindication to menopausal hormonal agents.
2. Has the member tried an oral bisphosphonate and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please list the dates/duration of oral bisphosphonate trial and outcomes in Section X below.*
   ☐ No. Please document if there is a contraindication to oral bisphosphonates.
3. Has the member had a trial with raloxifene and zoledronic acid 5 mg?
   ☐ Yes. Please list the dates/duration of trials and outcomes in Section X below.*
   ☐ No. Please explain if there is a contraindication to these trials.

Section X. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

Drug name/Therapy Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

Drug name/Therapy Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

** Please attach a letter documenting additional trials as necessary*.

Section XI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

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3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details. _____
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Otic Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ ciprofloxacin 0.2% otic solution
☐ ciprofloxacin/dexamethasone otic suspension
☐ Otovel (ciprofloxacin/fluocinolone)

Dose, frequency, and duration of medication requested

Drug NDC (if known) or service code

Indication(s) or ICD-10 code, if applicable

☐ Acute otitis media
Does the member have tympanostomy tubes?
☐ Yes ☐ No
☐ External otitis
☐ Other (please indicate)

Section I. Please complete for ciprofloxacin 0.2% otic solution requests for the diagnosis of external otitis.

Has the member had a trial with two of the following: Cipro HC, Cortisporin TC, a neomycin/polymyxin B/hydrocortisone product, or ofloxacin otic solution?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please explain why not.

Section II. Please complete for ciprofloxacin/dexamethasone otic suspension requests.

Has the member had a trial with Cipro HC?

☐ Yes. Please list the dates/duration of trial and outcomes below.*

Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please explain why not.

Section III. Please complete for Otovel requests for the diagnosis of acute otitis media with tympanostomy tubes.

Has the member had a trial with ciprofloxacin/dexamethasone otic suspension?

☐ Yes. Please list the dates/duration of trial and outcome below.*

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please explain why not.

* *Please attach a letter documenting additional trials as necessary.*

Section IV. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details.

   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Pediatric Behavioral Health Medication Initiative
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

The **Pediatric Behavioral Health Medication Initiative** requires prior authorization for pediatric members (generally members < 18 years of age) for certain behavioral health medication classes and/or specific medication combinations (i.e. polypharmacy) that have limited evidence for safety and efficacy in the pediatric population. For a comprehensive medication list and additional information about the **Pediatric Behavioral Health Medication Initiative**, including PA requirements and preferred products please refer to the MassHealth Drug List at **www.mass.gov/druglist.**

Please refer to the following table for guidance on filling out this PA form.
Complete Section I, and all pertinent Sections as described below.

For all requests, complete Section I in its entirety.	
Next, please complete all pertinent Sections as described below.	
Polypharmacy Request Within the Same Medication Class [e.g., regimen includes more than one antidepressant, benzodiazepine, cerebral stimulant, mood stabilizer (agents considered to be used only for seizure diagnoses are not included)]	Section II
Antipsychotic Polypharmacy Request	Section III
Behavioral Health Medication Request for Members < six years of age [e.g., antidepressant, armodafinil, atomoxetine, benzodiazepine, buspirone, donepezil, memantine, meprobamate, modafinil, mood stabilizer (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, viloxazine, or xanomeline/trospium]	Section IV
Antipsychotic Request for Members < ten years of age	Section V
Alpha$_2$ Agonist or Cerebral Stimulant Request for Members < three years of age	Section VI
Hypnotic Request for Members < six years of age	Section VII
Request for Members on Multiple Behavioral Health Medications	Section VIII
Request for Non-Preferred Drug Products	Section IX
Request for Exceptions to Step Therapy	Section X

Thank you for helping to ensure that MassHealth pediatric members receive medically necessary behavioral health medications that are safe, effective, and optimize patient care.

Medication information

Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name Dose/frequency Indication
2. Medication name Dose/frequency Indication
3. Medication name Dose/frequency Indication
4. Medication name Dose/frequency Indication
5. Medication name Dose/frequency Indication
6. Medication name Dose/frequency Indication
7. Other(s)

Is the member currently in an acute care setting?

☐ Yes. (Inpatient) ☐ Yes. (Community Based Acute Treatment) ☐ Yes. (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.

Prescriber name Contact information

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months. ☐ No

On the current regimen, is the member considered to be a severe risk of harm to self or others?

☐ Yes. Please provide details. ☐ No

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g., weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain.

Has informed consent from a parent or legal guardian been obtained?* ☐ Yes ☐ No

Please indicate prescriber specialty below.

☐ Psychiatry ☐ Neurology ☐ Other

☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

Name(s) of the specialist(s) Date(s) of last visit or consult

Contact information

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

over

Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility

☐ Uncertain ☐ Other

Please document agency involvement.

☐ DCF ☐ Department of Mental Health (DMH)

☐ Department of Developmental Services (DDS) ☐ Department of Youth Services (DYS)

Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions below, if applicable. ☐ No

Psychiatric care provided is coordinated with other psychotherapeutic and community based services. ☐ Yes ☐ No

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

** Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information go to: https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information*

Please complete for members who have been on one of the following for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation): a polypharmacy regimen, members < six years of age who have been on an applicable behavioral health medication, and members < ten years of age who have been on an antipsychotic.

Have previous efforts to reduce or simplify the regimen in the past 24 months resulted in symptom exacerbation? ☐ Yes ☐ No

The family or caregiver does not support the regimen change at this time due to risk of exacerbation. ☐ Yes ☐ No

Is there another significant barrier for therapy discontinuation? ☐ Yes ☐ No

If yes, please explain.

Section II. Polypharmacy within the same medication class (e.g., antidepressants, benzodiazepines, cerebral stimulants, mood stabilizers [agents considered to be used only for seizure diagnoses are not included]). Complete this section for all members < 18 years of age if request will result in polypharmacy within the same medication class.

Please document if monotherapy trials (include drug name, dates/duration of use, and outcome) were tried before prescribing polypharmacy with two or more agents within the same medication class for this member.**

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

over

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Other(s)

Please document clinical rationale for polypharmacy within the same medication class for this member.

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on an antidepressant or mood stabilizer polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?

☐ Yes. Please complete the applicable question in Section I. ☐ No

***Attach a letter with additional information regarding medication trials as applicable.*

Section III. Antipsychotic Polypharmacy. Complete this section for all members < 18 years of age if request will result in prescription of two or more antipsychotics for ≥ 60 days within a 90-day period.

Please select the stage of treatment and clinical rationale for antipsychotic polypharmacy.

☐ **Acute stage** (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects)

☐ Member experienced an inadequate response or adverse reaction to two monotherapy trials with antipsychotics.

Drug name 1 Dates/Duration of use

Drug name 2 Dates/Duration of use

☐ Member is transitioning from one antipsychotic to the other.

☐ Other, please explain.

☐ **Maintenance stage** (response to antipsychotic treatment with goal of remission or recovery)

1. Is the regimen effective, therapy benefits outweigh risks, and appropriate monitoring is in place?
   ☐ Yes ☐ No
2. Has the member been on an antipsychotic polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?
   ☐ Yes. Please complete the applicable question in Section I. ☐ No

☐ **Discontinuation stage** (clinically indicated that the antipsychotic regimen can likely be successfully tapered)

☐ Member is transitioning from one antipsychotic to the other.

☐ Member is tapering antipsychotic. Please describe taper plan including duration.

over

Section IV. Behavioral Health Medication (e.g., antidepressant, armodafinil, atomoxetine, benzodiazepine, buspirone, donepezil, memantine, meprobamate, modafinil, mood stabilizer [agents considered to be used only for seizure diagnoses are not included], naltrexone, prazosin, viloxazine, or xanomeline/trospium) for members < six years of age.

Please document any previous medication trial(s). Include drug name, dates/duration of use, and outcome.**

Please document clinical rationale for use of an antidepressant, armodafinil, atomoxetine, benzodiazepine, buspirone, donepezil, memantine, meprobamate, modafinil, mood stabilizer, naltrexone, prazosin, or viloxazine for this member < six years of age.

Has the member been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

***Attach a letter with additional information regarding medication trials as applicable.*

Section V. Antipsychotic Request for Members < ten years of age.

Please select the stage of treatment and clinical rationale for use of an antipsychotic for this member < ten years of age.

☐ **Acute stage** (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects)

☐ **Maintenance stage** (response to antipsychotic treatment with goal of remission or recovery)

1. Is the regimen effective, therapy benefits outweigh risks, and appropriate monitoring is in place?
   ☐ Yes ☐ No
2. Has the member been on an antipsychotic agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?
   ☐ Yes. Please complete the applicable question in Section I. ☐ No

☐ **Discontinuation stage** (clinically indicated that the antipsychotic regimen can likely be successfully tapered)

☐ Member is transitioning from one antipsychotic to the other.

☐ Member is tapering antipsychotic. Please describe taper plan including duration.

Section VI. Alpha$_2$ Agonist or Cerebral Stimulant Request for Members < three years of age.

Please document any previous medication trial(s). Include drug name, dates/duration of use, and outcome. For requests for an amphetamine product, include drug name, dates/duration of use, and outcome to a trial with a methylphenidate product.**

over

Please document clinical rationale for use of an alpha2 agonist and/or cerebral stimulant for this member < three years of age.

***Attach a letter with additional information regarding medication trials as applicable.*

Section VII. Hypnotic Request for Members < six years of age.

Please document if member has other behavioral health comorbidities (e.g., anxiety, depression, ADHD).

Please document medication trials with melatonin and/or clonidine, if clinically appropriate. Include drug name, dates/duration of use, and outcome.**

Please document behavioral interventions (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques).

Please document clinical rationale for the use of a hypnotic agent for this member < six years of age.

Has the member been on the requested hypnotic agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

***Attach a letter with additional information regarding medication trials as applicable.*

Section VIII. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.**

Please document clinical rationale for use of multiple behavioral health medications for this member < 18 years of age.

over

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

***Attach a letter with additional information regarding medication trials as applicable.*

Section IX. Please complete for all requests for non-preferred drug products if one or more preferred drug products have been designated for this class of drugs.

If one or more preferred drug products have been designated for this class of drugs, and if you are requesting PA for a non-preferred drug product, please provide medical necessity for prescribing the non-preferred drug product rather than the preferred drug product.

Section X. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Pediculicides and Scabicides
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ crotamiton lotion ☐ Eurax cream ☐ malathion ☐ spinosad

Dose, frequency, and duration of medication requested

Indication or ICD-10 code, if applicable

☐ Crab lice ☐ Head lice ☐ Scabies ☐ Other (please indicate)

Section I. Please complete for crotamiton lotion and Eurax cream requests.

1. Has the member had a trial with permethrin 5%?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using permethrin 5% for this member.

2. Has the member had a trial with oral ivermectin?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using oral ivermectin for this member.

* *Please attach a letter documenting additional trials as necessary.*

Section II. Please complete for malathion, and spinosad requests.

Has the member had a trial with permethrin or piperonyl butoxide/pyrethrins?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using permethrin and piperonyl butoxide/pyrethrins for this member.

** Please attach a letter documenting additional trials as necessary.*

Section III. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Progesterone Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested (Check all that apply. Where applicable, the brand name is provided in brackets for reference.)

☐ Crinone 4% (progesterone gel)
☐ Crinone 8% (progesterone gel)
☐ Endometrin (progesterone vaginal insert)
☐ hydroxyprogesterone caproate injection

☐ Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Frequency and duration of therapy requested _____

Drug NDC (if known) or service code _____

Indication (Check all that apply, or ICD-10 code, if applicable) _____

☐ Amenorrhea
  ☐ Primary ☐ Secondary
☐ Progestin challenge for the diagnosis of secondary amenorrhea
☐ Other (Please indicate.) _____

Please note: MassHealth does not pay for any drug when used to promote fertility as described in 130 CMR 406.413(B) "Limitations on Coverage of Drugs-Drug Exclusion." For additional information go to: www.mass.gov/regulations/130-CMR-406000-pharmacy-services.

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Section I. Please complete for all requests, if applicable.

1. Is the member currently pregnant with a singleton gestation? ☐ Yes ☐ No. Please explain.
   _____
   _____
2. Please indicate the current gestational week. _____
3. Was there a prior spontaneous preterm delivery with a singleton gestation? ☐ Yes ☐ No. Please explain.
   _____
   _____
4. Please indicate the gestational week(s) for the member's prior preterm delivery, if applicable. _____

Section II. Please complete for Crinone 4% and 8% gel requests for progestin challenge for the diagnosis of secondary amenorrhea.

1. Has the member experienced an adverse reaction to oral progesterone (micronized), medroxyprogesterone, or norethindrone?

   ☐ Yes. Name _____ Please describe trial below.

   Dose and frequency _____ Dates of Use _____ Outcome _____

   ☐ No. Explain why oral progesterone (micronized), medroxyprogesterone, or norethindrone have not been tried.

   _____

2. For Crinone 8% gel requests, has the member had a trial with Crinone 4% gel?

   ☐ Yes. Please list the dates/duration of use and outcomes below.

   Dates/duration _____ Outcome _____

   ☐ No. Please explain. _____

Section III. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

   _____

   _____

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen? ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

   _____

   _____

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

   _____

   _____

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details. _____

   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Prostate Cancer Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ abiraterone 250 mg, 500 mg
☐ Akeega (niraparib/abiraterone)
☐ Erleada (apalutamide)
☐ Jevtana (cabazitaxel) [MB]
☐ Nubeqa (darolutamide)
☐ Provenge (sipuleucel-T) [MB]
☐ Xtandi (enzalutamide)
☐ Yonsa (abiraterone 125 mg)

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose of medication requested **Frequency of medication requested**

Duration/Cycles of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Prostate cancer
☐ Other
☐ Metastatic ☐ Non-metastatic
☐ Castration-resistant ☐ Castration-sensitive
☐ Hormone-sensitive

Please indicate prescriber specialty. ☐ Oncology ☐ Urology ☐ Other

Section I. Please complete for Jevtana requests.

1. Has the member had an inadequate response or adverse reaction to a docetaxel containing regimen?
   ☐ Yes ☐ No
2. Please list previous regimen(s).
   Regimen Dates of use
   Regimen Dates of use
3. Will the requested medication be used in combination with prednisone? ☐ Yes ☐ No

Section II. Please complete for Provenge requests.

1. Does the member have an Eastern Cooperative Oncology Group (ECOG) performance score between 0-1?
   ☐ Yes ☐ No

   Please list ECOG performance score
2. Does the member have an estimated life expectancy > 6 months? ☐ Yes ☐ No
3. Does the member have hepatic metastases? ☐ Yes ☐ No
4. Does the member currently have symptoms? ☐ Yes ☐ No

   If yes, are the symptoms minimal? ☐ Yes ☐ No (please explain)

Section III. Please complete for abiraterone 250 mg and 500 mg, Erleada, Nubeqa, Xtandi, and Yonsa requests.

1. Will the requested medication be used in combination with a gonadotropin-releasing hormone (GnRH) analog?

   ☐ Yes. Drug name Dose and frequency ☐ No
2. Has the member had a bilateral orchiectomy? ☐ Yes ☐ No
3. For abiraterone 250 mg and 500 mg, does the member have metastatic high-risk castration-sensitive prostate cancer? ☐ Yes ☐ No

   If yes, will the requested medication be used in combination with prednisone? ☐ Yes ☐ No
4. For abiraterone 500 mg tablet, please provide medical necessity for use instead of abiraterone 250 mg tablet.
5. For Erleada and Xtandi for metastatic castration-sensitive prostate cancer, has the member tried abiraterone?
   ☐ Yes. Please list the dates/duration of use, dose and frequency, and outcome below.

   Dates of use Dose and frequency

   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Explain why not.
6. For Xtandi for metastatic castration-resistant prostate cancer, will the requested medication be used as monotherapy? ☐ Yes ☐ No

   If no, will the requested medication be used with Talzenna? ☐ Yes ☐ No
7. For Erleada and Nubeqa for non-metastatic castration-resistant prostate cancer, has the member tried Xtandi?
   ☐ Yes. Please list the dates/duration of use, dose and frequency, and outcome below.

   Dates of use Dose and frequency

   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Explain why not.
8. For Nubeqa for metastatic hormone-sensitive prostate cancer or metastatic castration-sensitive prostate cancer, will the requested medication be used in combination with docetaxel? ☐ Yes ☐ No
9. For Yonsa, will the requested medication be used in combination with methylprednisolone? ☐ Yes ☐ No

over

Section IV. Please complete for Akeega requests.

1. Does the member have deleterious or suspected deleterious germline or somatic BRCA gene mutation?
   ☐ Yes ☐ No
2. Will the requested medication be used in combination with prednisone? ☐ Yes ☐ No

Section V. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen? ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

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Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Proton Pump Inhibitor
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Aciphex Sprinkle (rabeprazole delayed release capsule)
- ☐ dexlansoprazole
- ☐ esomeprazole magnesium capsule > 1 unit/day
- ☐ esomeprazole magnesium 20 mg, 40 mg suspension
- ☐ esomeprazole magnesium 2.5 mg, 5 mg, 10 mg suspension ≥ 2 years and > 1 unit/day
- ☐ esomeprazole sodium IV
- ☐ First-Omeprazole (omeprazole suspension compounding kit)
- ☐ Konvomep (omeprazole/sodium bicarbonate suspension)
- ☐ lansoprazole capsule > 1 unit/day
- ☐ omeprazole 10 mg > 1 unit/day
- ☐ omeprazole 20 mg > 4 units/day
- ☐ omeprazole 40 mg > 2 units/day
- ☐ omeprazole/sodium bicarbonate powder for oral suspension
- ☐ pantoprazole tablet > 4 units/day
- ☐ Prilosec (omeprazole suspension)
- ☐ rabeprazole delayed-release tablet > 1 unit/day

Dose and frequency of requested agent

Intended duration of therapy

Indication (Check all that apply or include ICD-10 code, if applicable)

- ☐ **GERD**
  - ☐ Moderate-severe erosive esophagitis
  - ☐ Uncomplicated nonerosive esophagitis
  - ☐ Barrett's esophagus
  - ☐ GERD in child with one of the following conditions
    - ☐ Severe chronic respiratory disease (specify)
    - ☐ Neurologic disability (specify)
    - ☐ Other (specify)
- ☐ **Condition associated with extraesophageal symptoms secondary to gastric reflux**
  - ☐ Noncardiac chest pain
  - ☐ Asthma
  - ☐ Idiopathic hoarseness
  - ☐ Chronic laryngitis
  - ☐ Other (explain)
- ☐ **Duodenal ulcer**
  - ☐ Helicobacter pylori
  - ☐ Drug-induced
  - ☐ Treatment. List causative agent(s).
  - ☐ Prevention. List risk factor(s).
  - ☐ Other cause (specify)
- ☐ **Gastric ulcer**
  - ☐ Positive
  - ☐ Negative

☐ **Pathological hypersecretory syndromes**
- ☐ Zollinger-Ellison syndrome
- ☐ MEN Type I
- ☐ Other

☐ **Other (explain)**

Diagnostic studies performed (include dates of studies). Describe any diagnostic studies performed, including dates of studies.

Section I. Please complete for requests for Aciphex Sprinkle, dexlansoprazole, esomeprazole magnesium 2.5 mg and 5 mg suspension, esomeprazole 20 mg, 40 mg suspension, and Prilosec suspension.

Has the member had a trial with esomeprazole magnesium capsule, lansoprazole, omeprazole, pantoprazole, or rabeprazole tablet?

☐ Yes. Please list the specific drug name, dates/duration of use, and outcomes below.

Drug name, dose and frequency Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name, dose and frequency Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please describe clinical rationale why these trials are not appropriate for this member.

Section II. Please complete for requests for omeprazole 20 mg capsules and pantoprazole tablets at quantities > 4 units/day, omeprazole 40 mg capsules > 2 units/day, and any other oral proton pump inhibitor at quantities > 1 unit/day.

Please describe medical necessity for use above the established quantity limits. Attach medical records documenting inadequate response to once daily dosing of the requested agent, with dates, as appropriate.

Section III. Please complete for requests for esomeprazole sodium IV and First-Omeprazole.

1. Please describe medical necessity for use of the requested formulation.
2. For esomeprazole sodium IV, has the member had a trial with pantoprazole IV?
   ☐ Yes. Please list dates/duration of use and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

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☐ No. Please describe clinical rationale why pantoprazole IV is not appropriate for this member.

Section IV. Please complete for requests for Konvomep or omeprazole/sodium bicarbonate powder for oral suspension.

1. Has the member had a trial with two of the following: esomeprazole suspension, lansoprazole orally disintegrating tablet, omeprazole capsule, or pantoprazole suspension?
   ☐ Yes. Please list the drug name, dose, frequency, dates/duration of use, and outcomes below.

   Drug name, dose, and frequency Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   Drug name, dose, and frequency Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe clinical rationale why these trials are not appropriate for this member.
2. For Konvomep, has the member had a trial with omeprazole/sodium bicarbonate powder for oral suspension [Zegerid]?
   ☐ Yes. Please list the dose, frequency, dates/duration of use, and outcomes below.

   Drug dose and frequency Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe clinical rationale why this trial is not appropriate for this member.
3. Please describe medical necessity for use of the requested formulation.

Section V. Please complete for requests for esomeprazole 2.5 mg, 5 mg, 10 mg suspension ≥ 2 years of age and > 1 unit/day.

Please attach medical records documenting inadequate response to once daily dosing of the requested agent, with dates, as appropriate.

Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

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2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Pulmonary Hypertension
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested (Check one or all that apply. Where applicable, the brand name is provided in brackets for reference.)

- ☐ Adempas (riociguat)
- ☐ ambrisentan
- ☐ bosentan
- ☐ epoprostenol [Veletri]
- ☐ Liqrev (sildenafil oral suspension)
- ☐ Opsumit (macitentan)
- ☐ Opsynvi (macitentan/tadalafil)
- ☐ Orenitram (treprostinil extended-release tablet)
- ☐ sildenafil 20 mg tablet
- ☐ sildenafil oral suspension [Revatio]
- ☐ tadalafil tablet
- ☐ Tadliq (tadalafil suspension)
- ☐ treprostinil injection
- ☐ Tyvaso (treprostinil inhalation solution)
- ☐ Tyvaso DPI (treprostinil inhalation powder)
- ☐ Uptravi (selexipag)
- ☐ Ventavis (iloprost inhalation)
- ☐ Winrevair (sotatercept-csrk)
- ☐ Other*

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Dose, frequency, and duration of medication requested

Is the member stabilized on the requested medication?

☐ Yes. Please provide start date. ☐ No

Section I. Please complete for all requests.

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Chronic thromboembolic pulmonary hypertension (CTEPH)
- ☐ Pulmonary arterial hypertension (PAH)
- ☐ Pulmonary hypertension associated with interstitial lung disease (PH-ILD)
- ☐ Other (Please indicate.)

Please indicate prescriber specialty below.

☐ Cardiology ☐ Pulmonology ☐ Other (Please indicate.)

Please attach copies of medical records and/or office notes from cardiologist or pulmonologist regarding the diagnosis.

Section II. Please also complete for tadalafil tablet and Tadliq requests.

1. Has the member tried sildenafil 20 mg tablet?
   ☐ Yes. Please provide the following information.*

   Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Does the member have a contraindication to sildenafil? Please explain.

2. Is the member treatment naïve? ☐ Yes ☐ No
   If yes, will the requested agent be used in combination with ambrisentan? ☐ Yes ☐ No
3. Will the requested agent be administered concurrently with Adempas? ☐ Yes. Please explain below. ☐ No
4. For Tadliq, please provide medical necessity for the use of the requested formulation instead of tadalafil tablet.

Section III. Please also complete for Adempas requests.

1. Will Adempas be administered concurrently with a phosphodiesterase-5 inhibitor (sildenafil or tadalafil)?
   ☐ Yes. Please explain below. ☐ No
2. For members with CTEPH, please describe surgical history and/or prognosis.
3. For members with pulmonary arterial hypertension, has the member tried sildenafil or tadalafil?
   ☐ Yes. Please provide the following information.*
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   ☐ No. Does the member have a contraindication to sildenafil and tadalafil? Please explain.

Section IV. Please also complete for Orenitram, treprostinil injection, Tyvaso, Tyvaso DPI, and Ventavis for PAH requests.

Has the member tried epoprostenol (Veletri) or Flolan?
☐ Yes. Please provide the following information.*
Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.
☐ No. Does the member have a contraindication to epoprostenol (Veletri) or Flolan? Please explain.

Section V. Please also complete for Tyvaso DPI for PH-ILD requests.

Please attach medical records documenting inadequate response, adverse reaction, or contraindication to Tyvaso inhalation solution.

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Section VI. Please also complete for epoprostenol (Veletri) requests.

Has the member tried Flolan?

☐ Yes. Please provide the following information.*

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

☐ No. Does the member have a contraindication to Flolan? Please explain.

Section VII. Please also complete for Liqrev, sildenafil 20 mg tablet and oral suspension [Revatio] requests.

1. Will sildenafil be administered concurrently with Adempas? ☐ Yes. Please explain below. ☐ No
2. For Liqrev and sildenafil oral suspension [Revatio], please provide medical necessity for the use of the requested formulation instead of sildenafil tablet.
3. For Liqrev, please provide medical necessity for the use of the requested formulation instead of sildenafil oral suspension [Revatio].

* Please attach a letter documenting additional trials as necessary.

Section VIII. Please also complete for bosentan for suspension requests.

Member's current weight Date

Section IX. Please also complete for Uptravi vial requests.

1. Is the member stabilized on Uptravi tablets?

   ☐ Yes. Please provide start date. ☐ No
2. Is the member temporarily unable to take oral medications?

   ☐ Yes. Please explain.

   ☐ No

Section X. Please also complete for Opsynvi requests.

1. Please provide medical necessity for the use of the combination product instead of the commercially available separate agents.

5. Will the requested agent be administered concurrently with Adempas? ☐ Yes. Please explain below. ☐ No

Section XI. Please also complete for Winrevair requests.

1. Member's current weight Date
2. Please document member's current WHO functional class. ☐ I ☐ II ☐ III ☐ IV

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3. Is the member stable on background therapy for PAH? ☐ Yes. ☐ No.
4. For recertification requests, please attach medical records documenting a positive response to therapy.

Section XII. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

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Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Rezdiffra
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Dose, frequency, and duration requested

Drug NDC (if known) or service code

Indication or ICD-10 code, if applicable

☐ Nonalcoholic steatohepatitis (NASH) or metabolic dysfunction-associated steatohepatitis (MASH), with moderate to advanced liver fibrosis

☐ Other

Is the prescriber a gastroenterologist or hepatologist?
☐ Yes
☐ No. Please attach consultation notes from a gastroenterologist or hepatologist addressing the use of the requested agent.

Section I. Please complete for all requests.

1. Please provide medical records documenting the results from liver biopsy or non-invasive testing (NIT) supporting diagnosis.
2. Please provide fibrosis stage (i.e., Metavir Score)
3. Please document member's current weight. Date
4. Has the member been counseled to continue a reduced-calorie diet and increased physical activity? ☐ Yes ☐ No.
5. Has the member been counseled to abstain from alcohol use? ☐ Yes ☐ No.
6. For recertification requests, please attach medical records documenting positive response to therapy (e.g., laboratory or imaging testing).

Section II. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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T-cell Immunotherapies
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Columvi (glofitamab-gxbm) [MB]
- ☐ Elrexfio (elranatamab-bcmm) [MB]
- ☐ Epkinly (epcoritamab-bysp) [MB]
- ☐ Imdelltra (tarlatamab-dlle) [MB]
- ☐ Lunsumio (mosunetuzumab-axgb) [MB]
- ☐ Talvey (talquetamab-tgvs) [MB]
- ☐ Tecvayli (teclistamab-cqyv) [MB]

[MB] *This drug is available through the healthcare professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other healthcare professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

[§] Columvi requests only
[‡] Elrexfio, Talvey, and Tecvayli requests only
*** Epkinly requests only**
[¶] Imdelltra requests only
[‖] Lunsumio requests only

- ☐ Extensive stage small cell lung cancer (ES-SCLC) [¶]
- ☐ Relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy [‖] *
- ☐ Relapsed or refractory DLBCL NOS, DLBCL arising from indolent lymphoma, DLBCL arising from high-grade B-cell lymphoma*
- ☐ Relapsed or refractory DLBCL, not otherwise specified or LBCL arising from follicular lymphoma [§]
- ☐ Relapsed or refractory multiple myeloma (RRMM) [‡]

Please describe pertinent mutations if applicable.

☐ HLA-A*02:01P ☐ HLA-A*02:02P ☐ HLA-A*02:03P ☐ HLA-A*02:06P ☐ Ph+

Please describe the cell histology, if applicable.

Please indicate prescriber specialty below.

☐ Hematology ☐ Oncology ☐ Other

Section I. Please complete for all requests.

1. Member's current weight Date
2. Please indicate billing preference. ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.
   Drug NDC (if known) or service code

3. Please provide anticipated dates for the following as applicable.
   Treatment date ☐ Admission ☐ Infusion ☐ Discharge ☐
4. Please provide the infusion setting. ☐ Inpatient ☐ Outpatient
5. Will the infusion take place in a qualified treatment facility or, as applicable, a healthcare facility that has been certified pursuant to the Risk Evaluation and Mitigation Strategy (REMS) program specific to the treatment being provided? ☐ Yes ☐ No
6. Please list any other prior trials including the drug names, dates/duration of use, and outcomes below. Please note, Elrexfio, Talvey, and Tecvayli are FDA-approved for use after four or more lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. *
   Drug ☐ Dates/duration ☐ ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   Drug ☐ Dates/duration ☐ ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   Drug ☐ Dates/duration ☐ ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   Drug ☐ Dates/duration ☐ ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

**Attach a letter with additional information regarding medication trials as applicable.*

Section II. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name ☐ Dates/duration of use ☐

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

☐ Yes. Please provide details.
☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
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☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Targeted Immunomodulators
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested	Requested indication
Anti-TNFs (See Section I for all requests, as applicable.)	
☐ Abrilada (adalimumab-afzb) ☐ adalimumab-aacf, unbranded ☐ adalimumab-aaty, unbranded ☐ adalimumab-adaz, unbranded ☐ adalimumab-adbm, unbranded ☐ adalimumab-fkjp, unbranded ☐ adalimumab-ryvk, unbranded ☐ Amjevita (adalimumab-atto) ☐ Avsola (infliximab-axxq) ☐ Cimzia (certolizumab) ☐ Cyltezo (adalimumab-adbm) ☐ Enbrel (etanercept) ☐ Hadlima (adalimumab-bwwd) ☐ Hulio (adalimumab-fkjp) ☐ Humira (adalimumab) ☐ Hyrimoz (adalimumab-adaz) ☐ Idacio (adalimumab-aacf) ☐ Inflectra (infliximab-dyyb) ☐ infliximab, unbranded ☐ Remicade (infliximab) ☐ Renflexis (infliximab-abda) ☐ Simlandi (adalimumab-ryvk) ☐ Simponi (golimumab) ☐ Simponi Aria (golimumab for infusion) ☐ Yuflyma (adalimumab-aaty) ☐ Yusimry (adalimumab-aqvh) ☐ Zymfentra (infliximab-dyyb)	☐ Ankylosing spondylitis (AS) (Section VII) ☐ Crohn's disease ☐ Fistulizing Crohn's disease ☐ Hidradenitis suppurativa (HS) (Hurley Stage II or III) ☐ Non-infectious uveitis (Section XIII) ☐ Non-radiographic axial spondyloarthritis (nr-AxSpA) (Section XI) ☐ Plaque psoriasis (PsO) (Section IV) ☐ Polyarticular juvenile idiopathic arthritis (Section VI) ☐ Psoriatic arthritis (PsA) ☐ Rheumatoid arthritis (RA) (Section II) ☐ Ulcerative colitis (UC) ☐ Other
Interleukin Antagonists (See Section I for all requests, as applicable.)	
☐ Actemra (tocilizumab auto-injection, prefilled syringe) ☐ Actemra (tocilizumab vial) MB ☐ Adbry (tralokinumab-ldrm) ☐ Arcalyst (rilonacept)	☐ Adult-onset Still's disease (AOSD) (Section XIX) ☐ Ankylosing spondylitis (AS) (Section VII) ☐ Atopic dermatitis (Section IX) ☐ Crohn's disease ☐ Cytokine release syndrome (Section XII)

☐ Bimzelx (bimekizumab-bkzx) ☐ Cosentyx (secukinumab auto-injection, prefilled syringe) ☐ Cosentyx (secukinumab 125 mg/5 mL vial) MB ☐ Ebglyss (lebrikizumab-lbkz) ☐ Ilaris (canakinumab) ☐ Ilumya (tildrakizumab-asmn) ☐ Kevzara (sarilumab) ☐ Kineret (anakinra) ☐ Omvoh (mirikizumab-mrkz) ☐ Otulfi (ustekinumab-aauz prefilled syringe) ☐ Otulfi (ustekinumab-aauz vial) MB ☐ Pyzchiva (ustekinumab-ttwe prefilled syringe) ☐ Pyzchiva (ustekinumab-ttwe vial) MB ☐ Selarsdi (ustekinumab-aekn prefilled syringe) ☐ Selarsdi (ustekinumab-aekn vial) MB ☐ Siliq (brodalumab) ☐ Skyrizi (risankizumab-rzaa) ☐ Spevigo (spesolimab-sbzo) (Section XXVI) ☐ Stelara (ustekinumab 45 mg/0.5 mL prefilled syringe, 90 mg/mL prefilled syringe, 45 mg/0.5 mL vial) ☐ Stelara (ustekinumab 130 mg/26 mL vial) MB ☐ Steqeyma (ustekinumab-stba prefilled syringe) ☐ Steqeyma (ustekinumab-stba vial) MB ☐ Taltz (ixekizumab) ☐ Tofidence (tocilizumab-bavi) MB ☐ Tremfya (guselkumab) ☐ Tyenne (tocilizumab-aazg auto-injection, prefilled syringe) ☐ Tyenne (tocilizumab-aazg vial) MB ☐ ustekinumab-aekn, unbranded prefilled syringe ☐ ustekinumab-ttwe, unbranded prefilled syringe ☐ ustekinumab-ttwe, unbranded vial MB ☐ Yesintek (ustekinumab-kfce prefilled syringe, 45 mg/0.5 mL vial) ☐ Yesintek (ustekinumab-kfce 130 mg/26 mL vial) MB	☐ Deficiency of interleukin-1 receptor antagonist (DIRA) (Section XVI) ☐ Enthesitis-related arthritis (ERA) ☐ Familial cold autoinflammatory syndrome (FCAS) (Section XVII) ☐ Familial Mediterranean fever (FMF) (Section XVIII) ☐ Generalized Pustular Psoriasis ☐ Giant cell arteritis (GCA) (Section XIV) ☐ Gout flares (Section X) ☐ Hidradenitis suppurativa (HS) (Hurley Stage II or III) (Section XXVII) ☐ Hyperimmunoglobulin D syndrome (HIDS)/ Mevalonate kinase deficiency (MKD) (Section XVIII) ☐ Juvenile idiopathic arthritis (JIA) ☐ Polyarticular (Section VI) ☐ Systemic (Section XIX, XX) ☐ Muckle-Wells syndrome (MWS) (Section XVII) ☐ Neonatal-onset multisystem inflammatory disease (NOMID) ☐ Non-radiographic axial spondyloarthritis (nr-AxSpA) ☐ Plaque psoriasis (PsO) (Section IV) ☐ Polymyalgia rheumatica (PMR) (Section XXIV) ☐ Psoriatic arthritis (PsA) (Section V) ☐ Recurrent pericarditis (Section XXII) ☐ Rheumatoid arthritis (RA) (Section II) ☐ Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) (Section XV) ☐ Tumor necrosis factor receptor associated periodic syndrome (TRAPS) (Section XVIII) ☐ Ulcerative colitis (UC) (Section III) ☐ Other
Oral Janus Kinase Inhibitors (See Section I for all requests, as applicable.)	
☐ Cibinqo (abrocitinib) ☐ Litfulo (ritlecitinib) ☐ Olumiant (baricitinib) ☐ Rinvoq (upadacitinib ER tablet) ☐ Rinvoq LQ (upadacitinib oral solution) ☐ Xeljanz (tofacitinib) ☐ Xeljanz XR (tofacitinib extended-release)	☐ Alopecia areata (Section XXIII) ☐ Ankylosing spondylitis (AS) (Section VII) ☐ Atopic dermatitis (Section IX) ☐ Crohn's disease (Section VIII) ☐ Non-radiographic axial spondyloarthritis (nr-AxSpA) (Section XI) ☐ Polyarticular juvenile idiopathic arthritis (Section VI) ☐ Psoriatic arthritis (PsA) (Section V) ☐ Rheumatoid arthritis (RA) (Section II) ☐ Ulcerative colitis (UC) (Section III) ☐ Other

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Miscellaneous Agents (See Section I for all requests, as applicable.)	
☐ Entyvio (vedolizumab) ☐ Orencia (abatacept auto-injection, prefilled syringe) ☐ Orencia (abatacept vial) [MB] ☐ Otezla (apremilast) ☐ Sotyktu (deucravacitinib) ☐ Velsipity (etrasimod) ☐ Zeposia (ozanimod)	☐ Acute graft versus host disease (aGVHD) prophylaxis (Section XXI) ☐ Crohn's disease (Section VIII) ☐ Fistulizing Crohn's disease ☐ Polyarticular juvenile idiopathic arthritis (Section VI) ☐ Oral ulcers associated with Behcet's disease ☐ Plaque psoriasis (PsO) (Section IV) ☐ Psoriatic arthritis (PsA) (Section V) ☐ Rheumatoid arthritis (RA) (Section II) ☐ Ulcerative colitis (UC) (Section III, XXV) ☐ Other

Dose, frequency, and duration of medication requested

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA and criteria, if applicable.*

Section I. Please complete for all requests, as applicable.

1. Member's current weight Date
2. Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.
   Drug NDC (if known) or service code
3. Is the member stabilized on the requested medication? ☐ Yes. Please provide start date. ☐ No
4. Please indicate prescriber specialty below.
   ☐ Allergy/Immunology ☐ Dermatology ☐ Gastroenterology ☐ Rheumatology ☐ Other
5. Please specify severity of indication.
   ☐ Mild ☐ Mild-moderate ☐ Moderate ☐ Moderate-severe ☐ Severe
6. For quantities above quantity limits, please describe the clinical rationale for exceeding the quantity limit.
7. For Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, has the member had a trial with Humira?
   ☐ Yes. Please attach medical records documenting an inadequate response or adverse reaction to Humira.
   ☐ No. Please document clinical rationale for use of the requested agent instead of Humira.
8. For Actemra, please provide clinical rationale for use instead of Tyenne.
9. For Cimzia vial, please provide clinical rationale for use instead of Cimzia prefilled syringe.
10. For Cimzia, all infliximab products, Simponi, and Simponi Aria, please provide clinical rationale for use instead of Enbrel and Humira, if applicable. For requests for all infliximab products for a diagnosis of UC, a trial with Humira is not required.

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11. For Inflectra, Remicade, and Renflexis, please provide clinical rationale for use instead of unbranded infliximab and Avsola.
12. For Olumiant, Rinvoq, and Rinvoq LQ, please document a trial with Xeljanz or Xeljanz XR, or provide clinical rationale for use of the requested agent instead of both Xeljanz and Xeljanz XR, if applicable.
13. For Omvoh 100 mg/mL and 200 mg/2 mL pen and syringe for Crohn's disease, please provide clinical rationale for use of the requested formulation instead of the 300 mg dose pack. For Omvoh 300 mg dose pack for ulcerative colitis, please provide clinical rationale for use of the requested formulation instead of the 100 mg/mL and 200 mg/2 mL pen and syringe.
14. For Otulfi, Pyzchiva, Selarsdi, Steqeyma, Yesintek, and unbranded ustekinumab generics, has the member had a trial with Stelara?
    ☐ Yes. Please attach medical records documenting an inadequate response or adverse reaction to Stelara.
    ☐ No. Please document clinical rationale for use of the requested agent instead of Stelara.
15. For Rinvoq LQ, please provide medical necessity for use of the oral solution formulation.
16. For Zymfentra, please document the medical necessity for the subcutaneous formulation instead of an intravenous infliximab formulation.
    Is the member currently stable on an infliximab product? ☐ Yes ☐ No
    If yes, provide start date. If no, explain why not.

Section II. Please also complete for treatment of RA with Actemra, any adalimumab product, Avsola, Cimzia, Enbrel, Inflectra, unbranded infliximab, Kevzara, Kineret, Olumiant, Orencia, Remicade, Renflexis, Rinvoq, Simponi, Simponi Aria, Tofidence, Tyenne, Xeljanz, or Xeljanz XR.

For Olumiant, Rinvoq, Xeljanz, and Xeljanz XR requests, only question 3 is required. For all other requests, please complete questions 1 and 2.

1. Has the member tried traditional disease-modifying antirheumatic drugs (DMARDs)?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.
2. Has the member tried one biologic DMARD that is FDA-approved for RA?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.
3. For Olumiant, Rinvoq, Xeljanz, and Xeljanz XR, has the member tried one anti-TNF agent that is FDA-approved for RA?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.

Section III. Please also complete for treatment of UC with Entyvio, Rinvoq, Tremfya, Xeljanz, and Xeljanz XR.

1. For Entyvio, Rinvoq, Xeljanz, and Xeljanz XR, has the member tried one anti-TNF agent that is FDA-approved for UC?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*

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☐ No. Please explain why not.

2. For Tremfya, has the member tried Stelara, Skyrizi, Omvoh, and one anti-TNF agent that is FDA-approved for UC?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.

Section IV. Please also complete for treatment of PsO with any adalimumab product, Avsola, Bimzelx, Cimzia, Cosentyx, Enbrel, Ilumya, Inflectra, unbranded infliximab, Otezla, Remicade, Renflexis, Siliq, Skyrizi, Sotyktu, Stelara, Taltz, Tremfya, or any ustekinumab product.

For Otezla requests, only question 1 is required. For Sotyktu requests, only questions 2 and 4 are required. For all other requests, please complete questions 1 through 3, as applicable.

1. Has the member tried other therapies to treat this condition including topical agents, systemic agents, and phototherapy?
   ☐ Yes. Please list the names of therapies, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.
2. Has the member tried one biologic DMARD that is FDA-approved for PsO?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.
3. For Bimzelx, Cosentyx, Ilumya, Siliq, and Tremfya, has the member tried Stelara, Skyrizi, Taltz, and one anti-TNF agent that is FDA-approved for PsO?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.
4. For Sotyktu, has the member tried Otezla?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.

Section V. Please also complete for treatment of PsA with Bimzelx, Cosentyx, Orencia, Rinvoq, Rinvoq LQ, Tremfya, Xeljanz, or Xeljanz XR.

1. For Bimzelx, Cosentyx for a member ≥ 18 years, and Tremfya, has the member tried Stelara, Skyrizi, Taltz, and one anti-TNF agent that is FDA-approved for PsA?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.
2. For Cosentyx for a member two to < 18 years, has the member tried Enbrel or Humira?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.
3. For Orencia, has the member tried one anti-TNF agent that is FDA-approved for PsA?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.
4. For Rinvoq, Rinvoq LQ, Xeljanz, or Xeljanz XR, has the member tried a traditional DMARD, and one anti-TNF agent that is FDA-approved for PsA?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.

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Section VI. Please also complete for treatment of polyarticular JIA with Actemra, any adalimumab product, Enbrel, Kevzara, Orencia, Rinvoq, Rinvoq LQ, Simponi Aria, Tofidence, Tyenne, or Xeljanz.

For Kevzara requests, only questions 1, 2, and 4 are required. For Rinvoq and Rinvoq LQ requests, only question 3 is required. For all other requests, please complete questions 1 through 3.

1. Has the member tried traditional disease-modifying antirheumatic drugs (DMARDs)?
   - ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   - ☐ No. Please explain why not.
2. Has the member tried one biologic DMARD that is FDA-approved for polyarticular JIA?
   - ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   - ☐ No. Please explain why not.
3. Has the member tried one anti-TNF agent?
   - ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   - ☐ No. Please explain why not.
4. For Kevzara, has the member tried Enbrel or Humira?
   - ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   - ☐ No. Please explain why not.

Section VII. Please also complete for treatment of AS with anti-TNFs, Bimzelx, Cosentyx, Rinvoq, Taltz, Xeljanz, and Xeljanz XR.

1. Has the member tried two nonsteroidal anti-inflammatory drugs (NSAIDs)?
   - ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   - ☐ No. Please explain why not.
2. For Bimzelx, Cosentyx, Rinvoq, Xeljanz, and Xeljanz XR, has the member tried one anti-TNF agent that is FDA-approved for AS?
   - ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   - ☐ No. Please explain why not.
3. For Bimzelx, Cosentyx, and Rinvoq, has the member tried Taltz?
   - ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   - ☐ No. Please explain why not.

Section VIII. Please also complete for treatment of Crohn's disease with Entyvio and Rinvoq.

Has the member tried one anti-TNF agent that is FDA-approved for Crohn's disease?

- ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
- ☐ No. Please explain why not.

Section IX. Please complete for treatment of atopic dermatitis with Adbry, Cibinqo, Ebglyss, and Rinvoq.

1. Body surface area (BSA) to be treated
2. Has the member tried a superpotent or potent topical corticosteroid to treat this condition?
   - ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   - ☐ No. Please explain why not.

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3. Has the member tried topical tacrolimus or Eucrisa to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   ☐ No. Please explain why not.
4. For Adbry and Ebglyss, has the member tried other medications to treat this condition, including a systemic immunomodulatory agent?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   ☐ No. Please explain why not.
5. For Cibinqo and Rinvoq, has the member tried Dupixent to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   ☐ No. Please explain why not.
6. For Cibinqo 200 mg tablet, has the member tried Cibinqo 100 mg dose?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   ☐ No. Please explain why not.

Section X. Please also complete for treatment of gout flares with Ilaris.

Has the member tried colchicine, corticosteroids, and NSAIDs?
☐ Yes. Please list the drug names, dates/duration of trial, and outcome in Section XXVIII below.*
☐ No. Please explain why not.

Section XI. Please also complete for treatment of nr-AxSpA with Bimzelx, Cimzia, Cosentyx, Rinvoq, and Taltz.

1. Has the member tried two nonsteroidal anti-inflammatory drugs (NSAIDs)?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.
2. For Bimzelx, Cosentyx, and Rinvoq, has the member tried one anti-TNF agent and Taltz?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.

Section XII. Please complete for treatment of cytokine release syndrome with Actemra IV, Tofidence, and Tyenne.

Please provide anticipated date of administration with concurrent CAR T-cell therapy.

Section XIII. Please complete for treatment of non-infectious uveitis with Humira and adalimumab.

Has the member tried other medications to treat this condition including glucocorticoid and immunosuppressive therapy?
☐ Yes. Please list the drug name, dates/duration of trials, and outcomes in Section XXVIII below.*
☐ No. Please explain why not.

Section XIV. Please complete for treatment of GCA with Actemra, Tofidence, and Tyenne.

Has the member tried other medications to treat this condition including glucocorticoid therapy?
☐ Yes. Please list the drug name, dates/duration of trials, and outcomes in Section XXVIII below.*
☐ No. Please explain why not.

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Section XV. Please complete for treatment of SSc-ILD with Actemra SC and Tyenne SC.

Has the member tried cyclophosphamide or mycophenolate?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes in Section XXVIII below.*

☐ No. Please explain why not.

Section XVI. Please complete for treatment of DIRA with Arcalyst and Kineret.

1. Has the diagnosis been confirmed through genetic testing? ☐ Yes ☐ No
2. For Arcalyst, has the member tried Kineret?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   ☐ No. Please explain why not.

Section XVII. Please complete for treatment of FCAS and MWS with Arcalyst and Ilaris.

1. Has the diagnosis been confirmed through genetic testing? ☐ Yes ☐ No
   If no, does the member have evidence of symptoms indicative of the disease?
   ☐ Yes. Please explain. ☐ No
2. For Arcalyst, has the member tried Ilaris?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   ☐ No. Please explain why not.

Section XVIII. Please complete for treatment of FMF, HIDS/MKD, and TRAPS with Ilaris.

1. Has the diagnosis been confirmed through genetic testing? ☐ Yes ☐ No
   If no, does the member have evidence of symptoms indicative of the disease?
   ☐ Yes. Please explain. ☐ No
2. If the request is for treatment of FMF, has the member tried colchicine?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   ☐ No. Please explain why not.

Section XIX. Please complete for treatment of AOSD and systemic JIA with Ilaris.

Has the member tried other medications to treat this condition, including corticosteroids and Kineret?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes in Section XXVIII below.*

☐ No. Please explain why not.

Section XX. Please complete for treatment of systemic JIA with Actemra, Tofidence, and Tyenne.

1. Has the member tried a traditional DMARD?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.
2. Has the member tried one biologic DMARD that is FDA-approved for systemic JIA?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   ☐ No. Please explain why not.

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Section XXI. Please complete for aGVHD prophylaxis with Orencia.

1. Will the requested agent be used in combination with a calcineurin inhibitor?
   - ☐ Yes. Please list drug name, dose, and frequency below.
     Drug name _____ Dose and frequency _____
   - ☐ No. Please explain why not. _____
2. Will the requested agent be used in combination with methotrexate?
   - ☐ Yes. Please list dose and frequency. _____
   - ☐ No. Please explain why not. _____

Section XXII. Please complete for treatment of recurrent pericarditis with Arcalyst.

1. Has the member tried aspirin or NSAIDs?
   - ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   - ☐ No. Please explain why not. _____
2. Has the member tried colchicine, corticosteroids, and Kineret?
   - ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   - ☐ No. Please explain why not. _____

Section XXIII. Please complete for treatment of alopecia areata with Litfulo and Olumiant.

Has the member tried other medications to treat this condition, including a topical corticosteroid, an intralesional corticosteroid, and Xeljanz or Xeljanz XR?

- ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
- ☐ No. Please explain why not. _____

Section XXIV. Please complete for treatment of PMR with Kevzara.

1. Has the member tried a systemic corticosteroid to treat this condition?
   - ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   - ☐ No. Please explain why not. _____
2. Has the member tried methotrexate to treat this condition?
   - ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   - ☐ No. Please explain why not. _____

Section XXV. Please also complete for treatment of UC with Velsipity and Zeposia.

1. Has the member tried one anti-TNF agent that is FDA-approved for UC?
   - ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.*
   - ☐ No. Please explain why not. _____
2. Has the member tried Entyvio?
   - ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   - ☐ No. Please explain why not. _____

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Section XXVI. Please also complete for Spevigo.

1. For Spevigo prefilled syringe, has the member tried a biologic DMARD?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XXVIII below.
   ☐ No. Please explain why not.
2. For Spevigo prefilled syringe, has the member had a positive response to treatment for an acute pustular psoriasis flare using Spevigo vial? ☐ Yes ☐ No

Section XXVII. Please also complete for treatment of HS with Bimzelx and Cosentyx.

1. For Bimzelx, has the member tried Cosentyx and Humira ?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   ☐ No. Please explain why not.
2. For Cosentyx, has the member tried Humira?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XXVIII below.*
   ☐ No. Please explain why not.

Section XXVIII. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

Drug name/Therapy Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

Drug name/Therapy Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

Drug name/Therapy Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

Drug name/Therapy Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

Drug name/Therapy Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

** Please attach a letter documenting additional trials as necessary.*

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Section XXIX. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

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Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Thrombocytopenic Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Alvaiz (eltrombopag choline)
- ☐ Cablivi (caplacizumab-yhdp)
- ☐ Doptelet (avatrombopag)
- ☐ Mulpleta (lusutrombopag)
- ☐ Nplate (romiplostim) [MB]
- ☐ Promacta (eltrombopag olamine)
- ☐ Tavalisse (fostamatinib)

Dose and frequency _____ **Duration of therapy** _____

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code _____

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Acquired thrombotic thrombocytopenic purpura (aTTP)
- ☐ Chronic, relapsed, or refractory immune thrombocytopenia (ITP)
- ☐ Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)/Acute exposure to myelosuppressive doses of radiation
- ☐ Severe aplastic anemia
- ☐ Thrombocytopenia due to chronic liver disease (CLD)
- ☐ Thrombocytopenia in the setting of hepatitis C
- ☐ Other _____

Section I. Please complete for Doptelet and Mulpleta requests for thrombocytopenia due to chronic liver disease.

1. Is a procedure planned? ☐ Yes. Please provide anticipated date of procedure. _____ ☐ No
2. Please provide date and results of most recent platelet count (including laboratory reference ranges).
   _____
3. For Mulpleta requests, has the member had a trial with Doptelet?
   ☐ Yes. Please list the dates/duration of use and outcomes below.
   Dates/duration of use _____ ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   _____

☐ No. Please explain why not.

Section II. Please complete for Alvaiz, Doptelet, Nplate, Promacta, and Tavalisse requests for chronic, relapsed or refractory ITP.

1. Please provide date and results of most recent platelet count (including laboratory reference ranges). For platelet count > 30,000 cells/mcL, describe medical necessity for platelet elevation.
2. Has the member had a trial with a corticosteroid or immunoglobulin therapy?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcomes below.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Please explain why not.
3. Has the member had a splenectomy? ☐ Yes ☐ No
4. For Alvaiz, please describe medical necessity for use instead of Promacta.
5. For Doptelet, Nplate, and Tavalisse requests, has the member had a trial with eltrombopag?
   ☐ Yes. Please list the dates/duration of use and outcomes below.
   Dates/duration of use ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Please explain why not.

Section III. Please complete for Alvaiz and Promacta requests for thrombocytopenia in the setting of hepatitis C.

1. Please provide date and results of most recent platelet count (including laboratory reference ranges).
2. Is the member currently on interferon therapy? ☐ Yes. Please provide start date. ☐ No
3. For members not currently on interferon therapy, does the treatment plan include initiation of therapy with interferon? ☐ Yes ☐ No
4. For Alvaiz, please describe medical necessity for use instead of Promacta.

Section IV. Please complete for Alvaiz and Promacta requests for severe aplastic anemia.

1. Please provide date and results of most recent platelet count (including laboratory reference ranges).
2. Has the member had a trial with anti-thymocyte globulin (ATG)?
   ☐ Yes. Please list the dates/duration of use and outcomes below.
   Dates/duration of use ☐ Adverse reaction ☐ Inadequate response ☐ Other

over

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not.

3. Has the member had a trial with cyclosporine?
   ☐ Yes. Please list the dates/duration of use and outcomes below.

   Dates/duration of use ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain why not.
4. For Alvaiz, please describe medical necessity for use instead of Promacta.
5. For use of Promacta in combination with ATG and cyclosporine, please provide clinical rationale.

Section V. Please complete for Cablivi requests.

Will the member be taking the requested medication concurrently with immunosuppressive therapy?
☐ Yes. Please list the drug name and dates/duration of use.

Drug name Dates/duration of use

☐ No. Please explain why not.

Section VI. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

over

Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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over

Topical Anesthetics
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ lidocaine 5% patch > 3 patches/day

Dose/frequency _____ patch/patches every 12 hours/24 hours (with 12 hours off)

☐ Other _____

☐ lidocaine 4%patch > 4 patches/day. Dose/frequency _____

☐ Qutenza (capsaicin high dose patch) [MB] Dose/frequency _____

☐ Ztlido (lidocaine 1.8% patch) Dose/frequency _____

Number of patches requested/30 days _____

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Dermatological procedure requiring local analgesia. Please describe. _____
☐ Diabetic peripheral neuropathy
☐ Neurologic pain
☐ Post herpetic neuralgia
☐ Other _____

If other, does the type of pain being treated have a neuropathic component? ☐ Yes ☐ No

Please list all other medications currently prescribed for the member for this indication.

_____

_____

Section I. Please complete for requests for lidocaine patch and Ztlido exceeding quantity limits.

Please describe the medical necessity for using the requested agent above the quantity limit.

Section II. Please also complete for Ztlido requests.

Has the member had a trial with lidocaine 4% patches and lidocaine 5% patches?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use Dose and frequency

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use Dose and frequency

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using lidocaine 4% patches and lidocaine 5% patches in this member.

** Please attach a letter documenting additional trials as necessary.*

Section III. Please complete for Qutenza requests.

For requests for postherpetic neuralgia, please complete questions 1 and 2. For requests for diabetic peripheral neuropathy, please complete all of the following questions.

1. Has the member had a trial with lidocaine patch and a topical capsaicin agent?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use Dose and frequency

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use Dose and frequency

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using lidocaine patch and a topical capsaicin agent in this member.

2. Has the member had a trial with a tricyclic antidepressant and an anticonvulsant (gabapentin or pregabalin)?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use Dose and frequency

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

over

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use Dose and frequency

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe medical necessity for transdermal formulation.

3. Has the member had a trial with venlafaxine or duloxetine?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use Dose and frequency

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe medical necessity for transdermal formulation.

** Please attach a letter documenting additional trials as necessary.*

Section IV. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?

   ☐ Yes. Please provide details.

   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

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Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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over

Topical Corticosteroids
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Class I Superpotent products (See Sections I., II., and III.)

- ☐ clobetasol propionate: cream (0.025%)
- ☐ diflorasone: ointment
- ☐ halobetasol: foam
- ☐ halobetasol (Bryhali, Ultravate): lotion

Class II Potent products (See Sections I., II., and III.)

- ☐ desoximetasone (Topicort): ointment (0.25%), spray (0.25%), gel (0.05%)
- ☐ diflorasone (Apexicon-E): cream
- ☐ halcinonide (Halog): cream, solution

Class III Upper Mid-Strength Potent products (See Sections I., II., and III.)

- ☐ amcinonide: cream
- ☐ desoximetasone (Topicort): cream (0.05%), ointment (0.05%)
- ☐ diflorasone: cream

Class IV Mid-Strength Potent products (See Sections I., II., and III.)

- ☐ clocortolone: cream
- ☐ fluocinolone (Synalar): ointment-kit
- ☐ flurandrenolide: ointment
- ☐ triamcinolone: ointment (0.05%), spray

Class V Lower Mid-Strength Potent products (See Sections I., II., and III.)

- ☐ fluocinolone shampoo (Capex)
- ☐ fluocinolone (Synalar): cream-kit
- ☐ flurandrenolide: cream, lotion
- ☐ fluticasone propionate: lotion
- ☐ hydrocortisone butyrate: lotion
- ☐ hydrocortisone butyrate/emollient (Locoid Lipocream): cream

Class VI Mild Potent products (See Sections I., II., and III.)

- ☐ fluocinolone (Synalar): solution-kit

Class VII Least Potent products (See Sections I., II., and III.)

- ☐ hydrocortisone: solution

Combination products

- ☐ betamethasone/calcipotriene (Taclonex): ointment, scalp suspension
- ☐ halobetasol/tazarotene (Duobrii): lotion
- ☐ neomycin/fluocinolone: cream, cream-kit

Strength and formulation requested

Frequency and duration of therapy **Drug NDC (if known)**

Indication(s) or ICD-10 code(s), if applicable

Section I. Please complete for all requests, excluding combination products.

Has the member had a trial with all topical corticosteroids of the same formulation and potency range that are available without prior authorization?

☐ Yes. Please list the specific drug name, dates/duration of use, and outcomes below*.

Drug name, strength, and formulation ______ Dates/duration of use ______
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.
______

Drug name, strength, and formulation ______ Dates/duration of use ______
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.
______

Drug name, strength, and formulation ______ Dates/duration of use ______
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.
______

Drug name, strength, and formulation ______ Dates/duration of use ______
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.
______

Drug name, strength, and formulation ______ Dates/duration of use ______
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.
______

☐ No. Please explain contraindication or clinical rationale for not using other topical corticosteroid(s) that are available without prior authorization in this member.
______

Section II. Please complete for foam and shampoo formulations in scalp-related conditions.

Has the member had a trial with one topical corticosteroid of a similar formulation and similar or greater potency range that is available without prior authorization?

☐ Yes. Please list the specific drug name, dates/duration of use, and outcomes below*.

Drug name, strength, and formulation ______ Dates/duration of use ______
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.
______

☐ No. Please explain contraindication or clinical rationale for not using other topical corticosteroid(s) that are available without prior authorization for this member.
______

over

Section III. Please complete for foam, gel, kit, shampoo, solution, and spray formulations.

Explain medical necessity for the requested formulation.

Section IV. Please complete for combination products.

1. Provide medical necessity for the combination product instead of the individual agents.
2. For Duobrii, has the member had a trial with one superpotent or potent topical corticosteroid?
   ☐ Yes. Please list the specific drug name, dates/duration of use, and outcomes below.*
   Drug name, strength, and formulation Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   ☐ No

**Attach a letter with additional information regarding medication trials as applicable*.

Section V. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the healthcare provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Topical Vitamin D Analogues
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested and tube size

- ☐ calcipotriene cream (quantity > 60 grams/30 days)
  - ☐ 60 gram tube ☐ 120 gram tube
- ☐ calcipotriene foam
  - ☐ 60 gram tube ☐ 120 gram tube
- ☐ calcipotriene ointment (quantity > 60 grams/30 days)
  - ☐ 60 gram tube ☐ 120 gram tube
- ☐ calcitriol ointment
  - ☐ 100 gram tube
- ☐ Other*

Frequency of application

Indication (Check all that apply, or ICD-10 code, if applicable)

- ☐ Plaque psoriasis
- ☐ Other (Please indicate.)

Drug NDC (if known) or service code

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Section I. Please complete for requests for calcitriol ointment and calcipotriene foam.

1. Has the member had a trial with a topical corticosteroid?
   - ☐ Yes. Please list the drug name, dates/duration of use, and outcome of trial as noted below.*

     Drug name Dates/duration of use

     Did the member experience any of the following outcomes? ☐ Adverse reaction ☐ Inadequate response

     Briefly describe details of adverse reaction or inadequate response.
   - ☐ No. Does the member have a contraindication to topical corticosteroids? Please explain.
2. Has the member had a trial with calcipotriene cream, ointment, or scalp solution?
   - ☐ Yes. Please list the drug name, dates/duration of use, and outcome of trial as noted below.*

     Drug name Dates/duration of use

     Did the member experience any of the following outcomes? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

☐ No. Does the member have a contraindication to calcipotriene cream, ointment, and scalp solution?
Please explain.

** Please attach a letter documenting additional trials as necessary.*

Section II. Please complete for requests for quantities exceeding established quantity limits.

Please describe the clinical rationale for exceeding the quantity limit.

Section III. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

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Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan contact information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ Austedo (deutetrabenazine)

☐ Austedo XR (deutetrabenazine extended-release)

☐ Ingrezza (valbenazine)

☐ tetrabenazine

☐ Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Dose, frequency, and duration of requested medication _____

Drug NDC (if known) or service code _____

Indication (Check all that apply, or ICD-10 code if applicable.) _____

☐ chorea associated with Huntington's disease

☐ tardive dyskinesia

☐ persistent, disabling, or intrusive

☐ Other (Please describe.) _____

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

_____

Section I. Please complete for Austedo, Austedo XR, and Ingrezza requests.

1. For Huntington's disease, has the member had a trial with tetrabenazine?

   ☐ Yes. Please list the dates/duration of trial and outcomes. Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other. _____

   _____

   ☐ No. Please explain why not. _____

2. For Austedo and Austedo XR, doses > 36 mg/day, has the member been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer? ☐ Yes. ☐ No.

Section II. Please complete for tetrabenazine requests > 50 mg/day.

Has the member been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer? ☐ Yes. ☐ No.

Section III. Please complete and provide documentation for exceptions to step therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to, the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in, or physical or mental harm to, the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

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Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am either the prescribing provider or duly authorized to act on behalf of the provider identified in the Prescriber information section of this form. Any attached statement on letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Signature of provider or individual duly authorized to act on behalf of the provider:

Printed legal name and title of signatory above

Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

MassHealth Concomitant Opioid and Benzodiazepine Initiative

BACKGROUND

The MassHealth Concomitant Opioid and Benzodiazepine Initiative (COBI) requires prior authorization for members using opioid and benzodiazepine medications concomitantly. This is due, in part, to the growing data supporting the significant risk associated with the concomitant use of these medications. As part of this initiative, prior authorization is required for any benzodiazepine in members who fill both ≥ 15 days supply of benzodiazepines and an opioid within the past 45 days. Effective with the March 2024 MassHealth Drug list update, PA is required for members who are newly starting opioid therapy and are stable on benzodiazepine therapy for ≥ 15 days supply within the past 45 days. Members can receive up to a combined total of 14 days supply of one or more opioid(s) within the past 45-day period without PA. Please note: In general, members that are residents of nursing homes or chronic care facilities, enrolled in hospice, or with a current diagnosis or cancer or sickle cell disease may be considered on a case-by-case basis for an exemption from COBI requirements.

The reference table below lists the opioid and benzodiazepine medications included in the Concomitant Opioid and Benzodiazepine Initiative. Further information on the prior authorization requirements, including approval criteria, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Concomitant Opioid and Benzodiazepine Initiative Medication List[1]	
Benzodiazepines	**Opioids**
alprazolam	buprenorphine[3]
chlordiazepoxide	butorphanol
chlordiazepoxide/clidinium	codeine
clonazepam	dihydrocodeine
clorazepate	fentanyl
diazepam[2]	hydrocodone
estazolam	hydromorphone
flurazepam	levorphanol
lorazepam	meperidine
midazolam[2]	methadone
oxazepam	morphine
quazepam	oxycodone
temazepam	oxymorphone
triazolam	opioid powders
	tapentadol
	tramadol

[1]Injectable benzodiazepine formulations are excluded from the Concomitant Opioid and Benzodiazepine Initiative requirements.

[2]Nasal and rectal diazepam and nasal midazolam formulations are excluded from the Concomitant Opioid and Benzodiazepine Initiative requirements.

[3]Buprenorphine formulations used in the treatment of substance use disorder are not included in the Concomitant Opioid and Benzodiazepine Initiative.

Q&A ABOUT THE MASSHEALTH CONCOMITANT OPIOID AND BENZODIAZEPINE INITIATIVE

What is the goal of this initiative?

The MassHealth Concomitant Opioid and Benzodiazepine Initiative focuses on safe prescribing practices for regimens incorporating both opioid and benzodiazepine medications in MassHealth members. The initiative includes prior authorization requirements for both opioids and benzodiazepines when used concomitantly.

What types of medications will be affected by this initiative?

This initiative targets both opioid and benzodiazepine medications. A comprehensive medication list and additional information about the MassHealth Concomitant Opioid and Benzodiazepine Initiative, including prior authorization requirements, are available on the MassHealth Drug List webpage at www.mass.gov/druglist.

Who will be affected by the MassHealth Concomitant Opioid and Benzodiazepine Initiative?

Currently the initiative impacts MassHealth members enrolled in the fee-for-service, Primary Care Clinician Plan, and Primary Care Accountable Care Organizations. Corresponding policies are in place or in development by MassHealth Managed Care Organizations and Accountable Care Partnership Plans.

When will the prior authorization requirements for the MassHealth Concomitant Opioid and Benzodiazepine Initiative take effect?

Polypharmacy within the same medication class currently exists and information can be found on the MassHealth Drug List website. The anticipated start date for this initiative will be November 25, 2019.

Will prescriptions written prior to the start of this initiative be grandfathered?

No. The initiative will take effect on November 25, 2019, with claims for benzodiazepine medications rejecting as early as January 2020. The pharmacy will be notified regarding the need for prior authorization as well as the availability of emergency supplies if required.

How will prescribers know what information needs to be submitted for a prior authorization?

The Benzodiazepines and Other Antianxiety Agents Prior Authorization form and the Opioids/Acetaminophen Analgesic Prior Authorization form have been updated with additional information about the MassHealth Concomitant Opioid and Benzodiazepine Initiative. Prior authorization requirements are available on the MassHealth Drug List webpage at www.mass.gov/druglist.

Is there a specific prior authorization form for the MassHealth Concomitant Opioid and Benzodiazepine Initiative?

No. The Benzodiazepines and Other Antianxiety Agents Prior Authorization form and the Opioids/Acetaminophen Analgesic Prior Authorization form are available on the MassHealth Drug List webpage at www.mass.gov/druglist.

Will a prior authorization request need to be submitted for each opioid and benzodiazepine medication?

No. Questions addressed in the Benzodiazepines and Other Antianxiety Agents Prior Authorization form and the Opioids/Acetaminophen Analgesic Prior Authorization form will allow documentation of the full Opioid and Benzodiazepine regimen, to include name, dose, frequency and indication. Additionally, questions regarding clinical rationale and tapering of agents will also be included.

Are any resources available to aid prescribers in determining which members will be affected by this initiative?

The MassHealth Drug Utilization Review (DUR) Program can provide prescribers with a list of members for whom the prescriber has (a) provided treatment and (b) may be affected by this initiative. Prescribers may request this list by contacting the DUR program at (800) 745-7318.

Are there any prescriber restrictions for prior authorization requests for this initiative?

All enrolled prescribers may submit prior authorization requests on behalf of the member.

Will a prior authorization request need to be submitted when a medication changes in the opioid and benzodiazepine regimen?

Prior authorization may be required for members with a change in therapy. Dose changes may require resubmission of prior authorization in members who also fall under the high dose opioid criteria, benzodiazepine polypharmacy criteria or in situations where the medication itself requires prior authorization. Prescribers who need to cross taper or titrate medications should clearly document the plan so that DUR can facilitate those changes. Prescribers are encouraged to submit prior authorization requests prior to implementing medication changes to avoid disruption in therapy.

If there is more than one prescriber involved in the medication regimen, which prescriber would be responsible for submitting the prior authorization request on behalf of the member?

Coordination of care between prescribers is strongly encouraged to ensure safe and effective prescribing practices. Any enrolled prescriber involved in the member's care may submit the prior authorization request. The prescriber who submits the prior authorization request is encouraged to coordinate with all other prescribers for the member and clearly document the diagnoses and corresponding treatment plan, including all current medications, on the prior authorization request.

Will member care be disrupted if the prior authorization request has not been submitted or processed before the prescription is filled?

Emergency supplies of medications will be available to avoid disruption in therapy. The prescriber, member, and/or member's caregiver may request an emergency supply of medication at the member's pharmacy. Emergency supplies of medications are available for any clinically appropriate duration of therapy, with a minimum of 72 hours. There is no limit to the number of subsequent emergency supplies of medications, if such supplies are medically necessary.

What is the approval duration for prior authorization requests submitted under the MassHealth Concomitant Opioid and Benzodiazepine Initiative?

The duration of a prior authorization approval and of a recertification may be up to 12 months, depending on the clinical situation.

What is a provisional prior authorization approval?

A prior authorization request may be approved provisionally for a duration of up to 6 months depending on the clinical situation. Prior authorization requests may be approved provisionally to avoid disruption in therapy when clinical documentation is required from a prescriber or during a documented taper plan. In circumstances where additional clinical documentation is required, prescribers will be notified via fax and/or telephone.

Who can answer additional questions?

For Pharmacists and Prescribers

If you have questions about a specific member or claim affected by the MassHealth Concomitant Opioid and Benzodiazepine Initiative, please contact the Drug Utilization Review Program at (800) 745-7318.

For MassHealth Members

If you have questions about the MassHealth Concomitant Opioid and Benzodiazepine Initiative, please call MassHealth Customer Service at (800) 841-2900 (TTY: (800) 497-4648).

MassHealth Opioid and Pain Initiative

A. Opioid Analgesics that Require Prior Authorization (PA) for All Dosage Forms and Strengths

Note: See Section B below for information regarding agents with additional restrictions such as age, dose, monotherapy, and/or quantity limits.

- dihydrocodeine/acetaminophen/caffeine – **PA**
- fentanyl buccal tablet – **PA**
- fentanyl transmucosal system – **PA**
- meperidine – **PA**

[MB] This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

B. Opioid Analgesics with Age, High Dose, High Dose Short-Acting Monotherapy, and/or Quantity Limit Restrictions that Require PA

Note: Some medications in the table below (notated with an asterisk) require PA for all dosage forms and strengths. Additional information is required for opioid requests that exceed age, dose, or quantity limits, or for use of a high-dose short-acting opioid as monotherapy. Please provide medical records and complete the appropriate section of the Opioids/Acetaminophen Analgesic Prior Authorization Request form when requesting PA for ages, quantities, or doses outside of the limits listed below, or for use of a high-dose short-acting opioid without a long-acting opioid agent. Certain exemptions may apply to high-dose criteria (e.g., diagnosis of sickle cell disease, active cancer pain, palliative care, hospice).

The accumulated high dose threshold is 120 mg of morphine or morphine equivalent (MME) per day for an individual agent, and 180 MME per day for the entire regimen. All buprenorphine formulations are excluded from the opioid accumulator.

Long-acting		
Drug	**Age/Dose Limit**	**Quantity Limit**
Belbuca (buprenorphine buccal film)*	> 1,800 mcg/day	> 2 films/day
Butrans (buprenorphine transdermal system)‡	> 20 mcg/hr (i.e. one 20 mcg/hr patch every 7 days)	> 4 patches/28 days
Conzip (tramadol extended-release capsule)*‡	< 12 years > 300 mg/day	> 1 capsule/day
Dolophine, Methadose (methadone)*†‡	> 25 mg/day	N/A
fentanyl transdermal system‡[2]	> 50 mcg/hr (i.e. one 50 mcg/hr patch every 72 hours)	> 10 patches/30 days
hydrocodone extended-release*‡	> 120 mg/day	> 2 capsules/day
hydromorphone extended-release*‡	> 24 mg/day	> 1 tablet/day
Hysingla ER (hydrocodone extended-release)*‡	> 120 mg/day	> 1 tablet/day
levorphanol*‡	> 4 mg/day	> 2 tablets/day
morphine extended-release capsule*‡	> 120 mg/day	> 1 capsule/day
MS Contin (morphine controlled-release)‡	> 120 mg/day	N/A
Oxycontin (oxycodone extended-release tablet)*‡	> 80 mg/day	> 3 tablets/day
oxymorphone extended-release*	> 40 mg/day	> 2 tablets/day
tramadol extended-release tablet*‡	< 12 years > 300 mg/day	> 1 tablet/day

* Both brand and generic (if available) require PA, even within dose and quantity limits; PA criteria available at www.mass.gov/druglist.

† Dose limits apply to both oral and injectable formulation.

‡ Available generically

[2] Fentanyl transdermal system 37.5, 62.5, and 87.5 mcg/hr require PA, even within dose and quantity limits.

Short-acting	
Drug	**Age/Dose/Quantity Limit**
acetaminophen products‡	> 4 grams/day
acetaminophen with codeine products‡[1]	< 12 years > 4 grams acetaminophen/day > 360 mg codeine/day
benzhydrocodone/acetaminophen*‡[1]	> 65.28 mg benzhydrocodone/day > 4 grams acetaminophen/day
butorphanol nasal spray*‡	> 2 canisters/30 days
codeine products‡[1]	< 12 years > 360 mg/day
Dilaudid (hydromorphone)†‡[1]	> 24 mg/day
hydrocodone/acetaminophen‡[1]	>120 mg hydrocodone/day > 4 grams acetaminophen/day
hydrocodone 5 mg, 10 mg/ibuprofen*‡[1]	> 120 mg hydrocodone/day > 3.2 grams ibuprofen/day
hydrocodone 7.5 mg/ibuprofen‡[1]	> 120 mg hydrocodone/day > 3.2 grams ibuprofen/day
morphine immediate-release†‡[1]	> 120 mg/day
oxymorphone immediate-release*†‡[1]	> 40 mg/day
oxycodone/acetaminophen 300 mg*‡[1]	> 80 mg oxycodone/day > 4 grams acetaminophen/day
oxycodone/aspirin‡	> 80 mg oxycodone/day > 4 grams aspirin/day
oxycodone immediate-release‡[1]	> 80 mg/day
Percocet (oxycodone/acetaminophen)‡[1]	> 80 mg oxycodone/day > 4 grams acetaminophen/day
Seglentis (celecoxib/tramadol)*[1]	< 12 years > 400 mg tramadol/day
tramadol 25 mg, 100 mg*‡[1]	< 12 years > 400 mg/day
tramadol 50 mg‡[1]	< 12 years > 400 mg/day
tramadol/acetaminophen‡[1]	< 12 years > 400 mg tramadol/day > 4 grams acetaminophen/day
tramadol solution*‡[1]	< 12 years > 400 mg/day

* Both brand and generic (if available) require PA, even within dose and quantity limits; PA criteria available at www.mass.gov/druglist.

† Dose limits apply to both oral and injectable formulation.
‡ Available generically
[1] High dose short-acting monotherapy limits apply.

C. Duplicate Opioid Therapy

PA is required for members taking ≥ two long-acting opioids for > two months.

PA is required for members taking ≥ two short-acting opioids for > two months.

D. Concurrent Therapy with Opioid Dependence Agents

For members determined to be stable on any opioid dependence therapy:

- PA is required for any long-acting opioid.
- PA is required for any short-acting opioid for > seven days supply.
- PA is required for any short-acting opioid(s) for > seven days of therapy within the last 30 days.

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E. Opioid First-Fill Seven-Day Supply Restriction

In general, members who have not filled an opioid prescription recently or who are naïve to opioids will be limited to a seven-day supply for their first fill. Seven-day supply opioid restrictions do not apply to members who already take opioids. Certain exemptions may apply to seven-day supply opioid restrictions.

F. Concomitant Opioid and Benzodiazepine Initiative

Effective with the March 2024 MassHealth Drug list update, PA is required for members who are newly starting opioid therapy and are stable on benzodiazepine therapy for ≥ 15 days supply within the past 45 days. Members can receive up to a combined total of 14 days supply of one or more opioid(s) within the past 45-day period without PA. Please note: In general, members that are residents of nursing homes or chronic care facilities, enrolled in hospice, or with a current diagnosis or cancer or sickle cell disease may be considered on a case-by-case basis for an exemption from COBI requirements.

A comprehensive medication list and additional information about the MassHealth Concomitant Opioid and Benzodiazepine Initiative, including prior authorization requirements, are available on the MassHealth Drug List webpage at **www.mass.gov/druglist.** Please refer to the Concomitant Opioid and Benzodiazepine Initiative for further information.

MassHealth Pediatric Behavioral Health Medication Initiative

BACKGROUND

The Pediatric Behavioral Health Medication Initiative proactively requires prior authorization for pediatric members (generally members less than 18 years of age) for certain behavioral health medication classes and/or specific medication combinations (i.e., polypharmacy) that have limited evidence for safety and efficacy in the pediatric population.

As part of this initiative, the following situations will require a prior authorization:

1. **Behavioral health medication polypharmacy**: (i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers [agents considered to be used only for seizure diagnoses are not included], naltrexone, prazosin, viloxazine, and xanomeline/trospium) filled within a 45-day period for members less than 18 years of age:
    - Pharmacy claims for 4 or more behavioral health medications **if one of the following is included**: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant
    - Pharmacy claims for 5 or more behavioral health medications (regardless of the medications included)
2. **Antipsychotic polypharmacy**: overlapping pharmacy claims for two or more antipsychotics for at least 60 days within a 90-day period for members less than 18 years of age;
3. **Antidepressant polypharmacy**: overlapping pharmacy claims for two or more antidepressants for at least 60 days within a 90-day period for members less than 18 years of age;
4. **Cerebral stimulant polypharmacy**: overlapping pharmacy claims for two or more cerebral stimulants (immediate-release and extended-release formulations of the same chemical entity are counted as one) for at least 60 days within a 90-day period for members less than 18 years of age;
5. **Mood stabilizer polypharmacy**: overlapping pharmacy claims for three or more mood stabilizers (agents considered to be used only for seizure diagnoses are not included) for at least 60 days within a 90-day period for members less than 18 years of age;
6. **Benzodiazepine polypharmacy**: overlapping pharmacy claims for two or more benzodiazepines (hypnotic benzodiazepine agents, clobazam, nasal and rectal diazepam, and nasal midazolam are not included) for at least 60 days within a 90-day period for members less than 18 years of age;
7. **Antipsychotic** pharmacy claim for members less than ten years of age;
8. **Antidepressant, armodafinil**, **atomoxetine, benzodiazepine, buspirone, donepezil, hypnotic, memantine, meprobamate, modafinil**, **mood stabilizer (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, viloxazine, or xanomeline/trospium** pharmacy claim for members less than six years of age;
9. **Alpha$_2$ agonist or cerebral stimulant** pharmacy claim for members less than three years of age.

The reference table below lists the behavioral health medications included in the Pediatric Behavioral Health Medication Initiative. Further information on the prior authorization requirements, including approval criteria, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Pediatric Behavioral Health Medication Initiative Medication List[1]

Antidepressants

amitriptyline
amoxapine
bupropion
citalopram
clomipramine
desipramine
desvenlafaxine
dextromethorphan/bupropion
doxepin
duloxetine
escitalopram
esketamine
fluoxetine
fluvoxamine
imipramine
isocarboxazid
levomilnacipran
mirtazapine
nefazodone
nortriptyline
paroxetine
phenelzine
protriptyline
selegiline[2]
sertraline
tranylcypromine
trazodone
trimipramine
venlafaxine
vilazodone
vortioxetine
zuranolone

Antipsychotics

aripiprazole
asenapine
brexpiprazole
cariprazine
chlorpromazine
clozapine
fluphenazine
haloperidol
iloperidone
loxapine
lumateperone
lurasidone
molindone
olanzapine
olanzapine/fluoxetine
olanzapine/samidorphan
paliperidone
perphenazine
perphenazine/amitriptyline
pimozide
quetiapine
risperidone
thioridazine
thiothixene
trifluoperazine
xanomeline/trospium
ziprasidone

Mood Stabilizers

carbamazepine
divalproex
gabapentin
lamotrigine
lithium
oxcarbazepine
pregabalin
topiramate
valproic acid

Antianxiety Agents

alprazolam
buspirone
chlordiazepoxide
chlordiazepoxide/ amitriptyline
clonazepam
clorazepate
diazepam[3]
lorazepam
meprobamate
midazolam[3]
oxazepam

Hypnotics

daridorexant
doxepin[4]
estazolam
eszopiclone
flurazepam
lemborexant
quazepam
suvorexant
temazepam
triazolam
zaleplon
zolpidem

Alpha$_2$ Agonists

clonidine
guanfacine

Stimulants

amphetamine
dexmethylphenidate
dextroamphetamine
dextroamphetamine/ amphetamine
lisdexamfetamine
methamphetamine
methylphenidate
serdexmethylphenidate/ dexmethylphenidate

Miscellaneous

armodafinil
atomoxetine
donepezil
memantine
modafinil
naltrexone[5]
prazosin
viloxazine

[1]Short-acting intramuscular injectable and intravenous formulations are excluded from the Pediatric Behavioral Health Medication Initiative requirements.

[2]Emsam (selegiline) is the only selegiline formulation included in the Pediatric Behavioral Health Medication Initiative.

[3]Nasal and rectal diazepam and nasal midazolam formulations are excluded from the Pediatric Behavioral Health Medication Initiative requirements.

[4]Doxepin tablet is classified as a hypnotic agent and the Pediatric Behavioral Health Medication Initiative requirements for antidepressants do not apply. Pediatric Behavioral Health Medication Initiative requirements for hypnotics apply.

[5]Vivitrol (naltrexone injection) is excluded from the Pediatric Behavioral Health Medication Initiative requirements.

10 Tips for a Good Night's Sleep

"Sleep hygiene" is a term used for the habits that help you get sleep that is both restful and long enough. Your activities throughout the day and close to bedtime can affect your sleep. The following tips apply to both adults and children. Be sure to check out the specific tips for children at the end. Always consult your health care provider before starting any medications including melatonin or other sleep aids for your child.

These tips can help you develop good sleep habits:

1) **Stay on a schedule**: Go to sleep and wake up at the same time every day. Aim for 7 to 8 hours of sleep (adults). Children may require longer sleep times (see tips for children below).

2) **Don't skip the "wind down**": Listen to calming music, take a warm bath, or read a relaxing book.

3) **Go to bed sleepy**: Set your bedtime to align with when your body starts to naturally feel tired.

4) **Keep it cool**: The ideal sleeping temperature is 60° to 67°F.

5) **Watch what you eat**: Don't eat a large meal before bed. Limit eating 2 to 3 hours before bed. If you are hungry, have a light and healthy snack.

6) **Silence is golden**: Turn off any noisy distractions, and use earplugs or a soft noise machine.

7) **Lights out**: Use a blackout shade, dim the lights on your digital clock, and stop using any electronic device at least 30 minutes before bedtime.

8) **Daily activity can help**: Exercise regularly and maintain a healthy diet.

9) **Avoid certain things**: Alcohol, caffeine, and nicotine can disrupt sleep. Avoid them starting in the afternoon or skip them altogether.

10) **Apply the "20-minute rule"**: If you are not asleep after 20 minutes, get out of bed and do a quiet activity in a dimly lit room, but avoid electronics.

Special considerations for children:

- **Children and infants require more sleep than adults:** Infants to children 2 years old may need 11 to 14 hours of sleep per 24 hours (including naps). Toddlers may need 10 to 13 hours per 24 hours (including naps). Teenagers generally need about 8 to 10 hours per night.

- **Children often wake at night:** It is normal for children to wake up several times at night and it's very important to teach them how to go back to sleep on their own.

- **Safe sleep for infants:** Infants should sleep **alone** on their **back** (with no loose toys or blankets), in a crib (or bassinet or portable play yard), with a **firm mattress** covered with a fitted sheet. **Avoid** sleeping on a couch, armchair, or swing. Never sleep with your baby.

- **Children and adolescents with autism spectrum disorders** may have difficulties falling asleep and staying asleep. Speak to your child's autism care provider for more information before initiating any medications for sleep.

- **Melatonin use in children and adolescents:** The American Academy of Sleep Medicine released a health advisory in 2022 regarding melatonin use that includes the following:
    - Melatonin should be handled as any other medication and kept out of reach of children.
    - Before starting melatonin or any supplement in children, parents should discuss this decision with a pediatric health care professional.
    - Many sleep problems can be better managed with a change in schedules, habits, or behaviors rather than taking melatonin.
    - If melatonin is used, the health care professional can recommend the dose and timing for the sleep problem. Parents should select a product with the **USP Verified Mark** for safer use.

For more information, check out resources from the American Academy of Sleep Medicine and the American Academy of Child and Adolescent Psychiatry:

Adults:

- https://sleepeducation.org/healthy-sleep/healthy-sleep-habits/

Children:

- https://aasm.org/recharge-with-sleep-pediatric-sleep-recommendations-promoting-optimal-health/
- https://www.aap.org/en/patient-care/safe-sleep/

Medication use:

- https://www.aacap.org/App_Themes/AACAP/Docs/families_and_youth/med_guides/SleepDisorders_Parents-Medication-Guide-web.pdf
- https://aasm.org/advocacy/position-statements/melatonin-use-in-children-and-adolescents-health-advisory/

Certain MassHealth Outpatient Physician Administered Drugs to be Paid by Fee Schedule

This list identifies the current list of "**Fee Schedule Drugs**" for purposes of Section 5.C.14 of the Acute Hospital Request for Applications (the RFA). The list of Fee Schedule Drugs may be updated from time-to-time. Hospitals will be reimbursed for Fee Schedule Drugs in accordance with Section 5.C.14 of the RFA.

The Fee Schedule Drugs are listed sequentially by J-Code as follows:

- J2182 – Mepolizumab
- J2350 – Ocrelizumab
- J9022 – Atezolizumab
- J9047 – Carfilzomib
- J9173 – Durvalumab
- J9266 – Pegaspargase
- J9271 – Pembrolizumab
- J9299 – Nivolumab
- J9306 – Pertuzumab

Pharmacy Selection Form

Controlled Substance Management Program

Use this form to request a different primary pharmacy from the one that MassHealth assigned to you upon enrollment into the Controlled Substance Management Program (CSMP) or to request a different pharmacy after you have been enrolled. Until MassHealth notifies you that your request has been approved, you must continue to use your current (or MassHealth-assigned) primary pharmacy.

Reminder: You can request a change in your pharmacy no more than once per year, unless the primary pharmacy is unable to address due to a change in your residence, your medical condition, or the primary pharmacy's business practices.

To request a different pharmacy, fill out the information below, and mail or fax this form to:

MassHealth Drug Utilization Review
Program P.O. Box 2586
Worcester, MA 01613-2586
Fax: (877) 208-7428

Member Information

Your Name: _____ Your MassHealth ID Number: _____

Name and Address of Current Pharmacy

_____

_____

_____

Name and Address of New Pharmacy

_____

_____

_____

Reason for change in your primary pharmacy: _____

Effective Date

Please enter the requested effective date of the change in your primary pharmacy. Please allow four business days for mailing and processing. We will send you a letter confirming your selection. Until MassHealth notifies you that your request has been approved, you must continue to use your current (or MassHealth-assigned) primary pharmacy.

Requested Effective Date: _____

Member Authorization: I understand that I may not change my primary pharmacy again for at least one year from the date of signature below, unless for one of the reasons listed above.

_____

Your Signature Date

Controlled Substances Management Program (CSMP): Criteria for Member Enrollment

The MassHealth agency has established a Controlled Substance Management Program (CSMP) for MassHealth members who overutilize or improperly utilize prescribed drugs. Members in the CSMP are restricted to obtaining all prescribed drugs only from the provider that the MassHealth agency designates as the member's primary pharmacy.

Members who meet one of the following will be enrolled in the program.

- All of the following:
  - Member's average daily morphine equivalent dose is ≥ 90 milliequivalents in both three-month periods of the previous six-month period; **and**
  - These prescriptions were written by three or more prescribers or filled by three or more pharmacies.

- All of the following:
  - Member's average daily morphine equivalent dose is ≥ 90 milliequivalents in both three-month periods of the previous six-month period; **and**
  - These prescriptions were written by two or more prescribers or filled by two or more pharmacies; **and**
  - Member filled three or more prescriptions and/or refills for high-risk medications (i.e., benzodiazepine agents, gabapentin, or stimulant agents) in both three-month periods of the previous six-month period.

- All of the following:
  - Member's average daily morphine equivalent dose is ≥ 90 milliequivalents in both three-month periods of the previous six-month period; **and**
  - Member had six or more emergency department visits during the previous six-month period.

Long-Acting Injectable Antipsychotic Medications Administered in Inpatient Psychiatry Units

Effective May 15, 2024, the Long-Acting Injectable Antipsychotic Medication Administered in Inpatient Psychiatry Units section of the MassHealth Drug List (MHDL) applies to participating in-state MassHealth acute hospital (acute) and freestanding inpatient psychiatric hospital (psychiatric) providers of inpatient psychiatric services. This list identifies the current list of long-acting injectable antipsychotic medications that, when administered in an inpatient psychiatry unit, are reimbursable outside of the applicable per diem rates for acute and psychiatric hospitals. Drug specific prior authorization criteria, if applicable, must be met as listed on the MHDL. Other requirements, such as preferred drug designation or quantity limits, may apply. This list, prior authorization status, and other requirements may be updated from time to time.

The Antipsychotic Prior Authorization Form includes a section to denote that the request is for a member currently admitted to an inpatient psychiatry unit.

Hospitals should also review any special billing instructions for Long-Acting Injectable Antipsychotic Medications Administered in Inpatient Psychiatry Units posted on the "Billing Tips" section of the MassHealth website.

The Long-Acting Injectable Antipsychotics are listed sequentially by J-Code as follows:

- J0401 – Aripiprazole (Abilify Maintena), extended release 1 mg
- J0402 – Aripiprazole (Abilify Asimtufii), 1 mg
- J1631 – Haloperidol decanoate, per 50 mg
- J1943 – Aripiprazole lauroxil (Aristada Initio), 1 mg
- J1944 – Aripiprazole lauroxil (Aristada), 1 mg
- J2358 – Olanzapine (Zyprexa Relprevv), long acting, 1 mg
- J2426 – Paliperidone palmitate extended release (Invega Sustenna), 1 mg
- J2427 – Paliperidone palmitate extended release (Invega Hafyera, or Invega Trinza), 1 mg
- J2680 – Fluphenazine decanoate, up to 25 mg
- J2794 – Risperidone (Risperdal Consta), 0.5 mg
- J2798 – Risperidone (Perseris), 0.5 mg
- J2799 – Risperidone (Uzedy), 1 mg
- J2801 – Risperidone (Rykindo), 0.5 mg

Long-Acting Injectable Antipsychotics covered outside the per diem for Acute and Psychiatric Hospitals shall be billed using the appropriate J-Code (according to the Physician Subchapter 6). Definitions, payment rules, and rates for these Long-Acting Injectable Antipsychotics are contained in 101 CMR 317.00: *Rates for medicine services*.

MassHealth Acute Hospital Carve-Out Drugs List

This section of the MassHealth Drug List (MHDL) applies to participating in-state MassHealth Acute Hospital providers and, as applicable, to out-of-state MassHealth acute hospital providers pursuant to 130 CMR 450.233(D). It identifies the current list of “Adjudicated Payment Amount per Discharge (APAD) Carve-Out Drugs” and “Adjudicated Payment per Episode of Care (APEC) Carve-Out Drugs” for purposes of Sections 5.B.8.b and 5.C.9 of the current MassHealth Acute Hospital Request for Applications (Acute Hospital RFA) for in-state acute hospitals and regulations at 130 CMR 450.233(D) for out-of-state acute hospitals. APAD and APEC one-time cell and gene therapies on this list are part of the Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) unified pharmacy policy. Prior authorization (PA) requests for one-time cell and gene therapies for members with ACPP and MCO plans will be reviewed by the MassHealth Drug Utilization Review (DUR) Program.

Hospitals and prescribers must obtain PA from MassHealth for both APAD and APEC Carve-Out Drugs on this list (**see Table 1**). The associated treatments will also be subject to monitoring, as indicated below, and other requirements may apply. This list, along with the PA and other requirements, may be updated periodically. Hospitals should review any special billing instructions for APAD Carve-Out Drugs and APEC Carve-Out Drugs posted in the "Billing Tips" section of the MassHealth website.

For both APAD and APEC Carve-Out Drugs, the drugs and biologics are listed alphabetically by drug name (brand). Prescribers must submit a request for PA using a Prior Authorization Request form. Once the PA request is reviewed by the MassHealth DUR Program, the prescriber will be notified via fax if the request has been approved.

For APAD Carve-Out Drugs (administered in an acute inpatient hospital setting), if PA is granted, the admitting provider must submit a preadmission screening request for the acute inpatient hospital admission to the MassHealth acute hospital utilization review contractor, Permedion, in accordance with applicable MassHealth regulations and guidelines. Once both the PA and preadmission screening are adjudicated and approved, the treatment plan can be initiated.

In addition to PA and other requirements, both APAD and APEC Carve-Out Drugs require short- and long-term monitoring for efficacy and durability of response. MassHealth may conduct outreach to prescriber’s offices and/or hospitals to gather the necessary information.

FDA-Approved New-to-Market Drugs

FDA-approved new-to-market drugs and biologics that are not listed in the MHDL will be handled on a case-by-case basis until MassHealth has concluded its evaluation of the drug or biologic. Hospitals and prescribers should contact MassHealth to determine whether an FDA-approved new-to-market drug or biologic not listed in the MHDL is an “APAD Carve-Out Drug” or an “APEC Carve-Out Drug” for purposes of the Acute Hospital RFA (or MassHealth regulations, as applicable).

TABLE 1. MassHealth Acute Hospital Carve-Out Drugs List (APAD Carve-Out Drugs and APEC Carve-Out)

Drug	Generic Name	HCPCS Code	Therapeutic Class (Table on MHDL)	PA Request Form
Abecma	idecabtagene vicleucel	Q2055	Chimeric Antigen Receptor (CAR)-T Immunotherapies (Table 75)	One-Time Cell and Gene Therapies Prior Authorization Request form
Amtagvi	lifileucel	Unspecified*	Autologous T-Cell Immunotherapy (Table 75)	
Aucatzyl	obecabtagene autoleucel	Q2058	(CAR)-T Immunotherapies (Table 75)	
Beqvez	fidanacogene elaparvovec-dzkt	J1414	Hemophilia B Gene Therapy (Table 80)	
Breyanzi	lisocabtagene maraleucel	Q2054	(CAR)-T Immunotherapies (Table 75)	
Carvykti	ciltacabtagene autoleucel	Q2056	(CAR)-T Immunotherapies (Table 75)	
Casgevy	exagamglogene autotemcel	J3392	Beta Thalassemia Gene Therapy Sickle Cell Disease Gene Therapy (Table 45)	
Elevidys	delandistrogene moxeparvovec-rokl	J1413	Duchenne Muscular Dystrophy Agent (Table 76)	
Hemgenix	etranacogene dezaparvovec-drlb	J1411	Hemophilia B Gene Therapy (Table 80)	
Kebilidi	eladocagene exuparvovec-tneq	Unspecified*	Enzyme and Metabolic Disorder Therapy (Table 65)	
Kymriah	tisagenlecleucel	Q2042	(CAR)-T Immunotherapies (Table 75)	
Lenmeldy	atidarsagene autotemcel	J3391	Metachromatic Leukodystrophy Agent (Table 72)	
Luxturna	voretigene neparvovec-rzyl	J3398	Inherited Retinal Disease Gene Therapy (Table 72)	
Lyfgenia	lovotibeglogene autotemcel	J3394	Sickle Cell Disease Gene Therapy (Table 45)	

Drug	Generic Name	HCPCS Code	Therapeutic Class (Table on MHDL)	PA Request Form
Omisirge	omidubicel-onlv	Unspecified*	Stem Cell Therapy (Table 72)	One-Time Cell and Gene Therapies Prior Authorization Request form
Roctavian	valoctocogene roxaparvovec-rvox	J1412	Hemophilia A Gene Therapy (Table 80)	
Skysona	elivaldogene autotemcel	Unspecified*	Cerebral Adrenoleukodystrophy Agent (Table 72)	
Tecartus	brexucabtagene autoleucel	Q2053	(CAR)-T Immunotherapies (Table 75)	
Tecelra	afamitresgene autoleucel	Q2057	Autologous T-Cell Immunotherapy (Table 75)	
Yescarta	axicabtagene ciloleucel	Q2041	(CAR)-T Immunotherapies (Table 75)	
Zolgensma	onasemnogene abeparvovec-xioi	J3399	Spinal Muscular Atrophy Agent (Table 76)	
Zynteglo	betibeglogene autotemcel	J3393	Beta Thalassemia Gene Therapy (Table 45)	

*For drugs with an unspecified HCPCS code, please use J3490 (unclassified drugs), J3590 (unclassified biologics), or J9999 (not otherwise classified, antineoplastic drugs), as clinically appropriate.

MassHealth Brand Name Preferred Over Generic Drug List

This is the list of brand name drugs that MassHealth prefers over their generic equivalents because the net cost of the brand name drugs adjusted for rebates is lower than the net cost of the generic equivalents.

Please note that MassHealth may still require prior authorization (PA) for clinical reasons. Drugs that require additional PA requirements are noted with "PA" on this list.

In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

This list may be updated often and is subject to change at any time.

- Absorica (isotretinoin) – **PA**
- Adderall XR (amphetamine salts extended-release) – **PA < 3 years or ≥ 21 years and PA > 2 units/day**
- Advair (fluticasone/salmeterol inhalation)
- Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablet) – **PA**
- Afinitor Disperz (everolimus tablets for oral suspension) – **PA**
- Airduo Respiclick (fluticasone/salmeterol inhalation powder) – **PA**
- Alphagan P (brimonidine 0.1%, 0.15% eye drops)
- Ancobon (flucytosine)
- Apriso (mesalamine 0.375 gram extended-release capsule)
- Atelvia (risedronate delayed-release) – **PA**
- Atralin (tretinoin 0.05% gel) – **PA**
- Atrovent HFA (ipratropium inhalation aerosol)
- Auryxia (ferric citrate) – **PA**
- Azasite (azithromycin ophthalmic solution)
- Azopt (brinzolamide)
- Banzel (rufinamide) – **PA**
- Bepreve (bepotastine)
- Bethkis (tobramycin inhalation solution) – **PA**
- Betimol (timolol) – **PA**
- Breo (fluticasone/vilanterol)
- Buphenyl (sodium phenylbutyrate)
- Butrans (buprenorphine transdermal) – **PA > 20 mcg/hr and PA > 4 patches/28 days**
- Byetta (exenatide 5 mcg injection) – **PA > 1.2 mL/30 days**
- Byetta (exenatide 10 mcg injection) – **PA > 2.4 mL/30 days**
- Carac (fluorouracil 0.5% cream) – **PA**
- Carbaglu (carglumic acid) – **PA**
- Clindagel (clindamycin gel)
- Combigan (brimonidine/timolol, ophthalmic)
- Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)
- Concerta (methylphenidate extended-release) – **PA < 3 years or ≥ 21 years and PA > 2 units/day**
- Condylox (podofilox gel)
- Copaxone (glatiramer)
- Cosopt PF (dorzolamide/timolol, preservative free) – **PA**
- Cuprimine (penicillamine capsule)
- Cystadane (betaine)
- Daytrana (methylphenidate transdermal) – **PA < 3 years or ≥ 21 years and PA > 1 unit/day**
- Demser (metyrosine)
- Denavir (penciclovir)
- Depakote Sprinkle (divalproex delayed-release capsule) – **PA < 6 years**
- Depen (penicillamine tablet)

- Dexilant (dexlansoprazole) – **PA**
- Diclegis (doxylamine/pyridoxine delayed-release) – **PA**
- Divigel (estradiol)
- Duetact (glimepiride/pioglitazone) – **PA**
- Dulera (mometasone/formoterol)
- Dymista (azelastine/fluticasone propionate)
- Edurant (rilpivirine)
- Efudex (fluorouracil 5% cream)
- Emflaza (deflazacort) – **PA**
- Emtriva (emtricitabine)
- Entresto (sacubitril/valsartan tablet) – **PA**
- Exelon (rivastigmine patch) – **PA > 1 unit/day**
- Exjade (deferasirox 125 mg, 250 mg, 500 mg)
- Fabior (tazarotene foam) – **PA**
- Farxiga (dapagliflozin)
- Finacea (azelaic acid foam) – **PA**
- Firvanq (vancomycin oral solution)
- Forteo (teriparatide 600 mcg/2.4 mL) – **PA**
- Frova (frovatriptan) – **PA**
- Fycompa (perampanel) – **PA**
- Gattex (teduglutide injection) – **PA**
- Hetlioz (tasimelteon) – **PA**
- Horizant (gabapentin enacarbil) – **PA < 6 years and PA > 1200 mg/day**
- Humira (adalimumab) – **PA**
- Inspra (eplerenone)
- Intelence (etravirine)
- Isentress (raltegravir)
- Isordil (isosorbide dinitrate 40 mg tablet) – **PA**
- Istalol (timolol)
- Jentadueto (linagliptin/metformin)
- Jentadueto XR (linagliptin/metformin)
- Kitabis Pak (tobramycin inhalation solution) – **PA**
- Lantus (insulin glargine)
- Lotemax (loteprednol 0.5%)
- Lyrica CR (pregabalin extended-release) – **PA**
- Mesnex (mesna tablet)
- Mestinon (pyridostigmine bromide solution, 60 mg tablet, 180 mg extended-release tablet)
- Minivelle (estradiol)
- Mitigare (colchicine capsule) – **PA**
- Motegrity (prucalopride) – **PA**
- Moviprep (polyethylene glycol-electrolyte solution)
- Myrbetriq (mirabegron extended-release)
- Namzaric (memantine/donepezil extended-release) – **PA**
- Nexavar (sorafenib) – **PA**
- Nexium (esomeprazole magnesium 2.5 mg, 5 mg, 10 mg suspension) – **PA ≥ 2 years and PA > 1 unit/day**
- Nexium (esomeprazole magnesium 20 mg, 40 mg suspension) – **PA**
- Nitrolingual (nitroglycerin lingual spray) – **PA**
- Norvir (ritonavir tablet)
- Noxafil (posaconazole injection) – **PA**
- Olux-E (clobetasol propionate foam/emollient)
- Onexton (clindamycin/benzoyl peroxide gel pump) – **PA**
- Oxtellar XR (oxcarbazepine extended-release) – **PA**
- Oxycontin (oxycodone extended-release tablet) – **PA**
- Pentasa (mesalamine 250 mg, 500 mg controlled-release capsule)
- Pradaxa (dabigatran capsule)
- Prevacid Solutab (lansoprazole orally disintegrating tablet)
- Proglycem (diazoxide)
- Prolensa (bromfenac 0.07%)
- Promacta (eltrombopag olamine) – **PA**
- Protonix (pantoprazole 40 mg suspension)
- Pylera (bismuth subcitrate/metronidazole/tetracycline)
- Qudexy XR (topiramate extended-release capsule) – **PA < 6 years**
- Ravicti (glycerol phenylbutyrate) – **PA**
- Remodulin (treprostinil injection) – **PA**
- Restasis (cyclosporine 0.05% ophthalmic emulsion)
- Retin-A (tretinoin) – **PA ≥ 21 years**
- Retin-A Micro (tretinoin microspheres) – **PA**
- Revlimid (lenalidomide) – **PA**
- Ridaura (auranofin)
- Risperdal Consta (risperidone 12.5 mg, 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection) – **PA < 10 years and PA > 2 injections/28 days**

- Rozerem (ramelteon) – **PA > 1 unit/day**
- Rytary (carbidopa/levodopa extended-release capsule) – **PA**
- Sabril (vigabatrin powder packet, tablet) – **PA**
- Sancuso (granisetron transdermal system) – **PA**
- Sandostatin LAR (octreotide injectable suspension)
- Spiriva Handihaler (tiotropium inhalation powder)
- Sporanox (itraconazole 100 mg capsule)
- Spritam (levetiracetam tablet for oral suspension) – **PA**
- Sprycel (dasatinib)
- Suboxone (buprenorphine/naloxone film ≤ 24 mg/day)
- Suboxone (buprenorphine/naloxone film) – **PA > 90 days (> 24 mg/day and ≤ 32 mg/day)**
- Suboxone (buprenorphine/naloxone film) – **PA > 32 mg/day**
- Suprep (sodium sulfate/potassium sulfate/ magnesium sulfate)
- Sutent (sunitinib) – **PA**
- Symbicort (budesonide/formoterol)
- Syprine (trientine 250 mg capsule)
- Taclonex (betamethasone/calcipotriene topical suspension) – **PA**
- Tasigna (nilotinib capsule)
- Targretin (bexarotene)
- Teflaro (ceftaroline)
- Tegretol XR (carbamazepine extended-release) – **PA < 6 years**
- Tekturna (aliskiren) – **PA**
- Testim (testosterone 1% gel tube) – **PA**
- Thiola (tiopronin)
- Thiola EC (tiopronin delayed-release)
- Timoptic Ocudose (timolol 0.5% ophthalmic unit dose solution) – **PA**
- Toujeo (insulin glargine)
- Tracleer (bosentan) – **PA**
- Tradjenta (linagliptin)
- Transderm-Scop (scopolamine transdermal patch)
- Travatan Z (travoprost 0.004% eye drop)
- Tresiba (insulin degludec)
- Trileptal (oxcarbazepine suspension) – **PA < 6 years**
- Trokendi XR (topiramate extended-release capsule) – **PA**
- Tykerb (lapatinib)
- Uceris (budesonide extended-release tablet)
- Ventolin (albuterol inhaler)
- Victoza (liraglutide) – **PA > 9 mL/30 days**
- Vivelle-Dot (estradiol)
- Votrient (pazopanib) – **PA**
- Vusion (miconazole/zinc oxide ointment)
- Vyvanse (lisdexamfetamine capsule) – **PA < 3 years or ≥ 21 years and PA > 2 units/day**
- Vyvanse (lisdexamfetamine chewable tablet) – **PA**
- Xarelto (rivaroxaban 10 mg, 15 mg, 20 mg tablet, starter pack)
- Xarelto (rivaroxaban 2.5 mg tablet) – **PA**
- Xeljanz (tofacitinib) – **PA**
- Xeljanz XR (tofacitinib extended-release) – **PA**
- Xenical (orlistat) – **PA**
- Xigduo XR (dapagliflozin/metformin extended-release)
- Xyrem (sodium oxybate) – **PA**
- Zavesca (miglustat 100 mg) – **PA**
- Zioptan (tafluprost) – **PA**
- Zituvio (sitagliptin) – **PA**
- Zortress (everolimus 0.25 mg, 0.5 mg, 0.75 mg, 1 mg)
- Zovirax (acyclovir cream)
- Zyclara (imiquimod 2.5%, 3.75% cream) – **PA**
- Zyvox (linezolid suspension) – **PA**

MassHealth 90-Day Supply

The MassHealth agency has established a 90-Day Supply Medication Initiative that includes mandatory and allowable dispensing of certain medications.

Certain generic drugs and other low-net-cost drugs, designated with M90, will be mandated to a 90-day supply after an initial fill of medication. Medications designated with M90 are typically maintenance medications. Mandatory dispensing in a 90-day supply may not apply to all formulations of a drug, and certain other restrictions including but not limited to Prior Authorization (PA) requirements and quantity limits may apply. In general, generic formulation will be required unless a particular form of the drug (for example, specific strength or formulation) does not have a generic equivalent, or the drug is listed on the MassHealth Brand Name Preferred Over Generic Drug List, in which case the brand name drug may be dispensed. Where applicable due to package size, allowances may be made for dispensing greater or less than exactly a 90-day supply of medication. The 90-Day Supply mandate may apply to medications not listed on the MassHealth Drug List. This requirement does not apply to drugs dispensed to members in certain long term care facilities, hospices, and group homes, or as specified by law or regulation.

Certain generic drugs and other low-net-cost drugs, designated with A90, may be allowed to be dispensed in up to a 90-day supply. Allowed dispensing in a 90-day supply may not apply to all formulations of a drug, and certain other restrictions including but not limited to PA requirements and quantity limits may apply. In general, the generic formulation will be required unless the drug is listed on the MassHealth Brand Name Preferred Over Generic Drug List, in which case the brand name drug may be allowed.

In addition, medications not designated with A90 or M90 will be excluded from dispensing in a 90-day supply. Examples of medications and medication formulations that are excluded from dispensing in a 90-day supply include but are not limited to health care professional administered drugs, hospital outpatient administered drugs, injectable formulations, and Prescription Monitoring Program (PMP) designated agents.

Medication status denoted as mandatory 90-day dispensing, allowed 90-day dispensing, or excluded from 90-day dispensing may be updated often and is subject to change at any time.

MassHealth Medication Therapy Management Program

BACKGROUND

The MassHealth Medication Therapy Management (MTM) program is a clinical outreach initiative developed to provide additional support to MassHealth members enrolled in fee-for-service (FFS), primary care clinician (PCC), or primary care accountable care organization (PCACO) plans who may benefit from medication reviews by a pharmacist. Members will be enrolled quarterly based on targeted disease states and MassHealth eligibility.

The goals of the program are to serve as a resource for members to learn more about their medications by conducting personalized medication reviews and to work with their health care providers to optimize their medication regimens. Additional program goals include improving medication adherence, increasing the use of appropriate preventive measures such as vaccines, identifying potential drug-related problems, and improving overall health outcomes.

Members will receive a letter informing them of their enrollment in the outreach program, with the opportunity to opt out. They will then be contacted by phone to schedule an appointment with a MassHealth pharmacist to complete an annual medication review. Pharmacists will review the member's medications with them, discuss any of the member's medication-related concerns, and create a comprehensive medication list that will be shared with the member. The member will also receive a to-do list that will highlight any counseling points and recommendations to be discussed with their provider. Members will be instructed not to make any changes without discussing with their health care provider(s). After the appointment, the pharmacist will contact the member's provider(s) with any medication-related questions or recommendations.

Interpretation and translation services will be available for all aspects of this program.

CURRENT ELIGIBLE MEMBERS

- Members diagnosed with sickle cell disease (SCD)

Q&A ABOUT THE MASSHEALTH MEDICATION THERAPY MANAGEMENT PROGRAM

What are the goals of this initiative?

The primary goals of the program include educating members about their medications, resolving potential drug-related problems, collaborating with providers to optimize medication regimens, and improving health outcomes of members.

What is a medication review?

Medication reviews are scheduled annually with a pharmacist. During the appointment, the pharmacist will ask about a member's medical history, recent hospitalizations or emergency department visits, and their medications. Any problems, questions, or concerns about medications can be discussed during this appointment. The pharmacist may share their recommendations with the member's providers. A comprehensive medication list will be mailed to the member and include any recommendations to discuss with their provider. The appointment typically takes about 30 minutes.

How often will medication reviews occur?

Medication reviews will occur annually with a pharmacist. Follow-up calls may occur if necessary.

Will there be a copay for the appointment?

No, there is no cost for the annual medication review or any follow-up calls.

Can the pharmacist prescribe medications or make changes to medications?

No, the pharmacist cannot prescribe medications. If the pharmacist has any recommendations, they will follow up with the member's provider. The provider will then make any changes to medications if necessary.

Is it possible to be removed from the program?

Yes. If a member would like to be removed, they can call us at 877-297-3776 from 8:00 a.m. to 4:00 p.m., Monday through Friday, and opt out of the program. Members can sign back up at any time.

Is there anything health care providers need to do?

Health care providers do not need to do anything for members to be enrolled in this program. Health care providers caring for enrolled members may receive phone calls and faxes from a MassHealth pharmacist with questions or recommendations related to a member's medications.

How can the program be contacted?

For Pharmacists and Prescribers

If you have questions about a specific member affected by the program, please call the direct phone number, 877-297-3776, Monday through Friday, from 8:00 am to 4:00 pm or email questions to MassHealthClinicalOutreachProgram@umassmed.edu.

For MassHealth Members

If you have questions about the program, please call the direct phone number, 877-297-3776, Monday through Friday, from 8:00 am to 4:00 pm or email questions to MassHealthClinicalOutreachProgram@umassmed.edu.

MassHealth Non-Drug Product List

This page lists the non-drug products that MassHealth pays for through the Pharmacy Online Processing System (POPS). Products that require prior authorization are noted with the designation "PA." Payment is calculated in accordance with the Executive Office of Health and Human Service's regulations at 114.3 CMR 22.00: Durable Medical Equipment and 101 CMR 317.00: Medicine.

Medical Supplies

- Alcohol swabs
- Automatic blood pressure monitors
- Disposable syringe and needle units
- Freestyle (test strips, blood glucose, preferred) – **PA > 100 units/30 days**
- Freestyle Insulinx (test strips, blood glucose, preferred) – **PA > 100 units/30 days**
- Freestyle Lite (test strips, blood glucose, preferred) – **PA > 100 units/30 days**
- Freestyle Neo (test strips, blood glucose, preferred) – **PA > 100 units/30 days**
- Lancets
- Medically necessary enteral nutritional liquid
- Medically necessary formula
- Peak flow meters
- Pediatric enteral special formula
- Precision Xtra (test strips, blood glucose, preferred) – **PA > 100 units/30 days**
- Test strips, blood glucose, all other non-preferred – **PA**
- Thickening agents
- Urine glucose testing reagent strips used for the management of diabetes
- Urine protein testing reagent strips
- Vaporizers

Devices

- Cequr Simplicity (insulin bolus delivery patch) – **PA**
- Dexcom G6 (continuous glucose monitoring system) – **PA**
- Dexcom G7 (continuous glucose monitoring system) – **PA**
- Drug delivery systems for use with metered dose inhalers (for example, aerochambers)
- Freestyle Libre 14 day (continuous glucose monitoring system) – **PA**
- Freestyle Libre 2 (continuous glucose monitoring system) – **PA**
- Freestyle Libre 3 (continuous glucose monitoring system) – **PA**
- Hyper-Sal (sodium chloride 3.5%, 7% for inhalation)
- Insulin cartridge delivery devices and needles or other devices for injection of medication (for example, epinephrine auto-injectors)
- Nasal adaptor/mucosal atomization device (needle-free injection device) as part of nasal naloxone rescue kit, two per kit
- Nebusal (sodium chloride 6% for inhalation)
- Omnipod 5 (insulin continuous subcutaneous infusion pump) – **PA**
- Omnipod Classic (insulin continuous subcutaneous infusion pump) – **PA**
- Omnipod Dash (insulin continuous subcutaneous infusion pump) – **PA**
- Omnipod Go (insulin continuous subcutaneous infusion pump) – **PA**
- Pulmosal (sodium chloride 7% for inhalation)
- sodium chloride for inhalation
- V-Go (insulin continuous subcutaneous infusion patch) – **PA**

COVID-19 at-home antigen self-test kits

- Binaxnow – **PA > 2 tests/28 days**
- Carestart – **PA > 2 tests/28 days**
- CVS COVID-19 At-Home Test – **PA > 2 tests/28 days**
- Flowflex – **PA > 2 tests/28 days**
- Genabio – **PA > 2 tests/28 days**
- Ihealth – **PA > 2 tests/28 days**
- Inteliswab – **PA > 2 tests/28 days**
- On-Go – **PA > 2 tests/28 days**
- Quickvue – **PA > 2 tests/28 days**

MassHealth Over-the-Counter Drug List

This page lists the only over-the-counter (OTC) drugs that are covered by MassHealth without prior authorization (PA). All other OTC drugs require PA, except select OTC insulins. All OTC insulins are covered for members at home, in nursing facilities, or in rest homes; however, PA restrictions apply as listed in the MassHealth Drug List. Please refer to 130 CMR 406.411(A) and 406.412 (A)(2) for further information on OTC drugs. The items are listed alphabetically by therapeutic class, then by the generic name of the drug or drug ingredients. In general, MassHealth pays only for generic versions of these OTC drugs, singly or in combination, regardless of strength or dosage formulation unless otherwise specified. Combination products that contain active ingredients that are not included in this list require PA. Notwithstanding the above, MassHealth may pay for a brand-name OTC product if that product is medically necessary under 130 CMR 450.204. All brand-name OTC products currently covered by MassHealth without PA are listed by brand name, below.

Allergy Agents, Ophthalmic
alcaftadine
ketotifen
naphazoline
Naphcon-A (naphazoline/ pheniramine)
Opcon-A (naphazoline/ pheniramine)

Analgesics
acetaminophen ≤ 4 grams/day
aspirin 81 mg
aspirin 325 mg, 500 mg, 650 mg
aspirin suppository
aspirin with buffers
capsaicin
diclofenac 1% gel
ibuprofen
lidocaine 4% patches ≤ 4 patches/day
naproxen capsule, tablet

Anthelmintic Agents
Reese's Pinworm (pyrantel pamoate)

Antihistamines/ Decongestants
cetirizine syrup, tablet
cetirizine/pseudoephedrine
chlorpheniramine
diphenhydramine
doxylamine
fexofenadine tablet
fexofenadine/pseudoephedrine
loratadine tablet, solution
loratadine/pseudoephedrine
pseudoephedrine ≤ 240 mg/day

Antimicrobials, Topical
bacitracin
chlorhexidine gluconate
clotrimazole
double antibiotic ointment
hydrogen peroxide
iodine
isopropyl alcohol
miconazole
neomycin
povidone
terbinafine 1% cream
tolnaftate cream, powder
triple antibiotic ointment

Compounding Agents
cherry syrup
gelatin capsule, empty
Ora-Plus suspending vehicle
Ora-Sweet oral syrup
Ora-Sweet-SF oral syrup
simple syrup

Contraceptives, Oral
levonorgestrel 1.5 mg tablet
Opill (norgestrel tablet)

Contraceptives, Topical
nonoxynol-9 *

Dermatologic Agents, Topical
benzoyl peroxide
calamine lotion
colloidal oatmeal
hydrocortisone cream, lotion, ointment
hydrophilic ointment
lanolin
petrolatum
selenium sulfide
vitamin A and D ointment
witch hazel
zinc oxide

Gastrointestinal Agents
Align (bifidobacterium infantis) < 21 years
aluminum carbonate
aluminum hydroxide
bisacodyl enema, suppository
bisacodyl tablet
bismuth subsalicylate
calcium polycarbophil
cimetidine tablet
Culturelle (lactobacillus rhamnosus GG) < 21 years
dextrin
docusate sodium capsule, tablet
docusate sodium enema
docusate sodium solution, syrup

* Branded OTC nonoxynol-9 products are covered by MassHealth without PA.

Gastrointestinal Agents (continued)
famotidine tablet
Florastor (saccharomyces boulardii) < 21 years
glycerin
lactase
loperamide
magaldrate
magnesium salts
meclizine
methylcellulose
mineral oil
polyethylene glycol 3350
psyllium capsule
psyllium powder
sennosides tablet
sennosides syrup
simethicone
sodium bicarbonate
sodium phosphate

Intranasal Sprays
budesonide nasal spray ≤ 1 inhaler/30 days
triamcinolone nasal spray ≤ 1 inhaler/30 days

Medical Foods
levomethylfolate tablet ≤ 1 unit/day

Opioid Reversal Agents
Narcan (naloxone 4 mg nasal spray) †
Rivive (naloxone 3 mg nasal spray)

Otic Agents
carbamide peroxide

Pediculicides/Scabicides
permethrin
piperonyl butoxide/pyrethrins

Respiratory Agents
sodium chloride for inhalation

Smoking Cessation
nicotine gum, lozenge, patch

Tear/Saliva Replacement Agents
artificial tears
saliva substitute

Vitamins/Nutrients/ Supplements
calcium replacement
cod liver oil
coenzyme Q10 < 21 years
electrolyte solution, pediatric
ferrous fumarate
ferrous gluconate
ferrous sulfate
folic acid
glucose products < 21 years
iron polysaccharide complex
magnesium salts
melatonin
melatonin/pyridoxine tablet
multivitamins
niacinamide
nicotinic acid
pediatric multivitamins
Phos-Flur (sodium fluoride oral rinse)
prenatal vitamins
potassium phosphate
sodium chloride tablet
sodium fluoride
vitamin A (retinol)
vitamin B-1 (thiamine)
vitamin B-2 (riboflavin)
vitamin B-3 (niacin)
vitamin B-6 (pyridoxine)
vitamin B-12 (cyanocobalamin)
vitamin B complex
vitamin C (ascorbic acid)
vitamin D
vitamin E, oral
vitamins, multiple
vitamins, multiple/minerals
vitamins, pediatric
vitamins, prenatal

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† Brand and generic products are covered by MassHealth without PA.

MassHealth Pharmacy Covered Professional Services List

This page lists professional services that MassHealth pays for through the Pharmacy Online Processing System (POPS). The service must be provided by a properly trained and certified pharmacist or other appropriately certified health care professional in accordance with Massachusetts Department of Public Health regulations and employed or contracted by a MassHealth pharmacy provider. MassHealth pays for the services at the applicable mid-level practitioner rate found in 101 CMR 317.00: Medicine.

- Administration of the following vaccines
  - COVID-19 Moderna vaccine*
  - COVID-19 Novavax vaccine*
  - COVID-19 Pfizer vaccine*
  - diphtheria, tetanus, and acellular pertussis vaccine
  - diphtheria, tetanus vaccine
  - DTaP, hepatitis B, and inactivated poliovirus vaccine
  - DTaP, inactivated poliovirus, and *Haemophilus influenzae* type B vaccine
  - DTaP, inactivated poliovirus, *Haemophilus influenzae* type B, and hepatitis B vaccine
  - DTaP and inactivated poliovirus vaccine
  - haemophilus influenzae type b
  - hepatitis A vaccine
  - hepatitis A and hepatitis B vaccine
  - hepatitis B vaccine
  - human papillomavirus vaccine
  - influenza vaccine
  - measles, mumps, and rubella vaccine
  - measles, mumps, rubella, and varicella vaccines
  - meningococcal serogroup B vaccine
  - pentavalent meningococcal vaccine
  - pneumococcal 13-valent conjugate vaccine
  - pneumococcal 15-valent conjugate vaccine
  - pneumococcal 20-valent conjugate vaccine
  - pneumococcal 21-valent conjugate vaccine
  - pneumococcal 23-valent polysaccharide vaccine
  - poliovirus vaccine (inactivated)
  - respiratory syncytial virus vaccine
  - respiratory syncytial virus vaccine, adjuvanted
  - rotavirus vaccine
  - smallpox and monkeypox vaccine
  - tetanus and diphtheria toxoids
  - tetanus and diphtheria toxoids and acellular pertussis vaccine
  - varicella vaccine
  - zoster vaccine, recombinant

*For billing details of COVID-19 vaccines and allowable administration fees, see Pharmacy Facts #170 available at https://www.mass.gov/doc/pharmacy-facts-170-august-19-2021-0/download.

MassHealth Pharmacy Naloxone Availability and Coverage

The standing order for dispensing naloxone rescue kits authorizes licensed pharmacists to dispense naloxone rescue kits to a person at risk of experiencing an opioid-related overdose. Licensed pharmacists may also dispense the naloxone rescue kits to a family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose. Please refer to M.G.L. c. 94C, § 19B for further information on the standing order for naloxone (https://www.mass.gov/doc/naloxone-standing-order-1/download).

This page lists prescription and over-the-counter (OTC) naloxone products that are covered by MassHealth without prior authorization (PA). These products are available at no out-of-pocket cost and without quantity limits. Naloxone products recently approved for OTC use have been added to the MassHealth OTC Drug List and the OTC Drug List will be updated as needed with new formulations.

- Kloxxado (naloxone 8 mg/0.1 mL nasal spray)
- naloxone 4 mg nasal spray
- naloxone vial, 0.4 mg/mL syringe, 2 mg/2 mL syringe
- Narcan (naloxone 4 mg nasal spray)
- Rivive (naloxone 3 mg nasal spray)*
- Zimhi (naloxone 5 mg /0.5 mL syringe)

* FDA-approved over-the-counter formulation

When dispensing naloxone products, pharmacies should submit claims as a 1-day supply. If additional naloxone is needed for a member within the same day, pharmacists should contact the MassHealth Drug Utilization Review Program for an emergency override at 1-800-745-7318 during normal business hours. Outside of business hours, pharmacies may submit an emergency override claim with a value of “03” for level of service (Field 418-DI).

MassHealth Pharmacy Operational Page

This page lists operational information related to the MassHealth Pharmacy Program.

Any drug that does not appear on the MassHealth Drug List (MHDL) requires prior authorization (PA).

Brand name (no substitution) drugs with FDA "A"-rated generic equivalents and non-preferred drug generic equivalents for drugs appearing on the MassHealth Brand Name Preferred Over Generic Drug List

Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Documentation of all of the following is required:
    - individual drug PA criteria must be met first where applicable; **and**
    - medical records documenting one of the following:
        - an allergic response or adverse reaction to the preferred drug product or history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug product; **or**
        - an inadequate response to the preferred drug product.

New-to-market drugs and biologics

FDA-approved new-to-market drugs and biologics that are not listed in the MHDL are under review and will be handled on a case-by-case basis until MassHealth has concluded its evaluation of the drug or biologic.

- Documentation of all of the following is required:
    - appropriate diagnosis; **and**
    - medical necessity based on diagnosis and existing treatment options.

New indications evaluation for oncology drugs and biologics

New FDA-approved indications for oncology drugs and biologics that are not listed in the MHDL are under review and will be handled on a case-by-case basis until MassHealth has concluded its evaluation of the new indication. Evaluation of a new indication includes a thorough review by physicians and pharmacists using medical literature and consulting with specialists, other physicians, or both. References used may include National Comprehensive Cancer Network (NCCN).

Non-FDA-approved drugs and biologics

Non-FDA-approved drugs and biologics require PA and will be evaluated for medical necessity.

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - trials of all clinically appropriate FDA-approved alternatives.

Non-Rebate drugs and biologics

MassHealth does not pay for drugs that are manufactured by companies that have not signed rebate agreements with the U.S. Secretary of Health and Human Services. Non-rebate drugs and biologics require PA and will be evaluated for medical necessity. Rebate status is subject to change and the MassHealth Drug List may be updated at a future rollout.

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - trials of all clinically appropriate alternatives whose manufacturers participate in the federal rebate program; **and**
  - clinical rationale for use of a drug whose manufacturer does not participate in the federal rebate program.

Cosmetic or Hair Growth Agents for Medical Necessity:

The MassHealth agency does not pay for any drug when used for cosmetic purposes or for hair growth, unless medically necessary. Requests must have documentation of a severe and persistent or widespread condition, rationale or documentation of no other available treatment options, and a provider attestation of a negative impact on the member's life.

Gender-affirming Care Requests:

For a member who has undergone gender transition or is in the process of a gender transition, requests for the following may be approved with documentation of a severe and persistent or widespread condition, and rationale or documentation of no other available treatment options (pharmacological or non-pharmacological) for either of the following:

- an agent for the reduction of hair growth in a person with male sex assigned at birth/biologic male (transgender male to female)
- Both of the following:
  - The provider attests the drug is necessary to the member's identity
  - Documentation that the condition to be treated is negatively affecting the member's life as a transgender individual

MassHealth Preferred Non-Drug Product List

This page list those non-drug products for which MassHealth has entered into a rebate agreement with product manufacturers, allowing MassHealth the ability to provide coverage of non-drug products at the lowest possible costs.

The products are listed alphabetically by therapeutic class, then by the name of the non-drug product. Please note that MassHealth may still require prior authorization for clinical reasons. Products that require additional prior authorization requirements are noted with PA on this list.

Devices:

See Therapeutic Class Table 78 on the MassHealth Drug List for Diabetes Medical Supplies and Emergency Treatments.

- Cequr Simplicity (insulin bolus delivery patch) – **PA**
- Dexcom G6 (continuous glucose monitoring system) – **PA**
- Dexcom G7 (continuous glucose monitoring system) – **PA**
- Freestyle Libre 14 day (continuous glucose monitoring system) – **PA**
- Freestyle Libre 2 (continuous glucose monitoring system) – **PA**
- Freestyle Libre 3 (continuous glucose monitoring system) – **PA**
- Omnipod Classic (insulin continuous subcutaneous infusion pump) – **PA**
- Omnipod Dash (insulin continuous subcutaneous infusion pump) – **PA**
- Omnipod 5 (insulin continuous subcutaneous infusion pump) – **PA**
- Omnipod Go (insulin continuous subcutaneous infusion pump) – **PA**
- V-Go (insulin continuous subcutaneous infusion patch) – **PA**

Medical Supplies:

See Therapeutic Class Table 78 on the MassHealth Drug List for Diabetes Medical Supplies and Emergency Treatments.

- Freestyle (test strips, blood glucose, preferred) – **PA > 100 units/30 days**
- Freestyle Insulinx (test strips, blood glucose, preferred) – **PA > 100 units/30 days**
- Freestyle Lite (test strips, blood glucose, preferred) – **PA > 100 units/30 days**
- Freestyle Neo (test strips, blood glucose, preferred) – **PA > 100 units/30 days**
- Precision Xtra (test strips, blood glucose, preferred) – **PA > 100 units/30 days**

MassHealth Supplemental Rebate/ Preferred Drug List

This page list those drugs for which MassHealth has entered into a supplemental rebate agreement with drug manufacturers, allowing MassHealth the ability to provide medications at the lowest possible costs.

The items are listed alphabetically by therapeutic class, then by the name of the drug or drug ingredients. Please note that MassHealth may still require prior authorization for clinical reasons. Drugs that require additional prior authorization requirements are noted with PA on this list.

In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

Analgesic Agents:

See Therapeutic Class Table 8 on the MassHealth Drug List for Opioids and Analgesics.

- Journavx (suzetrigine) – **PA > 29 units/60 days**

Antidepressant Agents:

See Therapeutic Class Table 17 on the MassHealth Drug List for Antidepressant Agents.

- Zurzuvae (zuranolone) – **PA**

Antidiabetic Agents:

See Therapeutic Class Table 26 on the MassHealth Drug List for Antidiabetic Agents.

- Lantus (insulin glargine)

Anti-Hemophilia Agents:

See Therapeutic Class Table 80 on the MassHealth Drug List for Anti-Hemophilia Agents.

- Benefix (factor IX human recombinant)
- Hemlibra (emicizumab-kxwh)
- Jivi (antihemophilic factor, recombinant pegylated-aucl)
- Kogenate (antihemophilic factor, recombinant)
- Kovaltry (antihemophilic factor, recombinant)
- Xyntha (antihemophilic factor, recombinant)

Anti-Hypoglycemic Agent:

See Therapeutic Class Table 78 on the MassHealth Drug List for Diabetes Emergency Treatment Agents.

- Baqsimi (glucagon nasal powder)

Anti-Obesity Agent:

See Therapeutic Class Table 81 on the MassHealth Drug List for Anti-Obesity Agents.

- Zepbound (tirzepatide) – **PA**

Antiretroviral/HIV Agents:

See Therapeutic Class Table 38 on the MassHealth Drug List for Antiretroviral/HIV Agents.

- Apretude (cabotegravir injection)
- Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)
- Cabenuva (cabotegravir/rilpivirine)
- Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate)
- Descovy (emtricitabine/tenofovir alafenamide)
- Dovato (dolutegravir/lamivudine)
- Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide)
- Juluca (dolutegravir/rilpivirine)
- Norvir (ritonavir tablet)
- Odefsey (emtricitabine/rilpivirine/tenofovir alafenamide)
- Pifeltro (doravirine)
- Prezcobix (darunavir/cobicistat)
- Rukobia (fostemsavir) – **PA**
- Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide)
- Triumeq (abacavir/dolutegravir/lamivudine)

Anti-TNF Agents:

See Therapeutic Class Table 5 on the MassHealth Drug List for Anti-TNF Agents.

- Enbrel (etanercept) – **PA**
- Humira (adalimumab) – **PA**

Antipsychotic Agent oral Second Generation (Atypical):

See Therapeutic Class Table 24 on the MassHealth Drug List for oral Second Generation (Atypical) Antipsychotic Agents.

- Vraylar (cariprazine) – **PA**

Asthma and Allergy Agent:

See Therapeutic Class Table 64 on the MassHealth Drug List for Asthma/Allergy Monoclonal Antibodies.

- Dupixent (dupilumab) – **PA**

Calcitonin Gene-Related Peptide Inhibitors:

See Therapeutic Class Table 14 on the MassHealth Drug List for Calcitonin Gene-Related Peptide Inhibitors.

- Ajovy (fremanezumab-vfrm) – **PA**

- Emgality (galcanezumab-gnlm) – **PA**
- Nurtec (rimegepant) – **PA**
- Qulipta (atogepant) **– PA**
- Ubrelvy (ubrogepant) – **PA**

Cerebral Stimulant:

See Therapeutic Class Table 31 on the MassHealth Drug List for Cerebral Stimulants.

- Adderall XR (amphetamine salts extended-release) – **PA < 3 years or ≥ 21 years and PA > 2 units/day**

COVID-19 Agents:

See Therapeutic Class Table 72 on the MassHealth Drug List for COVID-19 Related Medications.

- Paxlovid (nirmatrelvir/ritonavir 150 mg-100 mg) – **PA < 12 years and PA > 20 units/claim**
- Paxlovid (nirmatrelvir/ritonavir 300-100 mg) – **PA < 12 years and PA > 30 units/claim**
- Paxlovid (nirmatrelvir/ritonavir 300/150-100 mg)

Cystic Fibrosis Agents:

See Therapeutic Class Table 21 on the MassHealth Drug List for Cystic Fibrosis Agents.

- Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) – **PA**
- Kalydeco (ivacaftor) – **PA**
- Orkambi (lumacaftor/ivacaftor) – **PA**
- Symdeko (tezacaftor/ivacaftor) – **PA**
- Trikafta (elexacaftor/tezacaftor/ivacaftor) – **PA**

Dermatologic Agents:

See Therapeutic Class Table 63 on the MassHealth Drug List for Dermatologic Agents.

- Ycanth (cantharidin) – **PA**

Drug and Alcohol Cessation Agents:

See Therapeutic Class Table 36 on the MassHealth Drug List for Drug and Alcohol Cessation Agents.

- Brixadi (buprenorphine extended-release injection)
- Sublocade (buprenorphine extended-release injection)
- Suboxone (buprenorphine/naloxone film ≤ 24 mg/day)
- Suboxone (buprenorphine/naloxone film) – **PA > 90 days (> 24 mg/day and ≤ 32 mg/day)**
- Suboxone (buprenorphine/naloxone film) – **PA > 32 mg/day**
- Vivitrol (naltrexone injection)

Enzyme and Metabolic Disorder Therapy:

See Therapeutic Class Table 65 on the MassHealth Drug List for Enzyme and Metabolic Disorder Therapies.

- Carbaglu (carglumic acid) – **PA**

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist:

See Therapeutic Class Table 26 on the MassHealth Drug List for GLP-1 Receptor Agonists.

- Trulicity (dulaglutide) – **PA > 2 mL/28 days**

Gonadotropin-Releasing Hormone Analogs:

See Therapeutic Class Table 2 on the MassHealth Drug List for Gonadotropin-Releasing Hormone Analogs.

- Fensolvi (leuprolide) – **PA**

Growth Hormone:

See Therapeutic Class Table 9 on the MassHealth Drug List for Growth Hormones.

- Genotropin (somatropin) – **PA**
- Skytrofa (lonapegsomatropin-tcgd) – **PA**
- Sogroya (somapacitan-beco) – **PA**

Hepatitis Antivirals:

See Therapeutic Class Table 44 on the MassHealth Drug List for Hepatitis Antiviral Agents.

- ledipasvir/sofosbuvir* – **PA**
- Mavyret (glecaprevir/pibrentasvir) – **PA**
- sofosbuvir/velpatasvir* – **PA**
- Vemlidy (tenofovir alafenamide)

* Please note, pediatric dosing formulations of Brand name Epclusa and Harvoni are preferred. For all other strengths, generics are preferred.

Inhaled Respiratory Agent:

See Therapeutic Class Table 23 on the MassHealth Drug List for Inhaled Respiratory Agents.

- Symbicort (budesonide/formoterol)

Interleukin Antagonists:

See Therapeutic Class Table 5 on the MassHealth Drug List for Interleukin Antagonist.

- Adbry (tralokinumab-ldrm) – **PA**
- Ebglyss (lebrikizumab-lbkz) – **PA**
- Omvoh (mirikizumab-mrkz auto-injection, prefilled syringe) – **PA**
- Skyrizi (risankizumab-rzaa auto-injection, on-body injector, prefilled syringe) – **PA**
- Stelara (ustekinumab 45 mg/0.5 mL prefilled syringe, 90 mg/mL prefilled syringe, 45 mg/0.5 mL vial) – **PA**
- Taltz (ixekizumab) – **PA**

Long-Acting Aripiprazole Agents:

See Therapeutic Class Table 24 on the MassHealth Drug List for Long-Acting Aripiprazole and Second Generation (Atypical) Antipsychotic Agents.

- Aristada (aripiprazole lauroxil 441 mg, 662 mg, 882 mg) – **PA < 10 years and PA > 1 injection/28 days**

- Aristada (aripiprazole lauroxil 1,064 mg) – **PA < 10 years and PA > 1 injection/56 days**
- Aristada Initio (aripiprazole lauroxil 675 mg) – **PA < 10 years and PA > 1 injection/28 days**

Long-Acting Risperidone Agents:

See Therapeutic Class Table 24 on the MassHealth Drug List for Long-Acting Risperidone and Second Generation (Atypical) Antipsychotic Agents.

- Perseris (risperidone 90 mg, 120 mg extended-release subcutaneous injection) – **PA < 10 years and PA > 1 injection/28 days**
- Uzedy (risperidone 50 mg, 75 mg, 100 mg, 125 mg extended-release subcutaneous injection) – **PA < 10 years and PA > 1 injection/28 days**
- Uzedy (risperidone 150 mg, 200 mg, 250 mg extended-release subcutaneous injection) – **PA < 10 years and PA > 1 injection/56 days**

Long-Acting Paliperidone Agents:

See Therapeutic Class Table 24 on the MassHealth Drug List for Long-Acting Paliperidone and Second Generation (Atypical) Antipsychotic Agents.

- Invega Hafyera (paliperidone extended-release 6-month injection) – **PA < 10 years and PA > 1 injection/168 days**
- Invega Sustenna (paliperidone extended-release 1-month injection) – **PA < 10 years, PA > 2 injections/28 days within the first 28 days of therapy and PA > 1 injection/28 days after 28 days of therapy**
- Invega Trinza (paliperidone extended-release 3-month injection) – **PA < 10 years and PA > 1 injection/84 days**

Oncology Agents:

See Therapeutic Class Table 57 on the MassHealth Drug List for Oncology Agents.

- Ibrance (palbociclib) – **PA**

Opioid Reversal Agent:

See Therapeutic Class Table 36 on the MassHealth Drug List for Drug and Alcohol Cessation Agents.

- Kloxxado (naloxone 8 mg nasal spray)

Sickle Cell Disease and Transfusion-Dependent Beta Thalassemia Gene Therapy:

See Therapeutic Class Table 45 on the MassHealth Drug List for Sickle Cell Disease and Transfusion-Dependent Beta Thalassemia Agents Gene Therapies.

- Casgevy (exagamglogene autotemcel) – **PA**

Small Interfering RNA Agents:

See Therapeutic Class Table 72 on the MassHealth Drug List for Agents not Otherwise Classified.

- Amvuttra (vutrisiran) – **PA**
- Givlaari (givosiran) – **PA**
- Onpattro (patisiran) – **PA**
- Oxlumo (lumasiran) – **PA**

Spinal Muscular Atrophy Agent:

See Therapeutic Class Table 76 on the MassHealth Drug List for Spinal Muscular Atrophy Agents.

- Zolgensma (onasemnogene abeparvovec-xioi) – **PA**

Topical Immune Suppressant:

See Therapeutic Class Table 42 on the MassHealth Drug List for Immune Suppressants – Topical.

- Eucrisa (crisaborole) – **PA**
- Opzelura (ruxolitinib cream) – **PA**
- Zoryve (roflumilast cream, foam) – **PA**

Medicare Part D Exclusion Drug List

The following drugs or drug classes are excluded by Medicare Part D. For dually eligible members (members who are eligible for both Medicare Part D and MassHealth), MassHealth may pay for some of these drugs or drug classes, subject to the prior authorization (PA) requirements listed on the MassHealth Drug List.

- **Over-the-counter (OTC) Drugs**
  Except for insulin and supplies associated with the injection of insulin, OTC drugs are excluded by Medicare Part D. OTC drugs that are covered by MassHealth can be found on the MassHealth OTC Drug List at www.mass.gov/druglist.

- **Prescription Vitamins and Minerals**
  Except for prenatal vitamins, fluoride-containing products, prescription vitamins, and minerals are excluded by Medicare Part D. Prescription vitamins that are covered by MassHealth are listed on the MassHealth Drug List.

- **Weight-management Drugs**
  Some drugs used for weight gain (dronabinol, megestrol, somatropin) may be excluded by Medicare Part D plans. MassHealth will cover these products only if they are denied by the Medicare Part D plan. PA requirements for these drugs can be found on the MassHealth Drug List.
  Drugs FDA-approved for treatment of obesity are excluded by Medicare Part D plans. PA requirements for these drugs can be found on the MassHealth Drug List.
  Some drugs may be excluded by Medicare Part D plans when used off-label for treatment of obesity. MassHealth will cover these products only if they are denied by the Medicare Part D plan. PA requirements for these drugs can be found on the MassHealth Drug List.

- **Medicare Part B**
  There has been no change to Medicare Part B. Products that were covered under Medicare Part B before January 1, 2006, continue to be covered under Medicare Part B. MassHealth continues to act as secondary payer for these services. PA requirements for drugs covered under Medicare Part B can be found on the MassHealth Drug List.

MassHealth Quick Reference Guide

Antibiotics
amoxicillin/clavulanate ER-PA
azithromycin-F
cefpodoxime susp-PA
cephalexin 100 mg tab, 750 mg cap-PA
linezolid suspension-PA
nitrofurantoin-F
ofloxacin-PA
tigecycline-PA
tinidazole
Baxdela-PA
Dificid-PA
Nuzyra-PA
Solosec-PA
Xifaxan 550 mg-PA

Anticonvulsants[1,3]
carbamazepine IR, XR
clobazam
clonazepam-F
clorazepate-PA
diazepam-F
divalproex
eslicarbazepine-PA
ethosuximide
felbamate
fosphenytoin
gabapentin-Q
lacosamide injection, tablet, solution
lamotrigine
lamotrigine ER, ODT-PA
levetiracetam injection, soln, tab
methsuximide
oxcarbazepine
oxcarbazepine extended release-PA
phenobarbital tablet, solution, injection
phenytoin
pregabalin-Q
primidone
rufinamide-PA
tiagabine-PA
topiramate tab, cap
topiramate ER cap-F
valproate
valproic acid
vigabatrin powder packet, tablet-PA
zonisamide capsule
Briviact-PA
Diacomit-PA
Elepsia XR-PA
Epidiolex-PA
Eprontia-PA
Equetro
Fintepla-PA
Fycompa-PA
Libervant-A,Q
Motpoly XR-PA
Nayzilam-Q
Spritam-PA
Sympazan-PA
Valtoco-Q
Vigafyde–PA
Xcopri-PA
Zonisade-PA
Ztalmy-PA

Antidepressants[1]
amoxapine-PA
bupropion IR
bupropion SR
bupropion XL 150mg, 300mg-Q
bupropion XL 450mg-PA
citalopram-F
clomipramine-PA
desipramine-PA
desvenlafaxine ER-PA
desvenlafaxine succinate ER-Q
duloxetine 20, 30, 60 mg
duloxetine 40 mg cap-PA
escitalopram
fluoxetine 10, 20, 40 mg cap, soln 10, 20 mg tab
fluoxetine 60 mg tab, 90 mg DR capsule-PA
fluvoxamine ER-PA
imipramine hydrochloride
imipramine pamoate-PA
mirtazapine
mirtazapine ODT-PA
nefazodone
paroxetine paroxetine CR-PA
protriptyline-PA
sertraline-F
trazodone
trimipramine-PA
venlafaxine IR
venlafaxine ER capsule
venlafaxine HC ER tab-PA
vilazodone-PA
Aplenzin-PA
Drizalma-PA
Emsam-PA
Fetzima-PA
Marplan-PA
Spravato-PA
Trintellix-PA
Zurzuvae-PA

Cerebral Stimulants and ADHD Agents[1]
amphetamine ER 1.25 mg/mL oral susp-A,PA
amphetamine salts ER and IR-A,F,Q
amphetamine sulfate-A,PA
atomoxetine
clonidine ER 0.1 mg tab-Q
dexmethylphenidate ER and IR-A,Q
methylphenidate transdermal-A,Q
methylphenidate ER tab, IR, SR, chew tab-A,Q
methylphenidate ER cap-A,PA
Adzenys XR-ODT-A,PA
Aptensio XR-A,PA
Azstarys-A,PA
Cotempla XR-ODT-A,PA
Dyanavel XR-A,PA,Q
Evekeo ODT-A,PA
Jornay PM-A,PA
Onyda XR–PA
Qelbree-PA
Quillichew ER-A,PA
Quillivant XR-A,PA,Q
Relexxi-A,PA
Vyvanse-A,F,Q
Xelstrym-A,PA

Antidiabetic: Insulin and Injectable Combinations
insulin aspart-PA
insulin glargine
insulin lispro
Admelog-PA
Afrezza-PA
Apidra-PA
Basaglar-PA
Basaglar Tempo-PA
Fiasp-PA
Humalog 50/50, 75/25
Humalog Tempo-PA
Humulin R
Humulin N-PA
Lantus
Levemir
Lyumjev-PA
Lyumjev Tempo-PA
Novolin R and N
Rezvoglar-PA
Semglee-PA
Soliqua-PA
Tresiba
Xultophy-PA

Antidiabetic: Non-Insulin Single Agents
alogliptin-PA
dapagliflozin
liraglutide (Victoza)-Q
metformin IR, ER-F
metformin IR solution-A
nateglinide
pioglitazone
repaglinide
Bydureon Bcise-PA
Byetta-Q
Invokana-PA
Januvia
Jardiance
Mounjaro-PA
Onglyza-PA
Ozempic-PA
Riomet ER-PA
Rybelsus-PA
Steglatro-PA
Symlinpen
Tradjenta
Trulicity-Q
Zituvio- PA

Antidiabetic: Non-Insulin Combinations
alogliptin/metformin-PA
alogliptin/pioglitazone-PA
dapagliflozin/metformin extended release
repaglinide/metformin-PA
saxagliptin/metformin extended release-PA
sitagliptin/metformin
Glyxambi-PA
Invokamet IR, XR-PA
Janumet IR, XR
Jentadueto IR, XR
Qtern-PA
Segluromet-PA
Steglujan-PA
Synjardy IR, XR
Trijardy XR-PA
Zituvimet IR, XR-PA

Antihistamines
carbinoxamine 4mg
carbinoxamine 6mg-PA
cetirizine
desloratadine tab-PA
dexchlorpheniramine-PA
diphenhydramine
hydroxyzine
levocetirizine soln-PA
levocetirizine tablet
loratadine

Antipsychotics[1]
aripiprazole-Q
aripiprazole ODT-PA
asenapine sublingual tablet-PA
clozapine
clozapine ODT-PA
lurasidone-Q
olanzapine-Q
olanzapine IM
olanzapine ODT-Q
paliperidone tablet-Q
quetiapine-Q
quetiapine ER-Q
risperidone-Q
risperidone ER IM injection-Q
risperidone ODT 3 mg, 4 mg-PA
risperidone ODT 0.25, 0.5, 1, 2 mg-Q
ziprasidone-Q
ziprasidone IM
Abilify Asimtufii-PA
Abilify Maintena-PA
Abilify Mycite-PA
Aristada-Q
Aristada Initio-Q
Caplyta-PA
Cobenfy-PA
Erzofri-PA
Fanapt-PA
Invega Hafyera-Q
Invega Sustenna-Q
Invega Trinza-Q
Lybalvi-PA
Opipza-PA
Perseris-Q
Rexulti-PA
Rykindo-PA
Secuado-PA
Uzedy-Q
Versacloz-PA
Vraylar-PA
Zyprexa IM
Zyprexa Relprevv-Q

Asthma
albuterol inhalation soln, syrup, tablet
albuterol inhaler-PA
budesonide-F
budesonide/formoterol
fluticasone propionate inh aerosol-A
fluticasone propionate inh powder-PA
fluticasone/salmeterol inhalation
fluticasone/vilanterol
ipratropium
levalbuterol inh soln-PA
levalbuterol inhaler
Airsupra-PA
Alvesco-PA
Armonair Digihaler-PA
Arnuity-PA
Asmanex HFA
Asmanex Twisthaler
Dulera
Proair Digihaler-PA
Proair Respiclick
Qvar Redihaler-PA
Serevent-PA
Spiriva
Ventolin

Hypnotics[1]
doxepin tab-PA
estazolam-Q
eszopiclone-Q
flurazepam-PA
temazepam 22.5mg-PA
temazepam 7.5 mg, 15 mg, 30 mg-Q
triazolam-Q
zaleplon-Q
zolpidem-Q
zolpidem ER-Q
zolpidem 1.75 mg, 3.5 mg sublingual tab-PA
Belsomra-PA
Dayvigo-PA
Edluar-PA
Quviviq-PA

Narcotic Agonist Analgesics[2, 3]
buprenorphine transdermal-Q
fentanyl buccal tab-PA
fentanyl patch-F, Q
fentanyl transmucosal system-PA
hydrocodone ER cap-PA
hydrocodone ER tab-PA
hydromorphone ER-PA
levorphanol-PA
meperidine-PA
methadone-PA
morphine CR tablet-Q
morphine ER cap-PA
oxycodone ER-PA
oxymorphone ER, IR-PA
tramadol-A,F,Q
Belbuca-PA
Seglentis-PA

This document does not represent the complete MassHealth Drug List. If applicable, drugs may also be subject to additional PA restrictions for polypharmacy, dose, quantity limit, and age. For more information, please visit the MassHealth web site at **www.mass.gov/druglist**. MassHealth evaluates the prior-authorization status of drugs on an ongoing basis and updates the MassHealth Drug List accordingly.

[1] = Listing may be subject to additional PA requirements per Pediatric Behavioral Health Medication Initiative (PBHMI) for members < 18 years of age.

[2] = Listing may be subject to additional PA requirements (Duplicate Opioid, Concurrent Opioid Dependence or Benzodiazepine Agent, High Dose Short-Acting Monotherapy).

[3] = Listing may be subject to additional PA requirements per Concomitant Opioid Benzodiazepine Initiative (COBI).

PA = Prior-authorization required. Prior-authorization forms can be found at www.mass.gov/druglist.

Q = PA is required to exceed certain quantity limits.

A = PA is required to exceed certain age limits.

F = PA depends on formulation.

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