



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

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 VI, X, or XIV as applicable.)	
<input type="checkbox"/> Casgevy (exagamglogene autotemcel) <input type="checkbox"/> Lyfgenia (lovotibeglogene autotemcel) <input type="checkbox"/> Zynteglo (betibeglogene autotemcel)	<input type="checkbox"/> Beta Thalassemia (provide documentation of genetic testing) <input type="checkbox"/> Sickle Cell Disease (SCD)
Enzyme and Metabolic Disorder Therapies	
<input type="checkbox"/> Kebilidi (eladocagene exuparvovec-tneq)	<input type="checkbox"/> Aromatic L-amino acid decarboxylase (AADC) deficiency
Hemophilia gene therapies (See Section IV and V as applicable.)	
<input type="checkbox"/> Hemgenix (etranacogene dezparvovec-drlb)	<input type="checkbox"/> Moderately severe to severe hemophilia B
Neuromuscular agents (See Section VII, XIII, or XVIII as applicable.)	
<input type="checkbox"/> Elevidys (delandistrogene moxeparvovec-rokl) <input type="checkbox"/> Itvisma (onasemnogene abeparvovec-brve) <input type="checkbox"/> Zolgensma (onasemnogene abeparvovec-xioi)	<input type="checkbox"/> Duchenne muscular dystrophy (DMD) <input type="checkbox"/> Spinal muscular atrophy (SMA) <input type="checkbox"/> Pre-symptomatic <input type="checkbox"/> Symptomatic Type <input style="width: 150px; height: 15px;" type="text"/>
T-cell immunotherapies (See Section I, II, and III as applicable.)	
<input type="checkbox"/> Abecma (idecabtagene vicleucel) <input type="checkbox"/> Amtagvi (lifileucel) <input type="checkbox"/> Aucatzyl (obecabtagene autoleucel) <input type="checkbox"/> Breyanzi (lisocabtagene maraleucel) <input type="checkbox"/> Carvykti (ciltacabtagene autoleucel) <input type="checkbox"/> Kymriah (tisagenlecleucel) <input type="checkbox"/> Tecartus (brexucabtagene autoleucel) <input type="checkbox"/> Tecelra (afamitresgene autoleucel) <input type="checkbox"/> Yescarta (axicabtagene ciloleucel)	<input type="checkbox"/> B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse <input type="checkbox"/> Large B-cell lymphoma that is refractory to firstline chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy <input type="checkbox"/> Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) <input type="checkbox"/> Relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy <input type="checkbox"/> 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 <input type="checkbox"/> 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 <input type="checkbox"/> 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 VIII, IX, XI, XII, XVI, or XVII as applicable.)

- | | |
|--|--|
| <ul style="list-style-type: none"> <input type="checkbox"/> Encelto (revakinagene taroretcel-lwey) <input type="checkbox"/> Lenmeldy (atidarsagene autotemcel) <input type="checkbox"/> Luxturna (voretigene neparvovec-rzyl) <input type="checkbox"/> Omisirge (omidubicel-only) <input type="checkbox"/> Skysona (elivaldogene autotemcel) <input type="checkbox"/> Zevaskyn (prademagene zamikeracel) | <ul style="list-style-type: none"> <input type="checkbox"/> Biallelic RPE65 mutation-associated retinal dystrophy <input type="checkbox"/> Cerebral adrenoleukodystrophy (CALD) <input type="checkbox"/> Hematologic malignancy <input type="checkbox"/> Macular telangiectasia type 2 <input type="checkbox"/> Metachromatic leukodystrophy <ul style="list-style-type: none"> <input type="checkbox"/> Presymptomatic late infantile <input type="checkbox"/> Presymptomatic early juvenile <input type="checkbox"/> Early symptomatic early juvenile <input type="checkbox"/> Recessive dystrophic epidermolysis bullosa (RDEB) |
|--|--|

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.

- Dermatologist
 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.

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 Aucztyl 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 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
4. Does the member currently use FIX prophylaxis therapy?
 Yes. Please provide details. No

over

5. FIX activity level Date
6. Does the member have factor IX inhibitor? (Please attach a copy of test.) Yes No
7. Does the member have NAb titer (AAV5)?
 Yes. Please attach a copy of CLIA-validated test. No

Section VI. 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.

- Please attach a copy of genetic test confirming diagnosis.
- Please provide anticipated dates and dosing for the following as applicable.
Apheresis Admission Infusion Dose Discharge
- Will the infusion take place in a qualified treatment center? Yes No
- Will the member receive pre-infusion conditioning with busulfan? Yes No
- Is the member clinically stable and eligible for hematopoietic stem cell transplantation (HSCT)? Yes No
over
- Does the member have active human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) infection? Yes. Please describe. No
- Has the member received any prior gene therapy for the requested diagnosis?
 Yes. Please describe.
 No
- For beta thalassemia, has the member required ≥ 100 mL/kg/year of pRBC or \geq ten units per year within the previous two years?
 Yes. Please describe.
 No
- 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
- 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 VII. Please complete for Elevidys requests.

- Please attach a copy of genetic test with a confirmed mutation in the DMD gene.
- Please attach a copy of baseline anti-AAVrh74 total binding antibody titers $< 1:400$.
- Will the infusion take place in a qualified treatment center? Yes No
- Please provide anticipated date of administration.
- Is the prescriber a neuromuscular specialist? Yes No
- Does the member have any deletion in exon 8 or exon 9 of the DMD gene? Yes No
- Is the member on a stable dose of corticosteroid? Yes No
- Will the member continue to utilize chronic corticosteroids after Elevidys infusion? Yes No
- Does the member have a contraindication to corticosteroids? Yes No

If yes, briefly describe details of contraindication.

[Empty text box for contraindication details]

10. Has the member been previously treated with a gene therapy for DMD? Yes No

11. Is the member currently utilizing disease modifying therapy for DMD (e.g., givinostat [Duvyzat®], or exon-skipping antisense oligonucleotides [Exondys®, Vyondys®, etc.]? 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 []

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 VIII. 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 | <input type="checkbox"/> Positive | <input type="checkbox"/> Negative | <input type="checkbox"/> Not completed |
| Human T-lymphotrophic virus (HTLV)-1/2 | <input type="checkbox"/> Positive | <input type="checkbox"/> Negative | <input type="checkbox"/> Not completed |
| Hepatitis B virus (HBV) | <input type="checkbox"/> Positive | <input type="checkbox"/> Negative | <input type="checkbox"/> Not completed |
| Hepatitis C virus (HCV) | <input type="checkbox"/> Positive | <input type="checkbox"/> Negative | <input type="checkbox"/> Not completed |
| Mycoplasma | <input type="checkbox"/> Positive | <input type="checkbox"/> Negative | <input type="checkbox"/> 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 No

Section IX. 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. Does the member have viable retinal cells (e.g., retinal thickness >100 microns) in the treatment eye?
 Yes No
4. Has the member had ocular surgery within the past six months? Yes No
5. Will the treatment procedure be performed at a specialized treatment center? Yes No
6. Has the member received any prior gene therapy for biallelic RPE65 mutation-associated retinal dystrophy?
 Yes. Please describe.
 No
7. For recertification requests (second eye), did the member tolerate the initial administration? Yes No

Section X. 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 ($-\alpha3.7/-\alpha3.7$)?

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

Section XI. Please complete for Omisirge requests.

Is the member planned for umbilical cord blood transplantation following myeloablative conditioning? Yes No

Section XII. 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 No

Section XIII. 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

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

8. 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

9. Please describe the functional tests that will be used to monitor this member and attach medical records with baseline functional test scores.

10. Has the member previously received treatment with a gene therapy for DMD? Yes No

11. 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 XIV. 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 \geq 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

Section XV. 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. Is the member unable to ambulate independently and is experiencing neurological defects despite treatment with a dopamine agonist, monoamine oxidase inhibitor and/or vitamin B6. Yes No

4. Has the member achieved skull maturity required for stereotactic surgical administration? Yes No

over

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 XVI. Please complete for Encelto requests.

1. Does the member have evidence of fluorescein leakage in treatment eye? Yes No
2. Does the member have absence of neovascularization in the treatment eye? Yes No
3. Has the member had previous treatment with the requested agent in the treatment eye? Yes No
4. Has the member had major surgery in the treatment eye or fellow eye within the past six months?
 Yes No
5. Is the member undergoing initial unilateral treatment? Yes No
6. Is the member undergoing bilateral treatment for the second eye? Yes No

Section XVII. Please complete for Zevaskyn requests.

1. Please attach a copy of genetic test confirming diagnosis of RDEB.
2. For members \geq six months to $<$ six years of age, is the member able to remain immobile and keep surgical area undisturbed for 5 to 10 days post transplantation? Yes No
3. Does the member have at least one wound site requiring treatment?

Yes. Please provide number of wounds. No

4. Is the wound area ≥ 20 cm²? Yes. Please provide wound area size. No

5. Has the wound been open for ≥ 6 months? Yes No

6. Is the wound classified as Stage 2 (defined as partial thickness loss of dermis presenting as shallow open ulcer with a pink or red wound bed, without slough or bruising)? Yes No

7. Is the wound free of infection? Yes No

8. The total number and size of wound site(s) intended for treatment?

9. Anticipated number of sheets required for treatment of wound site(s)?

10. Has the member had a trial with Vyjuvek? Yes No

If yes, please list the dose and frequency, dates of use, and outcome.

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.

11. Will the requested agent be used in combination with Filsuvez or Vyjuvek on the same target wound(s)?

Yes. Please explain.

No

12. Will the requested agent be used on wound(s) that are currently healed or have been previously treated with Zevaskyn?

Yes. Please provide clinical rationale for retreatment of Zevaskyn on the same wound area.

No

13. Will the infusion take place in a qualified treatment center? Yes No

over

Section XVIII. Please complete for Itvisma requests.

1. Please attach a copy of the genetic test showing mutations in the SMN1 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. Please provide pre-treatment baseline Hammersmith Functional Motor Scale-Expanded (HFMSE) score.
5. Please provide age of disease symptoms onset.
6. Is the member able to sit independently? Yes No
7. Has the member ever been able to walk independently? Yes No
8. Does the member require ventilator use, defined as any of the following?
Awake non-invasive ventilation for > 6 hours per 24-hour period. Yes No
Any non-invasive ventilation for > 12 hours per 24-hour period. Yes No
Invasive ventilation via endotracheal tube. Yes No
Invasive ventilation via tracheostomy. Yes No
9. Has the member previously received treatment with a gene therapy for SMA? Yes No

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

Prior Authorization Request Prescriber and Provider Information

Prescriber information

Last name*	<input type="text"/>	First name*	<input type="text"/>	MI	<input type="text"/>
NPI*	<input type="text"/>	Individual MH Provider ID	<input type="text"/>		
DEA No.	<input type="text"/>	Office Contact Name	<input type="text"/>		
Address	<input type="text"/>	City	<input type="text"/>	State	<input type="text"/>
E-mail address	<input type="text"/>				
Telephone No.*	<input type="text"/>				
Fax No.* (Please provide fax number for PA response notification.)	<input type="text"/>				

* Required

Please also complete for professionally administered medications, if applicable.

Start date	<input type="text"/>	End date	<input type="text"/>		
Servicing prescriber/facility name	<input type="text"/>	<input type="checkbox"/>	Same as prescribing provider		
Servicing provider/facility address	<input type="text"/>				
Servicing provider NPI/tax ID No.	<input type="text"/>				
Name of billing provider	<input type="text"/>				
Billing provider NPI No.	<input type="text"/>				
Is this a request for recertification?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	
CPT code	<input type="text"/>	No. of visits	<input type="text"/>	J code	<input type="text"/>
				No. of units	<input type="text"/>

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

<input type="text"/>	Date	<input type="text"/>
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(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.)