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, XIV, or XIX as applicable.)	
☐ Elevidys (delandistrogene moxeparvovec-rokl) ☐ Itvisma (onasemnogene abeparvovec-brve) ☐ 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, XIII, XVII, or XVIII as applicable.)	
☐ Encelto (revakinagene taroretcel-lwey) ☐ Lenmeldy (atidarsagene autotemcel) ☐ Luxturna (voretigene neparvovec-rzyl) ☐ Omisirge (omidubicel-onlv) ☐ Skysona (elivaldogene autotemcel) ☐ Zevaskyn (prademagene zamikeracel)	☐ Biallelic RPE65 mutation-associated retinal dystrophy ☐ Cerebral adrenoleukodystrophy (CALD) ☐ Hematologic malignancy ☐ Macular telangiectasia type 2 ☐ Metachromatic leukodystrophy ☐ Presymptomatic late infantile ☐ Presymptomatic early juvenile ☐ Early symptomatic early juvenile ☐ 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.

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

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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?
   ☐ Yes. Please attach a copy of CLIA-validated test. ☐ 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)?
    ☐ Yes. Please attach a copy of CLIA-validated test. ☐ No

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

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6. Does the member have active human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) infection? ☐ Yes. Please describe. _____ ☐ No
7. Has the member received any prior gene therapy for the requested diagnosis?
   ☐ Yes. Please describe. _____
   ☐ No

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8. 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

9. 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

10. 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 _____

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 _____

over

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 _____ ☐ No

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. 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

over

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 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

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

over

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 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
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 XV. Please complete for Zynteglo requests.

1. Please attach a copy of genetic test confirming diagnosis of beta thalassemia.

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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

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. 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
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 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 XVIII. Please complete for Zevaskyn requests.

1. Please attach a copy of genetic test confirming diagnosis of RDEB.
2. For members ≥ 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

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4. Is the wound area ≥ 20 cm^2? ☐ 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

Section XIX. 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 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.

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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.)