HIGHMARK HEALTH OPTIONS

Updated: 02/2024
DMMA Approved: 03/2024

Request for Prior Authorization for Gene Therapy Agents
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Gene Therapy Agents without their own policy require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Gene Therapy Agents Prior Authorization Criteria:

Gene therapies include betibeglogene autotemcel (Zynteglo), eladocagene exuparvovec (effective upon FDA approval), elivaldogene autotemcel (Skysona), etranacogene dezaparvovec (Hemgenix), valoctocogene roxaparvovec (Roctavian), delandistrogene moxeparvovec-rokl (Elevidys), Casgevy (Exagamglogene autotemcel) and Lyfgenia (Lovotibeglogene autotemcel). New products with this classification will require the same documentation.

For all requests the following criteria must be met in addition to the diagnosis specific criteria below:

- Is prescribed for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines

For Hemgenix (etranacogene dezaparvovec) requests:

Coverage may be provided with a diagnosis of Hemophilia B (congenital Factor IX deficiency) and the following criteria is met:

- Member must have severe or moderately severe hemophilia B (congenital factor IX deficiency) defined as equal to or less than 2% of normal circulating factor IX confirmed by blood coagulation testing
- Must have baseline liver function tests assessed prior to and after therapy for at least three months and be within normal range
- Members with preexisting risk factors for hepatocellular carcinoma (e.g., members with cirrhosis, advanced hepatic fibrosis, hepatitis C or B, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), and advanced age) must have abdominal ultrasound screenings and be monitored regularly (e.g., annually) for alpha-fetoprotein (AFP) elevations following administration
- Is prescribed by a hematologist or hemophilia treatment center practitioner
- Member has received IX prophylactic or on-demand replacement therapy for ≥ 150 accumulated days and is currently using factor IX prophylaxis therapy
- Member has ≥ 12 bleeding episodes if receiving on-demand therapy over the preceding 12 months. Does not apply to patients on prophylaxis.
- Member must have a baseline anti-AAV5 antibody titer of ≤ 1:678 measured by ELISA
- Member must not have any of the following:

- Inhibitor antibodies to factor IX
- A positive HIV test during time of screening that is not controlled with anti-viral therapy
- Active infection with hepatitis B or C virus at screening
- History of hepatitis B or C exposures, currently controlled by antiviral therapy
- Prior hemophilia AAV-vector based gene therapy

Duration of Approval: One lifetime dose

For Roctavian (valoctocogene roxaparvovec) requests:

Coverage may be provided with a diagnosis of Hemophilia A (congenital Factor VIII deficiency) and the following criteria is met:

- Member must have severe hemophilia A (congenital factor VIII deficiency) defined as less than 1% of normal circulating factor VIII confirmed by blood coagulation testing
- Member must not have any pre-existing antibodies to adeno-associated virus serotype 5 detected by an FDA approved test.
- Member must not have any contraindications to receiving therapy such as active infections (either acute or uncontrolled chronic), significant hepatic fibrosis (stage 3 or 4) or cirrhosis or a known hypersensitivity to mannitol.
- Member meets both of the following:
  - No previous documented history of a detectable FVIII inhibitor
  - Member has inhibitor level assay < 1 Bethesda units (BU) on 2 consecutive occasions at least one week apart within the last 12 months
- Must have baseline liver function tests assessed prior to and after therapy for at least three months and be within normal range
- Members with preexisting risk factors for hepatocellular carcinoma (e.g., members with cirrhosis, advanced hepatic fibrosis, hepatitis C or B, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), and advanced age) must have abdominal ultrasound screenings and be monitored regularly (e.g., annually) for alpha-fetoprotein (AFP) elevations following administration
- Is prescribed by a hematologist or hemophilia treatment center practitioner
- Member has received VIII prophylactic or on-demand replacement therapy for ≥ 150 accumulated days and is currently using factor VIII prophylaxis therapy
- Member has ≥ 12 bleeding episodes if receiving on-demand therapy over the preceding 12 months. Does **not** apply to patients on prophylaxis.
- Member must not have any of the following:
  - A positive HIV test during time of screening that is not controlled with anti-viral therapy
  - Active infection with hepatitis B or C virus at screening
  - History of hepatitis B or C exposures, currently controlled by antiviral therapy
  - Prior hemophilia AAV-vector based gene therapy

Duration of Approval: One lifetime dose

For Elevidys (delandistrogene moxeparvovec-rokl) requests:

Coverage may be provided with a diagnosis of Duchenne muscular dystrophy (DMD) and the following criteria is met:

- The member must be ambulatory and age 4 through 5 years of age
- A confirmed diagnosis of DMD by submission of lab testing demonstrating mutation of the dystrophin (DMD) gene by either:
  - A confirmed frameshift mutation OR
  - A premature stop codon mutation between exons 18 to 58 in the DMD gene
- The member must not have any deletion in exon 8 and/or exon 9 in the DMD gene
- The member must be on a stable dose of corticosteroids for DMD for at least 12 weeks prior to therapy
- The member must have a baseline anti-AAVrh74 antibody titers <1:400 measured by ELISA
- Must be prescribed by or in consultation with a neurologist who has experience in the treatment and management of DMD
- There is documentation of a baseline evaluation, including a standardized assessment of motor function, by a neurologist with experience treating DMD

Duration of Approval: One lifetime dose

For Zynteglo (betibeglogene autotemcel) requests:

Coverage may be provided with a diagnosis of beta-thalassemia and the following criteria is met:

- The member must be transfusion-dependent β-thalassaemia (TDT) who do not have a β0 /β0 genotype, for whom haematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte antigen (HLA)-matched related HSC donor is not available
- Members are considered to be transfusion-dependent if they had a history of transfusions of at least 100 mL/kg/year of RBCs or with ≥8 transfusions of RBCs per year in the 2 years preceding enrolment.
- Is prescribed by a hematologist, stem cell transplantation specialist or in the treatment of members with TDT
- Must be administered in a qualified treatment center
- Physician must confirm that HSC transplantation is appropriate for the member before myeloablative conditioning is initiated
- Does not have a history of a contraindication to the requested medication
- Member must not have had previous treatment with HSC gene therapy
- Member must not be pregnant or breast-feeding
- All patients should be tested for HIV prior to mobilization and apheresis to ensure acceptance of the apheresis material for manufacturing

Duration of Approval: One lifetime dose

For Skysona (elivaldogene autotemcel) requests:

Coverage may be provided with a diagnosis of **cerebral adrenoleukodystrophy (CALD)** and the following criteria is met:

- Member must be a male between the ages of 4-17 years of age

- Must have early, active CALD defined by:
  - Elevated very long chain fatty acids (VLCFA) values
  - Active CNS disease established by central radiographic review of brain magnetic resonance imaging (MRI)
  - Loes score between 0.5 and 9
  - Gadolinium enhancement (GdE+) on MRI of demyelinating lesions
  - Neurologic function score (NFS) of ≤ 1 demonstrating asymptomatic or mild disease
- Member must have confirmed mutations in the ABCD1 gene
- Must be prescribed by a neurologist or ALD specialist.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Skysona should not be administered in members with active infections.
- Member must have a negative serology test for HIV.
- Member must not have been a recipient of an allogenic transplant or gene therapy

Duration of Approval: One treatment per lifetime

For Casgevy (exagamglogene autotemcel) requests:

Coverage may be provided with a diagnosis of **severe sickle cell disease (SCD)** and the following criteria is met:

- Diagnosis is confirmed by electrophoresis demonstrating the presence of sickle cell disease (HbSS, HbSC, HbSβ^0-thalassemia, or HbSβ^+-thalassemia).
- Member must be eligible for a hematopoietic stem cell transplantation and a human leukocyte antigen matched related hematopoietic stem cell donor is not available
- Must have a history of at least 2 severe vaso-occlusive crisis (VOC) events during each of the prior 2 years. Severe VOC defined as :
  - Acute pain event requiring a visit to a medical facility and administration of pain medications (opioids or intravenous [IV] non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions
  - Acute chest syndrome
  - Priapism lasting > 2 hours and requiring a visit to a medical facility
  - Splenic sequestration
- Must be prescribed by or in consultation with a hematologist/oncologist or sickle cell disease specialist.
- Member must not have:
  - Advanced liver disease
  - History of untreated Moyamoya disease or presence of Moyamoya disease
- For members who are 12-18 years of age, members must have normal transcranial Doppler (TCD)
- Members who are currently on disease modifying therapies for SCD (e.g., hydroxyurea, crizanlizumab, voxelotor) must discontinue them 8 weeks before the planned start of mobilization and conditioning.
- Member must not have clinically significant and active bacterial, viral, fungal or parasitic infection.
- Member must not have been a recipient of an allogenic transplant or gene therapy

Duration of Approval: One treatment per lifetime

For Casgevy (exagamglogene autotemcel) requests:

Coverage may be provided with a diagnosis of beta-thalassemia and the following criteria is met:

- Transfusion-dependent β-thalassemia (TDT) as defined by:
  - Documented homozygous β-thalassemia or compound heterozygous β-thalassemia including β-thalassemia/hemoglobin E (HbE)
  - History of at least 100 mL/kg/year or ≥10 units/year of packed RBC transfusions in the prior 2 years
- Member must be eligible for autologous stem cell transplant
- Is prescribed by a hematologist, stem cell transplantation specialist or in the treatment of members with TDT
- Must be administered in a qualified treatment center
- Member must not have any of the following:
  - Severely elevated iron in the heart (i.e.cardiac T2* less than 10 msec by magnetic resonance imaging [MRI] or left ventricular ejection fraction [LVEF] < 45% by echocardiogram)
  - Advanced liver disease (aspartate transaminase [AST] or alanine transaminase [ALT] > 3 × the upper limit of normal [ULN], or direct bilirubin value > 2.5 × ULN, or if a liver biopsy demonstrated bridging fibrosis or cirrhosis [liver biopsy was performed if liver iron content was ≥ 15 mg/g by MRI])
  - An available 10/10 human leukocyte antigen matched related hematopoietic stem cell donor
  - Associated α-thalassemia and >1 alpha deletion or alpha multiplications
  - Sickle cell beta thalassemia variant
  - Clinically significant and active bacterial, viral, fungal, or parasitic infection
  - White blood cell (WBC) count <3 × 10^9/L or platelet count <50 × 10^9/L not related to hypersplenism
- Member must not have had previous treatment with a hematopoietic stem cell (HSC) gene therapy or prior allo-HSCT
- Member must not be pregnant or breast-feeding
- All members should be tested for HIV-1, HIV-2, HBV, HCV prior to mobilization and apheresis to ensure acceptance of the apheresis material for manufacturing
- **Duration of Approval:** One lifetime dose

For Lyfgenia (lovotibeglogene autotemcel) requests:

Coverage may be provided with a diagnosis of **severe sickle cell disease (SCD)** and the following criteria is met:

- Diagnosis is confirmed by electrophoresis demonstrating the presence of sickle cell disease with either βS/βS or βS/β0 or βS/β+ genotype
- Member must be eligible for a hematopoietic stem cell transplantation and a human leukocyte antigen matched related hematopoietic stem cell donor is not available

- Must have a history of at least 4 severe vaso-occlusive event (VOE) in the past 24 months. A severe VOE is defined as:
    - an event with no medically determined cause other than a vaso-occlusion, requiring a ≥ 24-hour hospital or Emergency Room (ER) observation unit visit or at least 2 visits to a day unit or ER over 72 hours with both visits requiring intravenous treatment. Exception: priapism does not require hospital admission but does require a medical facility visit; 4 priapism episodes that require a visit to a medical facility (without inpatient admission) are sufficient to meet criterion.
- Must be prescribed by or in consultation with a hematologist/oncologist or sickle cell disease specialist.
- Member must have a Karnofsky performance status of ≥ 60 (≥16 years of age) or a Lansky performance status of ≥60 (<16 years of age).
- The member has either experienced hydroxyurea (HU) failure at any point in the past or must have intolerance to HU (defined as patient being unable to continue to take HU)
- Member must not have:
    - Advanced liver disease
    - History of untreated Moyamoya disease or presence of Moyamoya disease
- For members who are 12-18 years of age, members must have normal transcranial Doppler (TCD)
- Member must not need curative anticoagulation therapy during the period of conditioning through platelet engraftment
- Member must be able to receive a red blood cell transfusion
- Member must have a negative serology test for HIV.
- Member must not have clinically significant and active bacterial, viral, fungal or parasitic infection
- Member must not have been a recipient of an allogenic transplant or gene therapy
- **Duration of Approval:** One treatment per lifetime

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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GENE THERAPY AGENTS
PRIOR AUTHORIZATION FORM- PAGE 1 of 4

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8:00 am to 7:00 pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No		

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____
Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Hemophilia A:
Does the member have severe hemophilia A? ☐ Yes, normal factor activity level:_____ ☐ No
Does the member have any pre-existing antibodies to adeno-associated virus serotype 5 detected by an FDA approved test? ☐ Yes ☐ No
Does the member have any contraindications to receiving therapy? ☐ Yes ☐ No
Did the member have baseline liver function tests assessed prior to therapy and was it within normal range? ☐ Yes ☐ No
Will the member have liver function testing done for at least 3 months after therapy? ☐ Yes ☐ No
Did the member have abdominal ultrasound screenings if they have preexisting risk factors for hepatocellular carcinoma? ☐ Yes ☐ No
Has the member had any documented history of a detectable FVIII inhibitor or an inhibitor level assay <1 BU on 2 consecutive occasions at least one week apart with the last 12 months? ☐ Yes, please explain below. ☐ No
Has the member had ≥ 12 bleeding episodes if receiving on-demand therapy over the preceding 12 months? Does **not** apply to patients on prophylaxis. ☐ Yes ☐ No
Has the member received FVIII prophylactic or on-demand replacement therapy for ≥ 150 accumulated days and still on current therapy? ☐ Yes ☐ No
Does the member have a positive HIV test or active infection with Hepatitis B or C? ☐ Yes ☐ No
Has the member had prior hemophilia AAV-vector based gene therapy? ☐ Yes ☐ No

Hemophilia B:
Does the member have severe or moderately severe B? ☐ Yes, normal factor activity level:_____ ☐ No
Did the member have baseline liver function tests assessed prior to therapy and was it within normal range? ☐ Yes ☐ No
Will the member have liver function testing done for at least 3 months after therapy? ☐ Yes ☐ No
Did the member have abdominal ultrasound screenings if they have preexisting risk factors for hepatocellular carcinoma? ☐ Yes ☐ No

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GENE THERAPY AGENTS
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 4

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MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Hemophilia B (continued):

Has the member had ≥ 12 bleeding episodes if receiving on-demand therapy over the preceding 12 months? Does **not** apply to patients on prophylaxis. ☐ Yes ☐ No

Has the member received IX prophylactic or on-demand replacement therapy for ≥ 150 accumulated days and still on current therapy? ☐ Yes ☐ No

What is the members baseline anti-AAV5 antibody titer measured by ELISA? _____

Does the member have inhibitor antibodies to factor IX? ☐ Yes ☐ No

Does the member have a positive HIV test or active infection with Hepatitis B or C? ☐ Yes ☐ No

Has the member had prior hemophilia AAV-vector based gene therapy? ☐ Yes ☐ No

DMD:

Does the member have a diagnosis of DMD confirmed by submission of lab testing demonstrating mutation of the dystrophin (DMD) gene by either a confirmed frameshift mutation OR a premature stop codon mutation between exons 18 to 58 in the DMD gene? ☐ Yes ☐ No

Is the member ambulatory? ☐ Yes ☐ No

Does the member have any deletion in exon 8 and/or exon 9 in the DMD gene? ☐ Yes ☐ No

Is the member on a stable dose of corticosteroids for DMD for at least 12 weeks prior to therapy? ☐ Yes ☐ No

What is the member's baseline anti-AAVrh74 antibody titers level measured by ELISA? _____

Is there documentation of a baseline evaluation including a standardized assessment of motor function done by a neurologist with experience in treating DMD? ☐ Yes ☐ No

Beta-Thalassemia:

Is the member transfusion-dependent β-thalassaemia (TDT) who does not have a β0 /β0 genotype, for whom haematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte antigen (HLA)-matched related HSC donor is not available? ☐ Yes ☐ No

Is the member considered transfusion-dependent? ☐ Yes ☐ No

Does the member have a history of at least 100 mL/kg/year or ≥10 units/year of packed RBC transfusions in the prior 2 years? ☐ Yes ☐ No

Is the medication being administered in a qualified treatment center? ☐ Yes ☐ No

Has the physician confirmed that HSC transplantation is appropriate for the member before myeloablative conditioning is initiated? ☐ Yes ☐ No

Does the member have any contraindications to requested therapy? ☐ Yes ☐ No

Has the member had previous treatment with HSC gene therapy? ☐ Yes ☐ No

Is the member pregnant or breast-feeding? ☐ Yes ☐ No

Has the member been tested for HIV prior to mobilization and apheresis to ensure acceptance of the apheresis material for manufacturing? ☐ Yes ☐ No

CALD:

Does the member have early, active CALD? ☐ Yes ☐ No

Does the member have elevated VLCFA? ☐ Yes ☐ No Value: _____

Has the member had an MRI establishing active CNS disease with GdE+ of demyelinating lesions? ☐ Yes ☐ No

What is the Loes score? _____

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GENE THERAPY AGENTS
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 3 OF 4

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MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

CALD (continued):
What is the NFS score? _____
Does the member have confirmed mutations in the ABCD1 gene? ☐ Yes ☐ No
Does the member have an active infection? ☐ Yes ☐ No
Does the member have HIV? ☐ Yes ☐ No
Has the member received an allogenic transplant or gene therapy previously? ☐ Yes ☐ No

Sickle Cell Disease (SCD):

For Casgevy only:
Does the member have severe sickle cell disease confirmed by electrophoresis? ☐ Yes, what is the genotype? _____ ☐ No
Is the member eligible for a hematopoietic stem cell transplant but a stem cell donor is not available? ☐ Yes ☐ No
Does the member have a history of at least 2 severe vaso-occlusive crisis (VOC) events during the past 24 months? ☐ Yes, please list the dates:_____ ☐ No
Does the member have advanced liver disease or a history of untreated Moyamoya disese or the presence of Moyamoya disease? ☐ Yes ☐ No
For members who are 12-18 years of age, does the member have a normal transcranial Doppler (TCD)? ☐ Yes ☐ No
If the member is currently on disease modifying therapies for SCD (e.g., hydroxyurea, crizanlizumab, voxelotor), have they discontinued the product at least 8 weeks prior to start of mobilization and conditioning? ☐ Yes ☐ No
Does the member have clinically significant and active bacterial, viral, fungal or parasitic infection? ☐ Yes ☐ No
Has the member been a recipient of an allogenic transplant or gene therapy previously? ☐ Yes ☐ No

For Lyfgenia only:
Does the member have severe sickle cell disease confirmed by electrophoresis? ☐ Yes, what is the genotype? _____ ☐ No
Is the member eligible for a hematopoietic stem cell transplant but a stem cell donor is not available? ☐ Yes ☐ No
Does the member have a history of at least 4 severe vaso-occlusive events (VOE) during the past 24 months? ☐ Yes, please list the dates:_____ ☐ No
Does the member have a Karnofsky performance status of ≥ 60 (≥16 years of age) or a Lansky performance status of ≥60 (<16 years of age)? ☐ Yes ☐ No
Has the member tried and failed hydroxyurea (HU) at any point in the past or had an intolerance to HU? ☐ Yes ☐ No
Does the member have advanced liver disease or a history of untreated Moyamoya disese or the presence of Moyamoya disease? ☐ Yes ☐ No
For members who are 12-18 years of age, does the member have a normal transcranial Doppler (TCD)? ☐ Yes ☐ No
Does the member need curative anticoagulation therapy during the period of conditioning through platelet engraftment?
Is the member able to receive a red blood cell transfusion? ☐ Yes ☐ No
Does the member have a negative serology test for HIV? ☐ Yes ☐ No
Does the member have clinically significant and active bacterial, viral, fungal or parasitic infection? ☐ Yes ☐ No
Has the member been a recipient of an allogenic transplant or gene therapy previously? ☐ Yes ☐ No

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GENE THERAPY AGENTS PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 4 OF 4			
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MEMBER INFORMATION			
Member Name:		DOB:	
Member ID:		Member weight:	Height:
CURRENT or PREVIOUS THERAPY			
Medication Name	**Strength/ Frequency**	**Dates of Therapy**	**Status (Discontinued & Why/Current)**
SUPPORTING INFORMATION or CLINICAL RATIONALE			
Prescribing Provider Signature		Date	