HIGHMARK HEALTH OPTIONS

Updated: 12/2022
DMMA Approved: 01/2023

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 (Lentiglobin) (effective upon FDA approval), eladocagene exuparvovec (effective upon FDA approval), elivaldogene tavalentivec (Lenti-DTM) (effective upon FDA approval), etranacogene dezaparvovec (Hemgenix), valoctocogene roxaparvovec (Roctavian) (effective upon FDA approval). 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

Coverage may be provided with a diagnosis of Hemophilia A or Hemophilia B and the following criteria is met:

- Member must have severe or moderately severe hemophilia A or B defined as equal to or less than 2% of normal factor VIII and FIX clotting activity (VIII levels ≤ 2 IU/dL)
- Must have liver function tests within normal range and no signs of NASH or other liver diseases
- Is prescribed by a hematologist or hemophilia treatment center practitioner
- Member has received FVIII or IX prophylactic or on-demand replacement therapy for ≥ 150 accumulated days
- 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:
    - Inhibitor antibodies to factor VIII or factor IX
    - Apositive 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
    - Previous gene therapy treatment
- **Duration of Approval:** One lifetime dose

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

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 2

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 or B:

Does the member have severe or moderately severe hemophilia A or B? ☐ Yes, normal factor activity level:_____ ☐ No

Does the member have liver function tests within normal range? ☐ Yes ☐ 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 or IX prophylactic or on-demand replacement therapy for ≥ 150 accumulated days? ☐ Yes ☐ No

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

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

Has the member have previous gene therapy treatment? ☐ 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

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

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

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**
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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