Hemgenix (etranacogene dezaparvovec-drlb)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Hemgenix (etranacogene dezaparvovec-drlb) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Hemgenix is an adeno-associated virus vector-based gene therapy indicated for treatment of adults with Hemophilia B (congenital Factor IX deficiency) who currently use Factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.

POLICY

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Chart notes, lab tests documenting all of the following (where applicable):
    1. Severe to moderately severe Factor IX deficiency (≤2% of normal circulating Factor IX)
    2. Absence of Factor IX inhibitors (lab test results required)
    3. Current use of Factor IX prophylaxis therapy
    4. History of life-threatening hemorrhage(s) or repeated, serious spontaneous bleeding episodes

Prescriber Specialties

This medication must be prescribed by or in consultation with a hematologist.

Criteria for Initial Approval

Hemophilia B

Authorization of 1 month for one dose total may be granted for the treatment of hemophilia B when ALL of the following criteria are met:

A. Member between 18 years of age and 75 years of age
B. Member was assigned male at birth
C. Member does not have a history of Factor IX inhibitors or a positive screen result of ≥ 0.6 Bethesda Units (BU) using the Nijmegen-Bethesda assay

D. Member does not have anti-adeno-associated virus antibodies titers.
E. Member has severe or moderately severe hemophilia B as defined by a plasma Factor IX (FIX) activity level ≤2%
F. Member is currently receiving Factor IX prophylaxis
G. Member meets one of the following:
    1. Member has current or historical life-threatening hemorrhage
    2. Member has repeated, serious spontaneous bleeding episodes
H. Member does not have a history of receiving prior gene therapy or under consideration for treatment for another gene therapy for hemophilia B
I. Member does not have any other bleeding disorders not related to hemophilia B
J. Member has received > 150 exposure days of treatment with Factor IX protein
K. Member has received a liver health assessment including enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and total bilirubin] AND a hepatic ultrasound and elastography
L. Medication is being prescribed by or in consultation with a hematologist or a prescriber who specializes in hemophilia B
M. Member is HIV negative or has a controlled HIV infection
N. Member does not have an active hepatitis B and/or hepatitis C infection

Continuation of Therapy

Repeat treatment of Hemgenix for any indication is considered investigational, as the safety and efficacy beyond one dose has not been studied. The evidence is insufficient to determine the effects on net health outcomes.

Dosing and Administration

The minimum recommended dose is 2×10^{13} genome copies (gc) per kg of body weight.
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Hemgenix approvals will be limited to one treatment per lifetime.

Other Considerations

A. Where feasible, the member's vaccinations should be up to date with all age-appropriate vaccines before etranacogene dezaparvovec-drlb administration.
B. Where feasible, the member should receive periodical monitoring for hepatotoxicity, hepatocellular carcinogenicity, and Factor IX activity/inhibitors.
C. Where feasible, it is recommended that the prescriber consult with a hepatoogist if there is significant concern regarding the member's liver function.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J1411 – Injection, hemgenix, per tx dose (effective 4/1/2023)
- C9399 – Unclassified drugs or biologicals
- J3590 – Unclassified biologicals

REFERENCES

- Hemgenix [package insert]. King of Prussia, PA: CSL Behring LLC; November 2022.

POLICY HISTORY

Policy #: 05.04.88
Original Effective Date: March 17, 2023
Reviewed: October 2023
Revised: April 2023
Current Effective Date: May 12, 2023