blue california
Promise Health Plan

etranacogene dezaparvovec-drlb (Hemgenix)

Medical Benefit Drug Policy

Place of Service

Hospital Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Gene Therapy, Adeno-Associated Virus
HCPCS:
J1411:Injection, etranacogene dezaparvovec-drlb, per therapeutic dose
How Supplied:

- Hemgenix is provided in kits containing 10 to 48 single-use vials, each kit constituting a dosage unit based on the patient's body weight.
- Hemgenix has a nominal concentration of 1×10^{13} gc/mL, and each vial contains an extractable volume of not less than 10 mL

Condition(s) listed in policy *(see coverage criteria for details)*

- Moderately Severe to Severe Hemophilia B

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Moderately Severe to Severe Hemophilia B
Meets medical necessity if all the following are met:

1. Diagnosis of hemophilia B (congenital Factor IX deficiency)
2. Patient is at least 18 years of age
3. Documentation that patient has a baseline Factor IX activity ≤ 2% of normal
4. Meets ONE of the following:

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a. Patient has been receiving regular prophylactic therapy with Factor IX replacement for at least 2 months
b. Patient has a history of life-threatening hemorrhage
c. Patient has a history of repeated, serious spontaneous bleeding episodes

5. Patient has not developed Factor IX inhibitors
6. Patient is tested for anti-adeno-associated virus serotype 5 (AAV5) to confirm suitable candidate for Hemgenix treatment
7. Documentation that the provider has completed a liver health assessment, consisting of ONE of the following:
   a. Patient does not have liver dysfunction, as indicated by any the following:
      i. Liver function tests (LFTs) [i.e., alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), total bilirubin] exceeding two-times the upper limit of normal (2x ULN)
      ii. Liver cirrhosis
      iii. Liver fibrosis
   b. For patients with either radiological liver abnormalities or sustained liver enzyme elevations: a consulting hepatologist has assessed that the patient is eligible to receive Hemgenix
8. Patient is negative for or controlled with antiviral medication for HIV-1, HIV-2, hepatitis B virus (HBV), and hepatitis C virus (HCV)
9. Patient has not previously received gene therapy

Covered Doses:
Not to exceed 2×10^{13} genome copies (gc)/kg of body weight given as an intravenous infusion

Coverage Period:
One-time treatment per lifetime

ICD-10:
D67

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Hemgenix (etranacogene dezaparvovec-drlb) Prescribing Information. CSL Behring LLC., King of Prussia, PA: 1/2025.

Review History

Date of Last Annual Review: 1Q2026

Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee