Etranacogene dezaparvovec-drlb (Hemgenix®)	Place of Service Hospital Administration Outpatient Facility Administration HCPCS: J3590 NDCs: See Section (5) Each kit contains 10 to 48 single-use vials, with the total number of vials in each kit corresponding to the dosing requirement for the individual patient depending on the patient's body weight

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

- Moderately severe to severe hemophilia B

AHFS therapeutic class: Antihemophilic Agent

Mechanism of action: Gene Therapy, Adeno-Associated Virus

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Hemgenix® (etranacogene dezaparvovec-drlb) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Moderately severe to severe hemophilia B

1. Diagnosis of hemophilia B (congenital Factor IX deficiency), **AND**
2. Patient is at least 18 years of age, **AND**
3. Patient has Factor IX activity ≤ 2% of normal, **AND**
4. One of the following:
    a. Patient has been receiving regular prophylactic therapy with Factor IX replacement for at least 2 months, or
    b. Patient has a history of life-threatening hemorrhage, or
    c. Patient has a history of repeated, serious spontaneous bleeding episodes

    AND
5. Patient has not developed Factor IX inhibitors, **AND**
6. Patient does not have neutralizing anti-AAV5 antibodies that exceed a titer of 1:3,212, **AND**
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), or
ii. Liver cirrhosis, or
iii. Liver fibrosis

OR

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

AND

8. Patient is negative for HIV-1, HIV-2, hepatitis B virus (HBV), and hepatitis C virus (HCV),
AND
9. Patient has not previously received gene therapy

Covered Doses
Up to 2 x 10^{13} genome copies (gc)/kg of body weight given as an IV infusion

Coverage Period
One-time treatment per lifetime

ICD-10:
D67

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Hemgenix® (etranacogene dezaparvovec-drlb) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT COVERED for the following condition(s)
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
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 x 10^{13} gc/mL, and each vial contains an
- extractable volume of not less than 10 mL

NDCs:

- 00053-0100-10: 10 single-use vials per kit (100 mL)
- 00053-0110-11: 11 single-use vials per kit (110 mL)
- 00053-0120-12: 12 single-use vials per kit (120 mL)
- 00053-0130-13: 13 single-use vials per kit (130 mL)
- 00053-0140-14: 14 single-use vials per kit (140 mL)
- 00053-0150-15: 15 single-use vials per kit (150 mL)
- 00053-0160-16: 16 single-use vials per kit (160 mL)
- 00053-0170-17: 17 single-use vials per kit (170 mL)
- 00053-0180-18: 18 single-use vials per kit (180 mL)

- 00053-0190-19: 19 single-use vials per kit (190 mL)
- 00053-0200-20: 20 single-use vials per kit (200 mL)
- 00053-0210-21: 21 single-use vials per kit (210 mL)
- 00053-0220-22: 22 single-use vials per kit (220 mL)
- 00053-0230-23: 23 single-use vials per kit (230 mL)
- 00053-0240-24: 24 single-use vials per kit (240 mL)
- 00053-0250-25: 25 single-use vials per kit (250 mL)
- 00053-0260-26: 26 single-use vials per kit (260 mL)
- 00053-0270-27: 27 single-use vials per kit (270 mL)
- 00053-0280-28: 28 single-use vials per kit (280 mL)
- 00053-0290-29: 29 single-use vials per kit (290 mL)
- 00053-0300-30: 30 single-use vials per kit (300 mL)
- 00053-0310-31: 31 single-use vials per kit (310 mL)
- 00053-0320-32: 32 single-use vials per kit (320 mL)
- 00053-0330-33: 33 single-use vials per kit (330 mL)
- 00053-0340-34: 34 single-use vials per kit (340 mL)
- 00053-0350-35: 35 single-use vials per kit (350 mL)
- 00053-0360-36: 36 single-use vials per kit (360 mL)
- 00053-0370-37: 37 single-use vials per kit (370 mL)
- 00053-0380-38: 38 single-use vials per kit (380 mL)
- 00053-0390-39: 39 single-use vials per kit (390 mL)
- 00053-0400-40: 40 single-use vials per kit (400 mL)
- 00053-0410-41: 41 single-use vials per kit (410 mL)
- 00053-0420-42: 42 single-use vials per kit (420 mL)
- 00053-0430-43: 43 single-use vials per kit (430 mL)
- 00053-0440-44: 44 single-use vials per kit (440 mL)
- 00053-0450-45: 45 single-use vials per kit (450 mL)
- 00053-0460-46: 46 single-use vials per kit (460 mL)
- 00053-0470-47: 47 single-use vials per kit (470 mL)
- 00053-0480-48: 48 single-use vials per kit (480 mL)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Hemgenix® (etranacogene dezaparvovec-drlb) [Prescribing information.] King of Prussia, PA: CSL Behring LLC.; 11/2022.

(7) Policy Update

Date of initial review: 1Q2023
Date of next review: 1Q2024
Changes from previous policy version:

- New policy

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee