ALASKA MEDICAID
Prior Authorization Criteria

# Hemgenix

**(Etranacogene dezaparvovec-drlb)**

## FDA INDICATIONS AND USAGE[1]

Hemgenix™ is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with hemophilia B (congenital Factor IX deficiency) who:

1. Currently use Factor IX prophylaxis therapy, **OR**
2. Have current or historical life-threatening hemorrhage, **OR**
3. Have repeated, serious spontaneous bleeding episodes.

## APPROVAL CRITERIA[1,2,3]

1. Patient is 18 years of age or older **AND**;
2. Prescribed by or in consultation with a hematologist **AND**;
3. Patient has the diagnosis of hemophilia B meeting one of the above listed FDA indications **AND**;
4. Patient has moderate to severe disease as defined by factor IX levels ≤2% of normal or <2IU/dl **AND;**
5. Patient has had >150 previous exposure days to factor IX **AND;**
6. Patient must have no history of inhibitors to factor IX, and a screen performed within two weeks prior to administration must be negative as defined as ≤0.5 Bethesda units **AND**;
7. Patient has had a hepatic ultrasound and elastography performed prior to administration.

## DENIAL CRITERIA [1,3]

1. Failure to meet approval criteria **OR**;
2. Patient currently has an active hepatitis B or hepatitis C infection **OR**;
3. Patient currently has an uncontrolled HIV infection **OR**;
4. Evidence of advanced hepatic impairment is present **OR**;
5. Patient has been previously treated with gene therapy for hemophilia B.

## CAUTIONS[1]

- Monitor transaminase levels once weekly for three months following administration to monitor for possible hepatotoxicity.
- Patients with preexisting risk factors for hepatocellular carcinoma should be monitored regularly for elevated alpha-fetoprotein (AFP) and receive abdominal ultrasound screenings for five years following administration.

## DURATION OF APPROVAL

- Initial Approval: 3 months
  - No reauthorization will be approved.

## QUANTITY LIMIT

- One infusion per lifetime.
- HCPCS: J3590

## REFERENCES / FOOTNOTES:

1. Hemgenix (etranacogene dezaparvovec-drlb) [package insert]. Lexington, MA: uniQure, Inc.; November 2022
2. Tice JA, Walton S, Herce-Hagiwara B, Fahim SM, Moradi A, Sarker J, Chu J, Agboola F, Pearson SD, Rind DM. Gene Therapy for Hemophilia B and An Update on Gene Therapy for Hemophilia A: Effectiveness and Value; Evidence Report. Institute for Clinical and Economic Review, December 22, 2022. https://icer.org/assessment/hemophilia-a-and-b-2022
3. HOPE-B Clinical Trial Protocol, Version 8.0 (Amendment 7.0). February 2022. Phase III trial of AMT-061 in subjects with severe or moderately severe hemophilia B. Available at https://clinicaltrials.gov/ProvidedDocs/91/NCT03569891/Prot_000.pdf.