Reference number(s)
5680-A

Specialty Guideline Management Hemgenix

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Hemgenix	etranacogene dezaparvovec-drlb

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

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.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

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

Chart notes, lab tests documenting all of the following (where applicable):

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- Severe or moderately severe Factor IX deficiency (≤2% of normal circulating Factor IX).
- Absence of Factor IX inhibitors (lab test results required).
- Current use of Factor IX prophylaxis therapy.
- History of life-threatening hemorrhage(s) or repeated, serious spontaneous bleeding episodes.
- Baseline hematologic, hepatic, and renal assessments.

Prescriber Specialties

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

Coverage Criteria

Hemophilia B[1]

Authorization of 3 months for one dose total may be granted for the treatment of hemophilia B (congenital factor IX deficiency) when all of the following criteria are met:

- Member is 18 years of age or older.
- Member meets both of the following:
  - Member does not have a history of Factor IX inhibitors (e.g., ≥ 0.6 Bethesda units [BU]).
  - Member has a negative Factor IX inhibitor test result within the past 30 days (e.g., < 0.6 Bethesda units [BU]).
- Member has severe or moderately severe Factor IX deficiency (≤ 2% of normal circulating Factor IX).
- Member has a history of prophylactic Factor IX (e.g., Alprolix, Ixinity, Rebinyn) use for at least 150 exposure days.
- Member is currently using Factor IX prophylactic therapy or has a contraindication to Factor IX prophylaxis and meets either of the following:
  - Current or historical life-threatening hemorrhage.
  - History of repeated, serious spontaneous bleeding episodes.
- Member has platelets ≥ 50,000 cells/microL at baseline.
- Member does not have alanine transaminase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), total bilirubin (unless there is a diagnosis of Gilbert's Syndrome and member is otherwise stable), and creatinine levels greater than 2 times the upper limit of normal (ULN).
- Member does not have current unstable liver or biliary disease as defined by the presence of ascites, hepatic encephalopathy, coagulopathy, hypoalbuminemia, esophageal or gastric varices, persistent jaundice, or cirrhosis.
- Member has undergone a hepatic ultrasound and/or elastography to rule out radiological liver abnormalities and/or sustained liver enzyme elevations.

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- Member meets both of the following:
  - Member does not have an active infection with hepatitis B virus or hepatitis C virus.
  - Member is not currently receiving antiviral therapy for a prior hepatitis B virus or hepatitis C virus exposure.
- Member does not have uncontrolled human immunodeficiency virus (HIV) infection as defined as a CD4 cell count $\leq$200 mm^3 or viral load > 20 copies/mL.
- Member has not received Hemgenix or any other gene therapy previously.
- Prophylactic use of Factor IX products will not be given after Hemgenix administration once adequate Factor IX levels have been achieved (note: Factor IX therapy may be given in case of surgery, invasive procedures, trauma, or bleeds in the event that Hemgenix-derived Factor IX activity is deemed insufficient for adequate hemostasis).
- Provider attests that liver enzymes and Factor IX activity will be followed per the protocol outlined in the prescribing information following receipt of Hemgenix infusion.

References

1. Hemgenix [package insert]. King of Prussia, PA: CSL Behring LLC; January 2025.

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