

Reference number
5680-A

SPECIALTY GUIDELINE MANAGEMENT

HEMGENIX (etranacogene dezaparvovec-drlb)

POLICY

I. 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 Indication

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.

II. 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):

- A. Severe to moderately severe Factor IX deficiency ($\leq 2\%$ of normal circulating Factor IX)
- B. Absence of Factor IX inhibitors (lab test results required)
- C. Current use of Factor IX prophylaxis therapy
- D. History of life-threatening hemorrhage(s) or repeated, serious spontaneous bleeding episodes.

III. PRESCRIBER SPECIALTIES

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

IV. 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 is 18 years of age or older
- B. Member meets either of the following:
 - 1. Member has a negative Factor IX inhibitor test result within the past 30 days
 - 2. If member has a positive Factor IX inhibitor test result within the past 30 days, there must be a negative test result within 2 weeks of the initial positive result
- C. Member has severe or moderately severe Factor IX deficiency ($\leq 2\%$ of normal circulating Factor IX) and meets any of the following:
 - 1. Member is currently using Factor IX prophylactic therapy
 - 2. Member has a current or history of a life-threatening hemorrhage
 - 3. Member has a history of repeated, serious spontaneous bleeding episodes

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D. Member has not previously received gene therapy treatment

V. REFERENCES

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