

Medical Policy Manual **Approved Policy: Do Not Implement 12/31/24**

Etranacogene Dezaparvovec-drlb (Hemgenix®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

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
- 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 6 months 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 and meets any of the following:



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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
- D. Member has not previously received gene therapy treatment
- E. Member has a baseline anti-AAV5 antibody titer measured by ELISA (*Note: this assay was used in the HOPE-B clinical trial and is assessable via CSL Behring*)

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Hemgenix [package insert]. King of Prussia, PA: CSL Behring LLC; November 2022.
2. S.W. Pipe, et al. N Engl J Med 2023;388:706-18. *Gene Therapy with Etranacogene Dezaparvovec for Hemophilia B* DOI: 10.1056/NEJMoa2211644
3. Lexi-Comp Online. (2024, March). AHFS DI. Hemgenix. Retrieved May 2024 from Lexi-Comp Online with AHFS.
4. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2024, April). Ranibizumab. Retrieved May 2024 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 12/31/2024

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