Reference number(s)
5681-A

STANDARD MEDICARE PART B 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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
Chart notes, lab tests documenting all of the following (where applicable):
A. Severe to moderately severe Factor IX deficiency (≤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 severe or moderately severe 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 (≤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

D. Member has not previously received gene therapy treatment

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Hemgenix.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Hemgenix are covered.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VII. REFERENCES

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