AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Hemgenix	Page:	1 of 2
Effective Date:	8/1/2024	Last Review Date:	7/2024

Applies to:	☐Illinois	☐Florida	☐Florida Kids
	☐New Jersey	☒Maryland	☐Michigan
	☐Pennsylvania Kids	☐Virginia	☐Arizona
	☐Kentucky PRMD		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Hemgenix under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Hemgenix

Policy/Guideline:

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 (≤2% of normal circulating Factor IX)
B. Absence of Factor IX inhibitors (lab test results required)
C. Current use of Factor IX prophylaxis therapy
   History of life-threatening hemorrhage(s) or repeated, serious spontaneous bleeding episodes

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

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 (≤2% of normal circulating Factor IX) and meets any of the following:
    3. Member is currently using Factor IX prophylactic therapy
    4. Member has a current or history of a life-threatening hemorrhage
    5. Member has a history of repeated, serious spontaneous bleeding episodes
D. Member has not previously received gene therapy treatment

Approval Duration and Quantity Restrictions:

Approval: 30 days

References:

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