AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Hemgenix	Page:	1 of 3
Effective Date:	4/25/2025	Last Review Date:	4/4/2025
Applies to:	☒Maryland	☒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 the following (where applicable):

- 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 Specialty:

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

Criteria for Initial Approval:

Hemophilia B

Authorization of 3 months for one dose total may be granted for the treatment of hemophilia B (congenital factor IX deficiency) when ALL 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 has uncontrolled disease while concurrently using Factor IX prophylactic therapy or has a contraindication to Factor IX prophylaxis. Uncontrolled disease is defined as ONE of the following:
    - Member has a current or history of a life-threatening hemorrhage.
    - Member has a 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.
- 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 ≤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

Approval Duration and Quantity Restrictions:

Approval: 3 months

References:

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