Reference number(s)
C26808-A

CAREFIRST: HEMGENIX

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

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.

I. PRESCRIBER SPECIALTIES

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

II. 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:
    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. Any prophylaxis trial will be discontinued 6 months following administration of Hemgenix infusion as clinically appropriate
F. Dosing and administration is consistent with product labeling (IV: $2x10^{13}$ genome copies/kg or 2mL/kg as a single, one-time dose)
G. Member has completed a liver health assessment including:
    1. Enzyme testing (alanine amino transferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin
    2. Hepatic ultrasound and elastography
    3. In case of patients with either radiological liver abnormalities or sustained liver enzyme elevations, a consulting hepatologist has assessed the member eligible to receive Hemgenix