Hemgenix
(etranacogene dezaparvovec-drlb)

Policy Number: 067

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<th>Authorization Required</th>
<th>Commercial and Qualified Health Plans</th>
<th>MassHealth</th>
<th>Medicare Advantage</th>
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Hemgenix is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with Hemophilia B (congenital Factor IX deficiency). Factor IX is abbreviated as FIX.

*The Mass Health program currently does not cover HCPC J1411 (Hemgenix/etranacogene dezaparvovec-drlb) as a covered service.

Criteria
1. Criteria for Initial Approval
   Authorization of a single treatment may be granted to biologic male (or male assigned at birth) members 18 years of age or older for treatment of moderately severe or severe Hemophilia B (congenital Factor IX deficiency documented FIX activity level ≤ 2% of normal) when ALL of the following criteria are met:
   A. Documentation of Hemophilia B (congenital FIX deficiency) as established by meeting one of the following:
      i. Currently use FIX prophylaxis therapy, or
      ii. Baseline Annualized bleeding rate (ABR) including:
         o Have current or historical life-threatening hemorrhage, or
         o Have repeated, serious spontaneous bleeding episodes.
   B. The member has received continuous FIX protein prophylaxis for > 2 months
   C. The member has had > 150 previous exposure days of treatment with FIX protein within their lifetime
   D. The member is not currently receiving immunosuppressive therapy
   E. The member does not have any current malignancies
   F. The member has not received Hemgenix or any other gene therapy
   G. The following require documentation:
      i. FIX activity level
      ii. FIX inhibitor level
      iii. Neutralizing Antibody to AAV5
   H. The member must have no evidence of FIX inhibitor at screening, defined as less than 0.6 Bethesda units.
      i. Individuals with a history of transient FIX inhibitor must document at least 6 months since testing positive, with at least 2 negative FIX inhibitor tests during that period
   I. The member does not have Neutralizing antibody to AAV5 equal or greater than 1600.
   J. The member must have adequate renal function as evidenced by BOTH of the following:
      i. Estimated creatinine clearance of at least 30 mL/min
      ii. Creatinine levels are less or equal to 2 times the upper limit of normal
K. Prior to treatment the member does not have liver function test values (ALT, AST, bilirubin, alkaline phosphatase [ALP]), greater than 2 times the upper limit of normal or evidence of advanced cirrhosis determined by hepatic ultrasound and elastography, unless a consulting hepatologist has assessed the member as being eligible to undergo treatment within Hemgenix.

L. The member is screened for acute infection prior to administration including HIV, Hepatitis B, and Hepatitis C.
   i. If HIV positive, virus must be well controlled on current therapy
   ii. Member has no evidence of active infection with Hepatitis B. If HBV requires treatment, a hepatologist must be consulted to optimize sustained suppression with current therapy
   iii. If member has had active infection or recent treatment for Hepatitis C, there must be evidence of Hepatitis C eradication following treatment.

M. Additional courses of therapy are considered experimental and investigational.

2. Dosing and Administration
   • The recommended dose is a single dose, given intravenously, containing a minimum of $2.0 \times 10^{13}$ genome copies (gc) of body weight in which body weight is based on individual’s weight prior to first apheresis. Appropriate dosing should follow the package insert.

3. Duration of Therapy
   • Single treatment course must be given within three months of approval.
   • Additional courses of therapy are considered experimental/investigational.

4. Facility Criteria
   • The medication is prescribed by a hematologist
   • The treatment will be administered at a Comprehensive Hemophilia Treatment Center

Medicare Variation
Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan’s medical policies are used for coverage determinations.

CPT/HCPC Codes

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<th>Authorized CPT/HCPCS Codes</th>
<th>Code Description</th>
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<tr>
<td>J1411</td>
<td>Injection, etranacogene dezaparvovec-drlb, per therapeutic dose</td>
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Effective
August 15, 2023: Correction of an error in the initial posting whereby the policy indicated that this service (J1411) is covered for Mass Health members.
August 2023: Effective Date.

References
Hemgenix Prescribing Information. King of Prussia, PA; Kankakee, IL; and Lexington, MA: CSL Behring and uniQure; November 2022.

Miesbach WA, Recht M, Key NS, et al. Durability of Factor IX activity and bleeding rate in people with severe or moderately severe hemophilia B after 5 years of follow-up in the Phase 1/2 study of AMT-060, and after 3 years of follow-up in the Phase 2b and 2 years of follow-up in the Phase 3 studies of etranacogene

