**RX.PA.083.CCH Hemgenix (etranacogene dezaparvovec-drlb)**

The purpose of this policy is to define the prior authorization process for Hemgenix (etranacogene dezaparvovec-drlb) for the treatment of hemophilia B in adults who currently use Factor IX prophylaxis therapy, have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.

**DEFINITIONS**

ALT – alanine aminotransferase

AST – aspartate aminotransferase

**POLICY**

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Hemgenix (etranacogene dezaparvovec-drlb), is subject to the prior authorization process.

**PROCEDURE**

**Initial Authorization Criteria:**

*Must meet all the criteria listed below:*

- Must be age 18 years or older
- Must be male sex assigned at birth
- Must be prescribed by or in consultation with a hematologist
- Must have a diagnosis of moderate-to-severe hemophilia B defined by Factor IX baseline residual level ≤ 2 IU/dL
- Must provide documentation of ONE of the following:
    - Member has been receiving routine Factor IX prophylaxis continuously for at least 2 months prior to the request
    - Member has a current, or history of, life-threatening hemorrhage
    - Member has a history of repeated, serious spontaneous bleeding episodes

- Must have documentation showing the member has received Factor IX prophylaxis with a minimum of 150 exposure days in their lifetime
- Must submit laboratory screening/results and imaging documentation of ALL the following, **collected within the last 3 months**:
    - Negative Factor IX inhibitor titer results
        - If the titer is positive, the member must undergo a subsequent confirmatory test within 2 weeks. If the subsequent inhibitor titer is positive, the request is denied.
    - Negative HIV screening **OR** HIV viral load <200 copies/mL and the member is on anti-retroviral therapy
    - Negative hepatitis B surface antigen
    - Negative hepatitis C virus (HCV) antibody **OR** HCV antibody is positive AND HCV RNA is negative
    - Liver Function Tests (LFTs) < 2 times the upper limit of normal
        - AST/ALT
        - Total bilirubin
        - Alkaline Phosphatase
    - Serum Creatinine < 2x upper limit of normal
    - Platelet counts $\geq$ 50 x $10^9$/L
    - Hepatic ultrasound and elastography to rule out radiological liver abnormalities [e.g., advanced liver fibrosis (stage 3 or 4)]
- Must have documentation or an attestation from the prescriber on all the following:
    - Must not have a history of Factor IX inhibitors
    - For members with a history of hepatitis B or C exposure, the member is not currently using antiviral therapy for hepatitis B or C
    - Must not have previously received Hemgenix or other gene therapies for hemophilia
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

**Limitations:**

| Length of Authorization (if above criteria met) | |
|---|---|
| Initial Authorization | 6 months |
| Reauthorization | N/A (Only single course allowed per lifetime) |

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

## Codes:

| CPT Codes / HCPCS Codes / ICD-10 Codes | | |
|---|---|---|
| Code | Brand | Description |
| J1411 | Hemgenix | Injection, etranacogene dezaparvovec-drlb, per therapeutic dose |

## References:

1. Hemgenix (etranacogene dezaparvovec) [prescribing information]. Kankakee, IL: CSL Behring LLC; November 2022
2. Pipe SW, Leebeek FWG, Recht M, et al. Gene Therapy with Etranacogene Dezaparvovec for Hemophilia B. N Engl J Med. 2023 Feb 23;388(8):706-718. doi: 10.1056/NEJMoa2211644. PMID: 36812434
3. National Hemophilia Foundation. MASAC Document #236: MASAC RECOMMENDATIONS ON STANDARDIZED TESTING AND SURVEILLANCE FOR INHIBITORS IN PATIENTS WITH HEMOPHILIA A AND B. URL: https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/MASAC-Recommendations-on-Standardized-Testing-and-Surveillance-for-Inhibitors-in-Patients-with-Hemophilia-A-and-B.

## Revision History

| DESCRIPTION OF REVIEW / REVISION | DATE APPROVED |
|---|---|
| New Policy | 08/24 |
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## Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

## Disclaimer

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CountyCare reserves the right to review and update the medical payment and prior

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