Louisiana Medicaid
Etranacogene dezaparvovec-drlb (Hemgenix®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for etranacogene dezaparvovec-drlb (Hemgenix®).

Additional Point-of-Sale edits may apply.

*This agent may have a **Black Box Warning**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- The recipient is male and ≥ 18 years of age on date of the request; **AND**
- The recipient has a diagnosis of congenital hemophilia B (congenital Factor IX deficiency); **AND**
- The recipient has ≤ 2% of Factor IX activity level (Factor IX level must be **stated on the request**); **AND**
- **ONE** of the following applies (must be **stated on the request**):
    - The recipient is currently using Factor IX prophylaxis therapy; **OR**
    - The recipient has current or historical life-threatening hemorrhage; **OR**
    - The recipient has repeated, serious spontaneous bleeding episodes; **AND**
- This medication is prescribed by a hematologist; **AND**
- The recipient does not have a positive Factor IX inhibitor test at time of screening **(documentation demonstrating the results of Factor IX inhibitor testing must be submitted with this request)**; **AND**
- Liver health assessments have been performed **(documentation of acceptable liver health assessments [as defined in the prescribing information] must be submitted with this request)**, including:
    - Enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin]; ~~,~~ **AND**
    - Hepatic ultrasound and elastography; **AND**~~,~~
- The following are true and **stated on the request:**
    - ~~The recipient does not have a history of factor IX inhibitors; **AND**~~
    - ~~The recipient does not have a positive factor IX inhibitor test at time of screening; **AND**~~
    - The recipient does not have an active infection with hepatitis B or C virus at time of screening; **AND**
    - The recipient **has never received a dose** of etranacogene dezaparvovec-drlb (Hemgenix®); **AND**
- If request is for a non-preferred agent - **ONE** of the following is required: (see Hemophilia Treatment on the PDL/NPDL for list of preferred agents)
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**

    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, prior treatment requirements and required storage and handling procedures; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of approval: 1 month – allow 1 dose per lifetime

References

ClinicalTrials.gov. HOPE-B: Trial of AMT-061 in Severe or Moderately Severe Hemophilia B Patients. https://clinicaltrials.gov/ct2/show/record/NCT03569891?view=record

Hemgenix (etranacogene dezaparvovec-drlb) [package insert]. Kankakee, IL: CSL Behring LLC; November 2022. https://labeling.cslbehring.com/PI/US/Hemgenix/EN/Hemgenix-Prescribing-Information.pdf

Shah J, Kim H, Sivamurthy K, Monahan PE, Fries M. Comprehensive analysis and prediction of long-term durability of factor IX activity following etranacogene dezaparvovec gene therapy in the treatment of hemophilia B [published online ahead of print, 2022 Oct 25]. *Curr Med Res Opin*. 2022;1-11. doi:10.1080/03007995.2022.2133492

UpToDate: Clinical manifestations and diagnosis of hemophilia. Current through November 2022. www.uptodate.com

Revision / Date	**Implementation Date**
Policy created / December 2022	April 2023
Added requirement to provide documentation of results of Factor IX inhibitor testing and acceptable liver health assessments / May 2023	July 2023