MEDICAL COVERAGE POLICY	
SERVICE:	**Etranacogene dezaparvovec (Hemgenix®)**
Policy Number:	**312**
Effective Date:	**09/01/2025**
Last Review:	**08/11/2025**
Next Review:	**08/11/2026**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

SERVICE: Etranacogene dezaparvovec (Hemgenix®)

PRIOR AUTHORIZATION: Required

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). Texas Mandate HB154 is applicable for Medicaid plans.

Determination: Baylor Scott & White Health Plan (BSWHP) may consider etranacogene dezaparvovec (Hemgenix®) medically necessary when documentation is submitted showing ALL of the following criteria are met:

1. Member has a diagnosis of hemophilia B (congenital factor IX deficiency); **AND**
2. Member is 18 years or older; **AND**
3. Etranacogene is prescribed by or in consultation with a physician who specializes in hemophilia; **AND**
4. Member has documentation of moderately severe or severe hemophilia B as evidenced by a baseline (without FIX replacement therapy) FIX level of ≤ 2% of normal; **AND**
5. Member meets one of the following criteria:
    a. Both of the following:
        i. Documentation of receiving routine prophylaxis with FIX therapy continuously for at least 2 months; **AND**
        ii. According to the prescriber, has at least a 150-exposure day history of FIX therapy;

    OR

    b. Both of the following:
        i. History of life-threatening hemorrhage; **AND**
        ii. On-demand use of FIX therapy was required for this life-threatening hemorrhage;

    OR

c. Both of the following:
    i. History of repeated, serious spontaneous bleeding episodes; **AND**
    ii. On-demand use of FIX therapy was required for these serious spontaneous bleeding episodes;

AND

6. Member has adequate liver function as defined by **ONE** of the following:
    a. Both of the following:
        i. Alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase [ALT, AST, or ALP] less than 2 times the upper limit of normal [ULN]; **AND**
        ii. Bilirubin less than 1.5 times ULN;

    OR

    b. In the presence of sustained liver enzyme elevations, attestation by a consulting hepatologist documenting eligibility to receive Hemgenix;

    AND
7. Member meets one of the following:
    a. Patient is not HIV positive; **OR**
    b. Patient is HIV positive and is virally suppressed (< 200 copies of HIV per mL);

    AND
8. Member does **NOT** meet any of the following:
    a. AAV5 antibodies titer ≥1:678; **OR**
    b. FIX inhibitors; **OR**
    c. Active infection with hepatitis B or C virus at screening**; OR**
    d. Current use of antiviral therapy for Hepatitis B or C**; OR**
    e. Prior gene therapy; **OR**

BSWHP considers only ONE treatment per lifetime is medically necessary as repeat administration of etranacogene dezaparvovec is experimental and investigational because the effectiveness of this strategy has not been established.

BSWHP considers etranacogene dezaparvovec for the treatment of all other indications to be experimental and investigational because the effectiveness of this strategy has not been established.

All requests will be reviewed by a clinical pharmacist and medical director.

BACKGROUND:
Hemophilia B is a rare inherited X-linked coagulation disorder caused by mutations in the *F9* gene that prevent adequate production of coagulation factor IX (FIX), a protein essential for blood clot formation. Decreased levels of FIX result in prolonged bleeding that may occur spontaneously or after a traumatic event. The severity of symptoms depends on the degree of FIX deficiency. Moderate severity can manifest as prolonged usually presenting after trauma, injury, dental work, or surgery, and recurrent joint bleeding may be present in up to 25% of cases. Severe hemophilia presents with frequent

spontaneous bleeding often during infancy when disease is usually diagnosed. Bleeding into joints and muscles is common and can lead to intense pain, immobility, and permanent damage if left untreated.

Etranacogene dezaparvovec (Hemgenix®) is a recombinant gene transfer therapy product indicated for the treatment of adults with hemophilia B (congenital factor IX deficiency) who currently use factor IX prophylaxis therapy, have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes. Etranacogene dezaparvovec consists of an adeno-associated virus 5 (AAV5) vector that delivers a highly functional variant of the *F9* gene (FIX-Padua) to the patient's liver, where FIX is produced. In the HOPE-B trial, etranacogene dezaparvovec was found to be superior to FIX prophylaxis therapy in patients with severe and moderately severe hemophilia B.

CODES:

Important note: *Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.*

CPT Codes:	96365: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour 96366: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
HCPCS Codes:	J1411: Injection, etranacogene dezaparvovec-drlb, per therapeutic dose
ICD10 codes:	D67: Hereditary factor IX deficiency
ICD10 Not covered:	

POLICY HISTORY:

Status	Date	Action
New	08/12/2024	New policy
Updated	08/11/2025	Added requirement of submitted documentation. Updated to standard language for indication and prescriber. Updated lifetime treatment and experimental and investigational language. Background section simplified.
Update	8/11/2025	Removed, Medicare NCD/LCD Interqual statement for clarity.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available, and they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Alshaikhli A, Rokkam VR. Hemophilia B. Updated October 9, 2022. In: StatPearls [Internet]. Treasure Island, FL: StatPearls Publishing; 2022. Available at: https://www.ncbi.nlm.nih.gov/books/NBK560792/. Accessed March 24, 2023.
2. Buckner TW, Bocharova I, Hagan K, et al. Health care resource utilization and cost burden of hemophilia B in the United States. Blood Adv. 2021;5(7):1954-1962. doi: 10.1182/bloodadvances.2020003424
3. Miesbach W, Meijer K, Coppens M, et al. Gene therapy with adeno-associated virus vector 5-human factor IX in adults with hemophilia B. Blood. 2018;131(9):1022-1031. doi:10.1182/blood-2017-09-804419
4. Miller CH. The clinical genetics of hemophilia B (factor IX deficiency). Appl Clin Genet. 2021;14:445-454. doi:10.2147/TACG.S288256
5. Perrin GQ, Herzog RW, Markusic DM. Update on clinical gene therapy for hemophilia. Blood. 2019;133(5):407-414. doi:10.1182/blood-2018-07-820720
6. Pipe SW, Leebeek FWG, Recht M, et al. Gene therapy with etranacogene dezaparvovec for hemophilia B. N Engl J Med. 2023;388(8):706-718. doi:10.1056/ NEJMoa2211644
7. Samelson-Jones BJ, Finn JD, George LA, Camire RM, Arruda VR. Hyperactivity of factor IX Padua (R338L) depends on factor VIIIa cofactor activity. JCI Insight. 2019;5(14):e128683. doi:10.1172/jci.insight.128683
8. Samelson-Jones BJ, Finn JD, Raffini LJ, et al. Evolutionary insights into coagulation factor IX Padua and other high-specific-activity variants. Blood Adv. 2021;5(5):1324-1332. doi:10.1182/bloodadvances.2019000405
9. 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. Curr Med Res Opin. 2023;39(2):227-237. doi:10.1080/03007995.2022.2133492
10. Soucie JM, Miller CH, Dupervil B, Le B, Buckner TW. Occurrence rates of haemophilia among males in the United States based on surveillance conducted in specialized haemophilia treatment centres. Haemophilia. 2020;26(3):487-493. doi:10.1111/hae.13998
11. Spronck EA, Liu YP, Lubelski J, et al. Enhanced factor IX activity following administration of AAV5-R338L "Padua" factor IX versus AAV5 WT human factor IX in NHPs. Mol Ther Methods Clin Dev. 2019;15:221-231. doi:10.1016/j.omtm.2019.09.005
12. Srivastava A, Santagostino E, Dougall A, et al. WFH guidelines for the management of hemophilia, 3rd edition [published correction appears in Haemophilia. July 2021;27(4):699]. Haemophilia. 2020;26 Suppl 6:1-158. doi:10.1111/hae.14046
13. Von Drygalski A, Giermasz A, Castaman G, et al. Etranacogene dezaparvovec (AMT-061 phase 2b): normal/near normal FIX activity and bleed cessation in hemophilia B [published correction appears in Blood Adv. August 11, 2020;4(15):3668]. Blood Adv. 2019;3(21):3241-3247. doi:10.1182/ bloodadvances.2019000811
14. Von Drygalski A, Gomez E, Giermasz A, et al. Stable and durable factor IX levels in hemophilia B patients over 3 years post etranacogene dezaparvovec gene therapy. Blood Adv. Epub ahead of print. December 9, 2022;bloodadvances.2022008886. doi:10.1182/bloodadvances.2022008886
15. Hemgenix [package insert]. Kankakee, IL: CSL Behring; 2022
16. IPD Analytics. (2023). Hemgenix (etranacogene dezaparvovec) suspension for intravenous infusion by CSL Behring LLC
17. Pipe S, van der Valk P, Verhamme P, et al. Long-Term Bleeding Protection, Sustained FIX Activity, Reduction of FIX Consumption and Safety of Hemophilia B Gene Therapy: Results from the HOPE-B Trial 3 Years after Administration of a Single Dose of Etranacogene Dezaparvovec in Adult Patients with Severe or Moderately Severe Hemophilia B. Presented at: ASH 2023 Annual Meeting & Exposition. December 9-12; San Diego, CA. Abstract 1055

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs.