TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Etranacogene dezaparvovec-drlb (Hemgenix®)	**CRITERIA ID:** TX.CC.PHAR.26
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 10/01/2023	**PRODUCT(S):** STAR, STAR Plus, STAR Kids, STAR Health, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 4/3/2024	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for etranacogene dezaparvovec-drlb (Hemgenix®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner, in which it is reimbursed. All determinations will be performed by an Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

Additionally, this medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage Precision Drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All Precision Drug requests or potential requests must be reported to the PDAC for tracking, regardless of whether agents are carved out, passed through, etc. All Precision Drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

The procedure code J1411 (used for Hemgenix) will be limited to one approval per lifetime, by any provider. If the code is updated in the future, it will still be limited to once per lifetime.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
NRB = Non-risk based
PDAC = Precision Drug Action Committee
UM = Utilization Management

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of etranacogene dezaparvovec-drlb (Hemgenix®); procedure code: J1411.

Description/Mechanism of Action:
Etranacogene dezaparvovec-drlb (Hemgenix®) is an adeno-associated virus serotype 5 (AAV5) based gene therapy designed to deliver a copy of a gene encoding the Padua variant of human coagulation Factor IX (hFIX-Padua). A single infusion of etranacogene dezaparvovec-drlb results in cell transduction and an increase in circulating factor IX activity in persons with hemophilia B.

FDA Approved Indications:
Etranacogene dezaparvovec-drlb (Hemgenix®) is an adeno-associated virus vector-based gene therapy 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.

PROCEDURE:

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Approval Criteria

A. Hemophilia B (congenital Factor IX deficiency):

Note: Pharmacy clinician will make one outreach attempt to the servicing provider (SP) to determine which NDC will be utilized for drug administration. (**Please Note** Sometimes not all NRB drug NDC's are covered on the VDP CAD Formulary) If the requested NDC is not covered, clinician should steer servicing provider to an NDC covered on VDP's CAD formulary based on client's weight). Call note details should be documented under applicable PA.

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. Medical necessity determinations will be supported by PDAC UM recommendation. The pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the Medical Director but will not make the ultimate determination on any case.
3. The client is 18 years of age or older.
4. The client has a confirmed diagnosis of Hemophilia B (Hereditary factor IX deficiency) (diagnosis code: D67) and all other bleeding disorders not related to Hemophilia B have been ruled out.
5. The client must meet one of the following criteria (a, b, or c):
    a. Is currently using Factor IX prophylaxis therapy;
    b. Has current or historical life-threatening hemorrhage;
    c. Has a history of repeated, serious spontaneous bleeding episodes;
6. Documentation of Factor IX inhibitor titer test confirming a baseline anti-AAV5 antibody titer of ≤1:678.
7. Documentation that the client was tested for Factor IX inhibitor presence and testing result was negative.
    Note: If testing yielded a positive result, a second Factor IX inhibitor titer test should have been performed within two weeks. Hemgenix should not be administered if the results for the initial and second test for human Factor IX inhibitor are positive.
8. The client's baseline liver condition and function assessment prior to Hemgenix infusion includes (a and b):
    a. Documentation includes, but is not limited to alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and total bilirubin;
    b. Documentation of hepatic ultrasound and elastography
9. The client does not have a history of previously receiving treatment with Hemgenix infusion.
10. Prescriber attestation to the following monitoring requirements following Hemgenix infusion (a and b):
    a. Liver transaminase levels must be assessed once weekly for at least 3 months after Hemgenix infusion to monitor for any potential signs of hepatotoxicity;
    b. Factor IX activity must be monitored weekly for at least 3 months post-infusion.

Approval duration: Only 1 dose per lifetime will be provided on this drug regardless of Provider.

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook
Hemgenix Prescribing Information. Kankakee, IL: CSL Behring; November 2022. Available at: https://labeling.cslbehring.com/PI/US/Hemgenix/EN/Hemgenix-PrescribingInformation.pdf.

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	N/A	10/01/2023
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement	4/3/2024