TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Valoctocogene roxaparvovec-rvox (Roctavian®)	**CRITERIA ID:** TX.CC.PHAR.29
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 01/01/2024	**PRODUCT(S):** STAR, STAR Plus, STAR Kids, STAR Health, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 04/03/2024	
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 valoctocogene roxaparvovec-rvox (Roctavian®).

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 a 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 J1412 (used for Roctavian) 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 valoctocogene roxaparvovec-rvox (Roctavian®); procedure code: J1412.

Description/Mechanism of Action:
Valoctocogene roxaparvovec (Roctavian®) is an adeno-associated virus serotype 5 (AAV5) based gene therapy vector that is designed to introduce a functional copy of a transgene encoding the B-domain deleted SQ form of human coagulation factor VIII (hFVIII-SQ). Transcription of this transgene occurs within the liver using a liver-specific promoter, which results in the expression of hFVIII-SQ. The expressed hFVIII-SQ replaces the missing coagulation factor VIII needed to achieve hemostasis. After administration of valoctocogene roxaparvovec, vector DNA is processed in vivo to form full-length, episomal transgenes that increase circulating hFVIII-SQ up to 5 years.

FDA Approved Indications:
Valoctocogene roxaparvovec-rvox (Roctavian®) is an adeno-associated virus vector-based gene therapy indicated to treat adult clients with severe hemophilia A (congenital Factor VIII deficiency with Factor VIII activity less than 1 IU/dL) without pre-existing antibodies to adenoassociated virus serotype 5 (AAV5) detected by an FDA-approved test.

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. Severe Hemophilia A (congenital Factor VIII deficiency) (must meet all):

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 severe Hemophilia A (congenital Factor VIII deficiency) as defined by Factor VIII activity level less than 1 IU/dL (in the absence of exogenous Factor VIII).
5. Documentation that all other bleeding disorders not related to Hemophilia A have been ruled out.
6. Documentation that the client has no history of Factor VIII inhibitors and a negative screening test prior to treatment.
7. Documentation that the client's baseline test (as determined by an FDA approved test) is negative for preexisting antibodies to adeno-associated virus serotype 5 (AAV5).
8. The client's baseline liver condition and function assessment prior to Roctavian 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 or laboratory assessments for liver fibrosis.
9. Prescriber attestation to counseling clients regarding consuming alcohol post administration of Roctavian.
10. The client does not have any active infections, either acute or chronic.
11. The client does not have stage 3 or 4 liver fibrosis or cirrhosis.
12. The client does not have a known hypersensitivity to mannitol.
13. The client does not have a history of previously receiving treatment with Roctavian infusion.
14. Prescriber attestation to the following monitoring requirements following Roctavian infusion (a, b, c and d):
    a. ALT must be assessed once weekly for at least 26 weeks after Roctavian infusion to monitor for any potential signs of hepatotoxicity;
    b. Assess and manage adverse reactions from corticosteroid use;
    c. Factor VIII activity must be monitored periodically as thromboembolic events may occur with elevated Factor VIII activity above the upper limit of normal (ULN).
    d. Assess liver ultrasound and alpha-fetoprotein testing annually to monitor for hepatocellular malignancy in patients with risk factors for hepatocellular carcinoma (e.g., hepatitis B or C, non-alcoholic fatty liver disease, chronic alcohol consumption, non-alcoholic steatohepatitis, advanced age).

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
Roctavian Prescribing Information. Novato, CA: BioMarin Pharmaceutical; June 2023. Available at: https://www.biomarin.com/wp-content/uploads/2023/06/ROCTAVIAN-Prescribing-Information_US.pdf

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document	N/A	01/01/2024
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement and criteria requirement for PDAC review prior to final determination and final determination must be made by a medical director	04/03/2024

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