Louisiana Medicaid
Valoctocogene Roxaparvovec-rvox (Roctavian™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for valoctocogene roxaparvovec-rvox (Roctavian™).

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 severe hemophilia A (congenital factor VIII deficiency with factor VIII activity level < 1 IU/dL [factor VIII level must be **stated on the request**]); **AND**
- This medication is prescribed by a hematologist; **AND**
- **Documentation of lab testing for the recipient demonstrating the following results (if defined) must be submitted with this request:**
    - The recipient does not have prior or active factor VIII inhibitors; **AND**
    - The recipient screened negative (less than 0.6 Bethesda Units [BU] for factor VIII inhibitors using Nijmegen modified Bethesda assays performed on 2 consecutive occasions at least one week apart within the past 12 months; **AND**
    - The recipient does not have pre-existing antibodies to adeno-associated virus serotype 5 (AAV5) based on the results of an FDA-approved test; **AND**
    - The following liver health assessments have been performed for this recipient:
        - Enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), gamma-glutamyl transferase (GGT), international normalized ration (INR) and total bilirubin]; **AND**
        - Hepatic ultrasound and elastography or laboratory assessments for liver fibrosis; **AND**
- The following are true and **stated on the request:**
    - The recipient has been treated with FVIII concentrates or cryoprecipitate for a minimum of 150 exposure days; **AND**
    - The recipient does not have an active infection with hepatitis B, hepatitis C or HIV at time of screening; **AND**
    - The recipient **has never received a dose** of valoctocogene roxaparvovec-rvox (Roctavian™); **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. Gene Therapy Study in Severe haemophilia A Patients. https://www.clinicaltrials.gov/study/NCT02576795

Roctavian (valoctocogene roxaparvovec-rvox) [package insert]. Novato, CA: BioMarin Pharmaceutical Inc; June 2023. https://www.biomarin.com/wp-content/uploads/2023/06/ROCTAVIAN-Prescribing-Information_US.pdf

Revision / Date	**Implementation Date**
Policy created / August	January 2024