ALASKA MEDICAID
Prior Authorization Criteria

Roctavian®
(valoctocogene roxaparvovec-rvox)

FDA INDICATIONS AND USAGE[1]

ROCTAVIAN is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 detected by an FDA-approved test.

APPROVAL CRITERIA[1,2]

1. Patient is 18 years of age or older **AND**;
2. Prescribed by or in consultation with a hematologist **AND**;
3. Patient has the diagnosis of hemophilia A **AND**;
4. Patient has moderate to severe disease as defined by factor VIII levels < 1 IU/dl **AND;**
5. Patient has had >150 previous exposure days to factor VIII **AND;**
6. Patient must have no history of inhibitors to factor VIII, and a screen performed within two weeks prior to administration must be negative as defined as <0.6 Bethesda units **AND**;
7. Patient does not have pre-existing antibodies to adeno-associated virus serotype 5 (AAV5) **AND**;
8. Patient has had liver health assessments including:
    a. A hepatic ultrasound and elastography performed prior to administration.
    b. Liver function tests (ALT, AST, GGT, ALP, total bilirubin, and INR).

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Patient currently has an active hepatitis B or hepatitis C infection **OR**;
3. Patient currently has an uncontrolled HIV infection **OR**;
4. Known hepatic fibrosis (stage 3 or 4) or cirrhosis **OR**;
5. Patient has a known hypersensitivity to mannitol **OR**;
6. Patient has been previously treated with gene therapy for hemophilia A.

CAUTIONS[1]

- Thromboembolic events may occur in the setting of elevated factor VIII activity above the upper limit of normal.
- Patients with preexisting risk factors for hepatocellular carcinoma should be monitored regularly for elevated alpha-fetoprotein (AFP) and receive abdominal ultrasound screenings for five years following administration.
- Monitor alanine aminotransferase (ALT) weekly post-administration for at least 26 weeks and institute corticosteroid treatment in response to ALT elevations as

required. Continue to monitor ALT until it returns to baseline.

- Monitor factor VIII activity levels since ALT elevation may be accompanied by a decrease in factor VIII activity.

DURATION OF APPROVAL

- Initial Approval: 3 months
    - No reauthorization will be approved.

QUANTITY LIMIT

- One infusion per lifetime.
- HCPCS: J3590

REFERENCES / FOOTNOTES:

1. Roctavian (valoctocogene roxaparvevec-rvox) [package insert]. Novato, CA: BioMarin Pharmaceutical, Inc.; June 2023
2. Tice JA, Walton S, Herce-Hagiwara B, Fahim SM, Moradi A, Sarker J, Chu J, Agboola F, Pearson SD, Rind DM. Gene Therapy for Hemophilia B and An Update on Gene Therapy for Hemophilia A: Effectiveness and Value; Evidence Report. Institute for Clinical and Economic Review, December 22, 2022. https://icer.org/assessment/hemophilia-a-and-b-2022