PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Roctavian (valoctocogene roxaparvovec)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

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

f) History of thromboembolic event
g) Any prior gene therapy; AND

9. .

10. **Dosage allowed/Quantity limit:** 6×10^{13} vector genomes (vg) per kg intravenously one time.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Not applicable; Roctavian is a one-time single dose.

CareSource considers Roctavian (valoctocogene roxaparvovec) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/02/2023	New policy for Roctavian created.

References:

1. Roctavian. [prescribing information]. BioMarin Pharmaceutical Inc.; 2023.
2. Ozelo MC, Mahlangu J, Pasi KJ, et al. Valoctocogene Roxaparvovec Gene Therapy for Hemophilia A. *N Engl J Med*. 2022;386(11):1013-1025. doi:10.1056/NEJMoa2113708
3. Pasi KJ, Laffan M, Rangarajan S, et al. Persistence of haemostatic response following gene therapy with valoctocogene roxaparvovec in severe haemophilia A. *Haemophilia*. 2021;27(6):947-956. doi:10.1111/hae.14391
4. Institute for Clinical and Economic Review (ICER). Gene Therapy for Hemophilia B and An Update on Gene Therapy for Hemophilia A: Final Policy Recommendations. December 2022.
5. IPD Analytics. Accessed August 2, 2023.

Effective date: 01/01/2024
Revised date: 08/02/2023