

valoctocogene roxaparvovec-rvox (Roctavian)

Medical Benefit Drug Policy

Place of Service

Outpatient Facility Administration

Hospital Administration

Drug Details

USP Category: BLOOD PRODUCTS AND MODIFIERS

Mechanism of Action: Gene transfer therapy

HCPCS:

J1412:Injection, valoctocogene roxaparvovec-rvox, per ml, containing nominal 2×10^{13} vector genomes

How Supplied:

NDCs:

- 68135-927-48: carton containing single-dose vial
- 68135-929-01: single-dose vial with an extractable volume of not less than 8 mL, containing 16×10^{13} vector genomes (vg)

Condition(s) listed in policy *(see coverage criteria for details)*

- Severe Hemophilia A

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Severe Hemophilia A

Meets medical necessity if all the following are met:

1. Diagnosis of hemophilia A (congenital Factor VIII deficiency)
2. Age is consistent with the FDA approved indication
3. Patient has baseline Factor VIII activity of less than 1% of normal (< 1 IU/dL)
4. Patient does not have Factor VIII inhibitors

5. Patient does not have antibodies to AAV5
6. Provider has completed a liver health assessment, consisting of either of the following (a or b):
 - a. Patient does not have liver dysfunction, as indicated by any of the following (i or ii):
 - i. Liver function tests (LFTs) [i.e., alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), total bilirubin] exceeding 1.25 times the upper limit of normal ($>1.25 \times \text{ULN}$) or international normalized ratio (INR) ≥ 1.4
 - ii. Liver fibrosis
 - b. For patients with either radiological liver abnormalities or sustained liver enzyme elevations: a consulting hepatologist has assessed that the patient is eligible to receive Roctavian
7. Patient does not have significant liver fibrosis (stage 3 or 4) or cirrhosis
8. Patient does not have an active acute or uncontrolled chronic infection with HIV-1, HIV-2, hepatitis B virus (HBV), or hepatitis C virus (HCV)
9. Patient has not previously received gene therapy

Covered Doses:

6×10^{13} vector genomes per kilogram (vg/kg) body weight given by intravenous infusion

Coverage Period:

One-time treatment per lifetime

ICD-10:

D68.311

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Roctavian (valoctocogene roxaparvovec) [prescribing information]. Novato, CA: BioMarin Pharmaceuticals Inc; June 2023.

Review History

Date of Last Annual Review: 3Q25

Changes from previous policy version:

- No clinical change following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*