valoctocogene roxaparvovec-rvox (Roctavian)

Commercial 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 x 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 x 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

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 (>1.25x 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:

- Removed Evio requirement for use of drug

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