blue california
Promise Health Plan

valoctocogene roxaparvovec-rvox (Roctavian)

Medical Benefit Drug Policy

Place of Service
Outpatient Facility Administration
Hospital Administration

Drug Details

USP Category: Genetic or Enzyme or Protein Disorder
Mechanism of Action: Gene transfer therapy
HCPCS:

- **Through 12/31/2023**: C9399, J3490, J3590
- **Effective 1/1/2024 and after**: J1412 per mL, containing nominal 2×10^{13} vector genomes

How supplied
NDC(s):

- 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

Special Instructions and pertinent Information

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

Blue Shield of California has partnered with Evio to track and monitor medical status and treatment outcomes for patients receiving this therapy. If the patient meets all clinical requirements for medical necessity and is approved for the drug, the **provider must attest and agree to provide clinical outcomes data and information to Evio**.

Coverage Criteria

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

Severe hemophilia A

1. Diagnosis of hemophilia A (congenital Factor VIII deficiency), AND
2. Patient is ≥ 18 years of age, AND
3. Patient has baseline Factor VIII activity of less than 1% of normal (< 1 IU/dL), AND

4. Patient does not have Factor VIII inhibitors, AND
5. Patient does not have antibodies to AAV5, AND
6. Provider has completed a liver health assessment, consisting of all of the following:
    a. Patient does not have liver dysfunction, as indicated by any of the following:
        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, or
        ii. Liver fibrosis

    OR

    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,

    AND
7. Patient does not have significant liver fibrosis (stage 3 or 4) or cirrhosis, and
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), and
9. Patient has not previously received gene therapy

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

Coverage Period
One-time treatment per lifetime

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-rvox). [Prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc. June 2023.

Policy Update

Date of Last Annual Review: 8/30/2023
Date of last revision: 1/3/2024
Changes from previous policy version:

- Added HCPCS J1412 per mL, containing nominal 2 × 10^13 vector genomes, effective 1/1/2024 and after.
- Clarified Evio expectations from providers

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