Medical Policy

BlueCross BlueShield Kansas
An Independent licensee of the Blue Cross Blue Shield Association

Title: Roctavian

Professional / Institutional
Original Effective Date: January 8, 2026
Latest Review Date:
Current Effective Date: January 8, 2026

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

Indication	Dose
Hemophilia A (Congenital Factor VIII Deficiency)	The recommended dose of Roctavian is 6×10^{13} vector genomes per kilogram (vg/kg) body weight, administered as a single intravenous infusion. **Calculating Dose in Milliliters (mL) and Number of Vials Required** • Patient dose volume in mL: – Body weight in kg multiplied by 3 = dose in mL. – *The multiplication factor 3 represents the per kilogram dose (6×10^{13} vg/kg) divided by the amount of vector genomes per mL of suspension (2×10^{13} vg/mL).* • Number of vials to be thawed:

Indication	Dose
	– Patient dose volume (mL) divided by 8 = number of vials to be thawed (round up to next whole number of vials). – *The division factor 8 represents the minimum volume extractable from a vial (8 mL).*

- Roctavian is administered using an infusion pump at a rate of 1 mL/min, which can be increased every 30 minutes by 1 mL/min up to a maximum rate of 4 mL/min.
- Do not expose Roctavian to the light of an ultraviolet radiation disinfection lamp.
- Prepare using aseptic technique. Wear gloves and safety glasses during preparation and administration.
- Treat spills with a virucidal agent with proven activity against non-enveloped viruses and blot using absorbent materials.
- Dispose unused medicinal product and materials that may have come in contact with Roctavian in accordance with the local biosafety guidelines.
- Thaw at room temperature. Do not thaw or warm vials any other way. Thawing time is approximately 2 hours. Thawed suspension can be held at room temperature, up to 25°C (77°F), for a maximum of 10 hours including hold time in intact vial, preparation time into the syringes, and duration of infusion.
- DO NOT administer as an intravenous push or bolus.
- DO NOT infuse in the same intravenous line with any other products.
- DO NOT use a central line or port.

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

I. Length of Authorization

Coverage will be provided for one dose and may not be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 352 billable units (352 mL) one time only
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III. Initial Approval Criteria [1-15]

Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:
Hemophilia A (Congenital Factor VIII Deficiency) † Φ

- Patient is at least 18 years of age; **AND**
- Patient has a diagnosis of severe hemophilia A (congenital factor VIII deficiency) as confirmed by a factor VIII activity level < 1 IU/dL; **AND**
- Evidence of any bleeding disorder NOT related to hemophilia A has been ruled out; **AND**
- Patient is on a stable dose of regularly administered exogenous factor VIII for the prevention and control of bleeding episodes; **AND**
- Patient does not have an active infection, either acute (such as acute respiratory infections or acute hepatitis) or uncontrolled chronic (such as chronic active hepatitis B); **AND**
- Patient is up to date with vaccinations prior to infusion and will avoid live vaccines while on immunosuppressive therapies; **AND**
- Patient does not have significant hepatic fibrosis (stage 3 or 4) or cirrhosis; **AND**
- Patient does not have a known hypersensitivity to mannitol: **AND**
- Patient has not received prior hemophilia AAV-vector–based gene therapy; **AND**
- Patient is adeno-associated virus serotype 5 (AAV5) antibody negative as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Patient has been tested and found negative for active factor VIII inhibitors *(i.e., results from a Bethesda assay or Bethesda assay with Nijmegen modification of less than 0.6 Bethesda Units (BU) on 2 consecutive occasions at least one week apart within the past 12 months)* and is not receiving a bypassing agent (e.g., Feiba, NovoSeven RT, SevenFact, etc.); **AND**
- Patient will have post-administration monitoring of serum ALT levels performed according to the monitoring schedule outlined in the product labeling with corticosteroids (or other immunosuppressive therapy) administered in response to elevations; **AND**
- Patients with preexisting risk factors for hepatocellular carcinoma [e.g., patients with hepatitis C or B, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), and advanced age] will have regular (e.g., annually) liver ultrasounds performed and will be tested for alpha-fetoprotein (AFP) elevations following administration; **AND**
- Patient will have factor VIII activity monitored according to the monitoring schedule outlined in the product labeling; **AND**
    - Patients with factor VIII activity levels >5 IU/dL will discontinue routine prophylactic exogenous factor VIII; **OR**
    - If the factor VIII activity levels decrease and/or if bleeding is not controlled, the patient will be assessed for the presence of factor VIII

- inhibitors and the need for hemostatic prophylaxis

Notes:

- It may take several weeks after valoctocogene roxaparvovec infusion before valoctocogene roxaparvovec-derived factor VIII activity rises to a level sufficient for prevention of spontaneous bleeding episodes. Therefore, continued routine prophylaxis support with exogenous factor VIII or other hemostatic products used in the management of hemophilia A may be needed during the first few weeks after valoctocogene roxaparvovec infusion.
- Exogenous factor VIII or other hemostatic products may continue to be required in the case of surgery, invasive procedures, trauma, or bleeds in the event that valoctocogene roxaparvovec-derived factor VIII activity is deemed insufficient for adequate hemostasis in such situations.
- Use of exogenous factor VIII products before and after valoctocogene roxaparvovec administration may impede assessment of valoctocogene roxaparvovec-derived factor VIII activity.

❖ If confirmed using an immunotherapy assay-*http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria

- Duration of authorization has not been exceeded (refer to Section I)

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CLINICAL RATIONALE

See package insert for FDA preshttps://dailymed.nlm.nih.gov/dailymed/index.cfm

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

HCPCS code:

- J1412 – Injection, valoctocogene roxaparvovec-rvox, per mL, containing nominal 2×10^{13} vector genomes; 1 billable unit = 1 mL, containing nominal 2×10^{13} vector genomes

NDC:

- Roctavian 2×10^{13} vector genomes (vg) per mL – 8 mL single dose vial: 68135-0927-xx

REVISIONS	
Posted: 12-9-2025 Effective: 01-08-2026	New medical policy added to the bcbsks.com web site. Policy is maintained by Prime Therapeutics LLC.

REFERENCES

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