Hemophilia Products:
Roctavian™ (valoctocogene roxaparvovec-rvox)
(Intravenous)

Document Number: IC-0718

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for one dose.
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

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

- 352 billable units (352 mL) one time only Δ

Δ ***Note****: The maximum unit dosing limits are applied operationally and should not be interpreted as a substitute for, or equivalent to, the dosing limitations set forth in the prescribing information.*

III. Initial Approval Criteria [1-15]

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. 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**.** Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided in the following conditions:

Hemophilia A (Congenital Factor VIII Deficiency) † Φ

- Member is at least 18 years of age; **AND**
- Member 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**
- Member is on a stable dose of regularly administered exogenous factor VIII for the prevention and control of bleeding episodes; **AND**

- Member 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**
- Provider will confirm that member is up to date with vaccinations prior to infusion and will avoid live vaccines while on immunosuppressive therapies; **AND**
- Member does not have significant hepatic fibrosis (stage 3 or 4) or cirrhosis; **AND**
- Member does not have a known hypersensitivity to mannitol: **AND**
- Member has not received prior hemophilia AAV-vector–based gene therapy; **AND**
- Member is adeno-associated virus serotype 5 (AAV5) antibody negative as determined by an FDA-approved or (Clinical Laboratory Improvement Amendments) CLIA-compliant test❖; **AND**
- Member 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**
- Member 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**
- Members with preexisting risk factors for hepatocellular carcinoma [e.g., members 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**
- Member will have factor VIII activity monitored according to the monitoring schedule outlined in the product labeling; **AND**
    - Members 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 member 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)

V. Dosage/Administration [1]

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** • Member 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: – Member 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.	

VI. Billing Code/Availability Information

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

VII. References

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14. MASAC Recommendations on Hemophilia Treatment Center Preparedness for Delivering Gene Therapy for Hemophilia. National Hemophilia Foundation. MASAC Document # 282 (Replaces Document #277). October 2023. Available at: https://www.bleeding.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-282-masac-recommendations-on-hemophilia-treatment-center-preparedness-for-delivering-gene-therapy-for-hemophilia. Accessed December 2025.
15. Thornburg, C.D., Simmons, D.H., von Drygalski, A. Evaluating gene therapy as a potential paradigm shift in treating severe hemophilia. BioDrugs. 2023. DOI: 10.1007/s40259-023-00615-4

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D66	Hereditary factor VIII deficiency

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC