Reset Form Print Form

Government of District of Columbia Department of Health Care Finance

Roctavian (valoctocogene roxaparvovec-rvox)

Request Date: _____

RECIPIENT INFORMATION

Recipient Medicaid ID: _____

Date of Birth: _____

Recipient Last Name: _____

Recipient First Name: _____ Middle Initial: _____

PRESCRIBER INFORMATION

Prescriber Last Name: _____

Prescriber First Name: _____

Prescriber Phone: _____

Prescriber Fax: _____

Prescriber DEA Number: _____

Prescriber NPI Number: _____

Prescriber Specialty: _____

PHARMACY INFORMATION

Pharmacy Name: _____

Pharmacy Phone: _____

Pharmacy Fax: _____

Pharmacy NPI Number: _____

Refer to FDA www.fda.gov for prescribing details and approved indications.

SUBMIT TO Comagine Health DHCF DC Medicaid:
https://comagine.org/program/dc-medicaid-um

Revision Date: 04/21/2026

Recipient's Name (Last, First): _____

PRIOR AUTHORIZATION CRITERIA

Instructions: Ensure the recipient meets all the criteria below and check applicable boxes.

☐ Recipient is at least 18 years of age.

☐ Recipient has severe hemophilia A (congenital factor VIII deficiency) confirmed by a factor VIII activity level < 1 IU/dL (in the absence of exogenous factor VIII). **Attach clinical documentation.**

☐ Recipient is adeno-associated virus serotype 5 (AAV5) antibody negative as determined by an FDA approved or CLIA-compliant test. Details about FDA-approved tests for the detection of antibodies to AAV5 are available at http://www.fda.gov/CompanionDiagnostics**. Attach clinical documentation.**

☐ Other bleeding disorders **NOT** related to hemophilia A have been ruled out.

☐ Recipient is on a stable dose of regularly administered exogenous factor VIII for the prevention and control of bleeding episodes.

Regimen and start date.

Regimen: _____

Start Date: _____

☐ Recipient does **NOT** have an active infection, either acute or uncontrolled chronic. **Contraindication**

☐ Recipient does **NOT** have significant hepatic fibrosis (stage 3 or 4) or cirrhosis. **Contraindication**

☐ Recipient does **NOT** have a known hypersensitivity to mannitol. **Contraindication**

☐ Recipient 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). **Attach clinical documentation of test dates and results.**

☐ Recipient has **NOT** received prior hemophilia AAV-vector–based gene therapy.

☐ Post administration monitoring of recipient's serum ALT levels will be performed according to the monitoring schedule outlined in the product labeling.

Recipient's Name (Last, First): _____

☐ Recipient with any preexisting risks factors for hepatocellular carcinoma as listed in the examples below, will have regular liver ultrasounds and testing for alpha-fetoprotein (AFP) elevations following administration.

- Hepatitis B or C
- Non-alcoholic fatty liver disease (NAFLD)
- Chronic alcohol consumption
- Non-alcoholic steatohepatitis (NASH)
- Advanced age

☐ Recipient's Factor VIII activity will be monitored periodically.

- Factor VIII activity levels > 5 IU/dL should discontinue routine prophylactic exogenous factor VIII; **OR**
- If Factor VIII activity levels decrease and/or if bleeding is not controlled, assess presence of factor VIII inhibitors and assess the need for hemostatic prophylaxis.

Please provide any additional information that would help in the decision-making process.

Submit to Comagine Health DHCF DC Medicaid: https://comagine.org/program/dc-medicaid-um

LENGTH OF AUTHORIZATION CRITERIA AND PRIOR AUTHORIZATION RENEWAL

Single-dose infusion. Not eligible for renewal.

DOSAGE AND ADMINISTRATION

Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/.

By signature, the prescriber confirms the above information is complete, accurate, and verifiable by recipient's records.

Prescriber's Signature: _____ **Date:** _____