ambetter. FROM peach state health plan

Telephone: (800) 514-0083 option 2
Fax: (866) 374-1579

Valoctocogene Roxaparvovec-rvox (Roctavian)
PDAC Drug Review Form

The information below can be completed by the Health Plan and/or Centene Pharmacy Services (CPS) staff

Patient Information

*Last Name:	*First Name:	Middle:	*DOB: / /
Daytime Phone:	Evening Phone:	*Sex: ☐ Male ☐ Female	

Insurance Information

*Primary Insurance (Health Plan Name and State)	*ID #:

Physician Information

*Name:	*Specialty:	*Phone #:

Procedural Hospital

*Hospital Name:

Primary Diagnosis

*ICD-10 Code: _____

☐Congenital hemophilia A ☐Other: _____

Prescription Information

MEDICATION	STRENGTH	*DIRECTIONS	QUANTITY	REFILLS
Roctavian (Valoctocogene Roxaparvovec-rvox)				

Clinical Information

***** *Please submit supporting clinical documentation* *****

* **THERAPY Start Date**: _____

1. Is therapy prescribed by or in consultation with a hematologist? ☐Yes ☐No
2. Please provide patient's weight: _____ kg
3. Does patient have severe hemophilia A defined as pre-treatment FVIII level < 1% or activity < 1 IU/dL?
   ☐Yes, FVIII level: _____ % or activity: _____ IU/dL ☐No
4. Has patient been adherent with use of a FVII product for routine prophylaxis for at least 12 months as assessed and documented by prescriber? ☐Yes ***Mark all that apply*** ☐No
   ☐Advate ☐Adynovate ☐Afstyla ☐Altuviiio ☐Eloctate ☐Esperoct ☐Helixate FS ☐Kogenate FS
   ☐Jivi ☐Kovaltry ☐NovoEight ☐Nuwiq ☐Wilate ☐Xyntha ☐Other: _____
5. Is there occurrence of at least 1 serious spontaneous (occurs without apparent cause and not result of trauma) bleeding event while on routine prophylaxis? ☐Yes ***Mark all that apply*** ☐No
   ☐Intracranial ☐Neck/Throat ☐Gastrointestinal ☐Joints (hemarthrosis) ☐Muscles
   ☐Mucous membranes of the mouth, nose, and genitourinary tract ☐Other: _____
6. Has patient been treated with FVIII concentrates or cryoprecipitate for a minimum of 150 exposure days? ☐Yes ☐No
7. Does patient have documented history of a detectable FVIII inhibitor? ☐Yes ☐No
8. Is patient's FVIII inhibitor level assay < 0.6 Bethesda units (BU) on 2 consecutive occasions at least 1 week apart within the last 12 months? ☐Yes: _____ BU, date: _____ and BU, date: _____ ☐No
9. Does patient have pre-existing antibodies to the AAV5 as measured by an FDA-approved test? ☐Yes ☐No
10. Is there documentation of hepatic ultrasound and elastography or laboratory assessments for liver fibrosis within the last 3 months showing there is not significant hepatic fibrosis (stage 3 or 4) or cirrhosis? ☐Yes, Date: _____ ☐No
11. Does hepatologist attest the patient is eligible for Roctavian if any of the following baseline liver abnormalities are present (assessed within the last 3 months)? ☐Yes ***Mark all that apply*** ☐No
    ☐Radiological liver abnormalities ☐International normalized ratio (INR) ≥ 1.4 ☐Liver Function tests (LFTs)*
    ☐Other: _____
    **e.g., alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), alkaline phosphatase (ALP), total bilirubin) measuring ALT, AST, GGT, ALP and total bilirubin > 1.25 × upper limit of normal (ULN)*
12. Does provider attest of patient's ability to receive corticosteroids and/or other immunosuppressive therapy that may be required for an extended period and that the risks associated with immunosuppression are acceptable for the patient? ☐Yes ☐No
13. Has patient received prior gene therapy? ☐Yes ☐No

PDAC updated: 09/08/2025
AMB25-GA-HP-00216

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14. Does provider attest that alcohol abstinence education has been completed with patient? ☐Yes ☐No
15. Does provider confirm patient will discontinue any use of hemophilia A prophylactic therapy within 4 weeks after administration of Roctavian? ☐Yes ☐No
16. Does provider agree to monitor patient according to the FDA-approved label (e.g., FVIII level tests, ALT monitoring and steroid treatment as appropriate)? ☐Yes ☐No

Please continue to page 2.

Patient Name: _____ **DOB**: _____

17. Does provider agree to submit all of the following medical information after Roctavian administration upon plan request?
☐Yes ***Mark all that apply*** ☐No
☐FVIII levels measured by the average of 2 consecutive chromogenic substrate or 1 stage assay measurements separated by one week
☐Documentation of all spontaneous bleeds after Roctavian administration
☐Documentation of any resumed continuous hemophilia A prophylaxis and duration of prophylaxis

Complete this section ONLY for indications other than Congenital hemophilia A:

18. Has patient tried and failed, or is contraindicated to, accepted standards of care? ☐Yes ☐No
If yes, submit documentation and answer the following:
a. Please list all previous therapies: _____
b. Was patient adherent to previously tried therapies? ☐Yes ☐No ☐No, patient intolerant to drug

Information	
***Number**:	***Date of Request**:
***HCPCS Code**:	***Decision Due Date**:
* **Line of Business**: ☐ Commercial ☐ Health Insurance Marketplace ☐ Medicaid ☐ Medicare	* **Benefit**: ☐ Medical ☐ Pharmacy

*** Choose one criteria option below based on line of business:**

Medicare Criteria Only:

☐ Medicare Local Coverage Decision (LCD) specific for your region
Please include policy of link to LCD, followed by any applicable Medicare Part B step therapy requirements in MCPB.ST.00.

☐ Medicare National Coverage Decision (NCD).
Please include policy of link to NCD, followed by any applicable Medicare Part B step therapy requirements in MCPB.ST.00.

Medicaid, Commercial, Exchange (Ambetter) Criteria:

☐ Centene Policy [**CP.PHAR.466 Valoctocogene Roxaparvovec-rvox (Roctavian)**]
Date Policy last reviewed/approved by plan (we want to be sure we are using the version approved by your plan):

_____

OR

☐ State or Health Plan Specific (please include policy)