peach state health plan

# Valoctocogene Roxaparvovec-rvox (Roctavian)

## Prior Authorization Form/Prescription

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

Date: _____ Date Medication Required: _____
Ship to: ❍ Physician ❍ Patient's Home ❍ Other

## Patient Information

| *Last Name: | *First Name: | Middle: | *DOB: ____/____/_____ |
|---|---|---|---|
| Daytime Phone: | Evening Phone: | *Sex: ☐ Male ☐ Female | |

## Insurance Information (*Attach copies of cards*)

| *Primary Insurance: | | Secondary Insurance: | |
|---|---|---|---|
| *ID #: | Group #: | ID #: | Group #: |

## Physician Information

| *Name: | *Specialty: | NPI: |
|---|---|---|
| *Phone #: | Secure Fax #: | Office Contact: |

## 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 TYPE (choose one):** ☐INITIAL THERAPY ☐CONTINUATION OF THERAPY

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 immunity 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


PDAC updated: 07/27/2023
PSHP_082523_0524

peach state health plan

# Valoctocogene Roxaparvovec-rvox (Roctavian)

## Prior Authorization Form/Prescription

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

Date: _____ Date Medication Required: _____
Ship to: ❍ Physician ❍ Patient's Home ❍ Other _____

**Please continue to page 2.**

**Patient Name:** _____ **DOB:** _____

13. Does provider attest that alcohol abstinence education has been completed with patient? ☐Yes ☐No
14. Does provider confirm patient will discontinue any use of hemophilia A prophylactic therapy within 4 weeks after administration of Roctavian? ☐Yes ☐No
15. 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
16. 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 <u>other</u> than Congenital hemophilia A:**

17. 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

**Physician's Signature** _____ **Date:** _____ ☐ **DAW**

## INFORMATION BELOW IS TO BE COMPLETED BY THE HEALTH PLAN / CPS PA STAFF

**Authorization Information**

| | |
|---|---|
| ***Authorization number:** | ***Decision Due Date:** |
| ***J-Code:** | **Coverage:**<br>☐State excludes ☐COB (secondary) |
| ***Line of Business:**<br>☐Commercial ☐Health Insurance Marketplace<br>☐Medicaid ☐Medicare | ***Benefit:**<br>☐Medical ☐Pharmacy |

***Choose one criteria option below based online of business:**

**Medicare Criteria Only:**

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

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

**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)


PDAC updated: 07/27/2023
PSHP_082523_0524