AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: 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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Roctavian® (valoctocogene roxaparvovec-rvox) **(J1412) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

❑ **Quantity Limit (max daily dose) [NDC Unit]:**
- Roctavian® 2 x 10^{13} vg/mL single-dose vial: 44 vials one-time only
- 1 treatment = 44 vials
- NDC: 68135-0927-xx

❑ **Max Units (per dose and over time) [HCPCS Unit]:**
- 44 vials one time only
- 1 vial = 8 billable units

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Coverage will be provided for one treatment course and may NOT be renewed.

- ❑ Member is male [**NOTE**: the specified gender is defined as follows: males are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression]
- ❑ Member is 18 years of age or older
- ❑ Medication is prescribed by a hemophilia specialist physician
- ❑ Member has **NOT** received Roctavian® in the past **(verified by medical paid claims)** [**NOTE**: If no claim for Roctavian® is present (or if claims history is not available), the prescribing physician confirms that the member has not previously received Roctavian®]
- ❑ Member has severe hemophilia A as evidence by a baseline (without Factor VIII replacement therapy) Factor VIII level of < 1 IU/dL **(submit documentation)**
- ❑ Member does **NOT** have detectable pre-existing antibodies to adeno-associated virus 5 (AAV5) by an FDA-approved test **(submit documentation)**
- ❑ According to the prescribing physician, member has a history of use of Factor VIII therapy for at least 150 exposure days
- ❑ Member meets **ALL** the following **(submit documentation)**:
  - ❑ Factor VIII inhibitor titer testing has been performed within the past 30 days
  - ❑ Member does **NOT** currently have an inhibitor to Factor VIII
  - ❑ Member does **NOT** have a history of Factor VIII inhibitors
- ❑ Prophylactic therapy with Factor VIII will **NOT** be given after Roctavian® administration once adequate Factor VIII levels have been achieved [**NOTE**: Use of episodic Factor VIII therapy is acceptable for the treatment of bleeds and for surgery/procedures if needed as determined by the hemophilia specialist physician]
- ❑ Member does **NOT** have a known hypersensitivity to mannitol
- ❑ Member does **NOT** have chronic or active hepatitis B **(submit documentation)**
- ❑ Member does **NOT** have active hepatitis C **(submit documentation)**
- ❑ Member is **NOT** human immunodeficiency virus positive **(submit documentation)**
- ❑ Member does **NOT** have evidence of significant hepatic fibrosis or cirrhosis

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- ❑ Member meets **ONE** of the following:
  - ❑ Member has undergone liver function testing within the past 30 days and meets **ALL** the following **(submit documentation)**:
    - ❑ Alanine aminotransferase levels are ≤ 1.25 times the upper limit of normal
    - ❑ Aspartate aminotransferase levels are ≤ 1.25 times the upper limit of normal
    - ❑ Total bilirubin levels are ≤ 1.25 times the upper limit of normal
    - ❑ Alkaline phosphatase levels are ≤ 1.25 times the upper limit of normal
    - ❑ Gamma-glutamyl transferase levels are ≤ 1.25 times the upper limit of normal
    - ❑ International Normalized Ratio is < 1.4
  - ❑ If the member had one or more of the laboratory values listed in criteria in bullets directly above that was **NOT** at the value specified in bullets directly above, then a hepatologist has evaluated the member and has determined that use of Roctavian® is clinically appropriate **(submit documentation)**
- ❑ Within the past 30 days, member's platelet count was ≥ 100 x 10^9/L **(submit documentation)**
- ❑ Within the past 30 days, member's creatinine level was < 1.4 mg/dL **(submit documentation)**
- ❑ Member's current body weight has been obtained within the past 30 days **(submit documentation)**

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.