POLICY Document for ROCTAVIAN (valoctocogene roxaparvovec-rvox)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

Hemophiliaq CAREFIRST: EXCEPTIONS CRITERIA

HEMOPHILIA A

PREFERRED PRODUCTS: ELOCTATE, HEMLIBRA, XYNTHA/SOLOFUSE, NUWIQ

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the Factor VIII products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members who are requesting treatment with the targeted products

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Factor VIII Products

	Product(s)
Preferred*	• **Eloctate** (antihemophilic factor [recombinant]) • **Hemlibra** (emicizumab-kxwh) • **Nuwiq** (antihemophilic factor [recombinant]) • **Xyntha (including Solofuse)** (antihemophilic factor [recombinant])
Targeted	• **Advate** (antihemophilic factor [recombinant]) • **Adynovate** (antihemophilic factor [recombinant]) • **Afstyla** (antihemophilic factor [recombinant]) • **Altuviiio** (antihemophilic factor [recombinant]) • **Esperoct** (antihemophilic [recombinant]) • **Jivi** (antihemophilic factor [recombinant]) • **Kogenate FS** (antihemophilic factor [recombinant]) • **Kovaltry** (antihemophilic factor [recombinant]) • **Novoeight** (antihemophilic factor [recombinant])

	• **Recombinate** (antihemophilic factor [recombinant]) • **Roctavian** (Valoctogene roxaparvovec-rvox)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for the targeted product is provided when the following criteria is met:

A. Member has a documented inadequate response, contraindication, or intolerable adverse event to all preferred products.

Section 2: Clinical Criteria

CAREFIRST: ROCTAVIAN

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

FDA-Approved Indication

Roctavian is indicated for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without antibodies to adeno-associated virus serotype 5 (AAV5) detected by an FDA-approved test.

All other indications are considered experimental/investigational and not medically necessary.

I. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a hematologist.

II. CRITERIA FOR INITIAL APPROVAL

Hemophilia A

Authorization of 3 months for one dose total may be granted for treatment of severe hemophilia A when all of the following criteria are met:

1. Member must be 18 years of age or older.
2. Member has severe disease with factor VIII activity levels less than or equal to 1 IU/dL.
3. Absence of pre-existing antibodies to AAV5 was confirmed by an FDA-approved test (e.g., AAV5 DetectCDx™).
4. Member does not have prior or active factor VIII inhibitors (inhibitor titer must be less than 0.6 Bethesda Units [BU]).
5. Member has not received treatment with the requested medication previously.
6. Dosing is in accordance with product prescribing label
7. Patient received education regarding alcohol abstinence and the use of concomitant medications
8. Any prophylaxis trial will be discontinued following administration of Roctavian

REFERENCES:

SECTION 1

1. Advate [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
2. Adynovate [package insert].Takeda Pharmaceuticals U.S.A., Inc.; August 2023.
3. Afstyla [package insert]. Kankakee, IL: CSL Behring LLC; June 2023.
4. Altuviio [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; May 2024.
5. Eloctate [package insert]. Waltham, MA: Sanofi Company; May 2023.
6. Esperoct [package insert]. Plainsboro, NJ; Novo Nordisk; February 2024.
7. Jivi [package insert]. Whippany, NJ: Bayer HealthCare LLC; August 2018.
8. Hemlibra [package insert]. South San Francisco, CA: Genentech, Inc; January 2024.
9. Kogenate FS [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
10. Kogenate FS with BIO-SET [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
11. Kogenate FS with Vial Adapter [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
12. Kovaltry [package insert]. Whippany, NJ: Bayer Healthcare LLC; December 2022.
13. Novoeight [package insert]. Plainsboro, NJ: Novo Nordisk Inc; July 2020.
14. Nuwiq [package insert]. Paramus, NJ: Octapharma USA, Inc., June 2021.
15. Recombinate [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
16. Roctavian [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; June 2023
17. Xyntha [package insert]. Philadelphia, PA; Wyeth Pharmaceuticals LLC; July 2022.

SECTION 2

1. Roctavian [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; June 2023.