POLICY Document for ESPEROCT (antihemophilic [recombinant])

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

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

Specialty Guideline Management
Factor VIII Concentrates

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Advate	antihemophilic factor [recombinant]
Adynovate	antihemophilic factor [recombinant], PEGylated
Alphanate	antihemophilic factor/von Willebrand factor complex [human]
Altuviiio	antihemophilic factor [recombinant], Fc-VWF-XTEN fusion protein-ehtl
Afstyla	antihemophilic factor [recombinant], single chain

Brand Name	Generic Name
Eloctate	antihemophilic factor [recombinant], Fc fusion protein
Esperoct	antihemophilic factor [recombinant], Glycopegylated-exei
Hemofil M	antihemophilic factor [human] monoclonal antibody purified
Humate-P	antihemophilic factor/von Willebrand factor complex [human]
Jivi	antihemophilic factor [recombinant], PEGylated-aucl
Koate	antihemophilic factor [human]
Kogenate FS	antihemophilic factor [recombinant]
Kovaltry	antihemophilic factor [recombinant]
Novoeight	antihemophilic factor [recombinant]
Nuwiq	antihemophilic factor [recombinant]
Recombinate	antihemophilic factor [recombinant]
Xyntha	antihemophilic factor [recombinant]

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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

Table: Factor VIII Concentrates and Covered Uses[1-19,20-24,34,35]

Recombinant Factor VIII Concentrates

Brand	Generic	FDA-Approved Indication(s)	Compendial Indication(s)
Advate	antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A
Afstyla	antihemophilic factor [recombinant], single chain	Hemophilia A	-
Kogenate FS	antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A
Kovaltry	antihemophilic factor [recombinant]	Hemophilia A	-
Novoeight	antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A
Nuwiq	antihemophilic factor [recombinant]	Hemophilia A	-

Brand	Generic	FDA-Approved Indication(s)	Compendial Indication(s)
Recombinate	antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A
Xyntha	antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A

Extended Half-life Recombinant Factor VIII Concentrates

Brand	Generic	FDA-Approved Indication(s)	Compendial Indication(s)
Adynovate	antihemophilic factor [recombinant], PEGylated	Hemophilia A	-
Altuviiio	antihemophilic factor [recombinant], Fc-VWF-XTEN fusion protein-ehtl	Hemophilia A	-
Eloctate	antihemophilic factor [recombinant], Fc fusion protein	Hemophilia A	-
Jivi	antihemophilic factor [recombinant], PEGylated-aucl	Hemophilia A	-
Esperoct	antihemophilic factor [recombinant], Glycopegylated-exei	Hemophilia A	-

Human Plasma-Derived Factor VIII Concentrate

Brand	Generic	FDA-Approved Indication(s)	Compendial Indication(s)
Hemofil M	antihemophilic factor [human] monoclonal antibody purified	Hemophilia A	Acquired Hemophilia A

Human Plasma-Derived Factor VIII Concentrates That Contain Von Willebrand Factor

Brand	Generic	FDA-Approved Indication(s)	Compendial Indication(s)
Alphanate	antihemophilic factor/von Willebrand factor complex [human]	Hemophilia A, von Willebrand Disease	Acquired Hemophilia A, Acquired von Willebrand Syndrome
Humate-P	antihemophilic factor/von Willebrand factor complex [human]	Hemophilia A, von Willebrand Disease	Acquired Hemophilia A, Acquired von Willebrand Syndrome
Koate	antihemophilic factor [human]	Hemophilia A	Acquired Hemophilia A, von Willebrand Disease

CVS/caremark

Prescriber Specialties

Must be prescribed by or in consultation with a hematologist.

Coverage Criteria

Hemophilia A[1,19,24,25,32,34,35]

Authorization of 12 months of Advate, Adynovate, Afstyla, Alphanate, Altuviiio, Eloctate, Esperoct, Hemofil M, Humate-P, Koate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Recombinate, or Xyntha may be granted for treatment of hemophilia A when either of the following criteria is met:

- Member has mild disease (see Appendix A) and has had an insufficient response to desmopressin or a documented clinical reason for not using desmopressin (see Appendix B).
- Member has moderate or severe disease (see Appendix A).

Authorization of 12 months of Jivi may be granted for treatment of hemophilia A when BOTH of the following criteria are met:

- Member has previously received treatment for hemophilia A with a factor VIII product.
- Member is ≥ 7 years of age.

Von Willebrand Disease (VWD)[20,21,23,24]

Authorization of 12 months of Alphanate, Humate-P, or Koate may be granted for treatment of VWD when any of the following criteria is met:

- Member has type 1, 2A, 2M, or 2N VWD and has had an insufficient response to desmopressin or a documented clinical reason for not using desmopressin (see Appendix B).
- Member has type 2B or type 3 VWD.

Acquired Hemophilia A[20,27,29]

Authorization of 12 months of Advate, Alphanate, Hemofil M, Humate-P, Koate, Kogenate FS, Novoeight, Recombinate, or Xyntha may be granted for treatment of acquired hemophilia A.

Acquired von Willebrand Syndrome[21,23]

Authorization of 12 months of Alphanate or Humate-P may be granted for treatment of acquired von Willebrand syndrome.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

CVS/caremark

Appendix

Appendix A: Classification of Hemophilia by Clotting Factor Level (% Activity) and Bleeding Episodes[24,30]

Factor assay levels are required to determine the diagnosis and are of value in monitoring treatment response.[23]

Severity	Clotting Factor Level % activity	Bleeding Episodes
Severe	<1%	Spontaneous bleeding episodes, predominantly into joints and muscles Severe bleeding with trauma, injury or surgery
Moderate	1% to 5%	Occasional spontaneous bleeding episodes Severe bleeding with trauma, injury or surgery
Mild	6% to 40%	Severe bleeding with serious injury, trauma or surgery

Appendix B: Clinical Reasons For Not Utilizing Desmopressin in Patients with Hemophilia A and Type 1, 2A, 2M and 2N VWD[20,25,31,32]

- Age < 2 years
- Pregnancy
- Fluid/electrolyte imbalance
- High risk for cardiovascular or cerebrovascular disease (especially the elderly)
- Predisposition to thrombus formation
- Trauma requiring surgery
- Life-threatening bleed
- Contraindication or intolerance to desmopressin
- Severe type 1 von Willebrand disease
- Stimate Nasal Spray is unavailable due to backorder/shortage issues (where applicable)

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