Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Antihemophilic Factor VIII Products***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***February 2018***

Last P & T Committee Approval Date: December 2018

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for antihemophilic factor products.

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.

Brand	Generic	FDA-Approved Indication(s)	Compendial Indication(s)
Recombinant Factor VIII Concentrates			
Advate	Antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A
Helixate FS	Antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A

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Kogenate FS	Antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A
Kovaltry	Antihemophilic factor [recombinant]	Hemophilia A	
Novoeight	Antihemophilic factor [recombinant]	Hemophilia A	
Nuwiq	Antihemophilic factor [recombinant]	Hemophilia A	
Recombinate	Antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A
Xyntha	Antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A
Prolonged Half-Life Recombinant Factor VIII Concentrate			
Adynovate	Antihemophilic factor [recombinant], PEGylated	Hemophilia A	
Afstyla	Antihemophilic factor [recombinant], single chain	Hemophilia A	
Eloctate	Antihemophilic factor [recombinant], Fc fusion protein	Hemophilia A	
Human Plasma-Derived Factor VIII Concentrates			
Hemofil M	Antihemophilic factor [human] monoclonal antibody purified	Hemophilia A	Acquired Hemophilia A
Monoclate-P	Antihemophilic factor [human] monoclonal antibody purified	Hemophilia A	Acquired Hemophilia A
Human Plasma-Derived Factor VIII Concentrates that Contain Von Willebrand Factor			
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

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drugs below, listed under antihemophilic factor products are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for non-preferred antihemophilic factor products are subject to the preferred medical drug list program. This program applies to the antihemophilic factor products specified in this policy. Coverage for non-preferred 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 requesting treatment with a targeted product. Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

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Table. Antihemophilic Factor Products

	Product(s)
Preferred	• Adynovate® (antihemophilic factor [recombinant], PEGylated) • Jivi® (antihemophilic factor [recombinant], PEGylated-aucl) • Kogenate® FS (antihemophilic factor [recombinant]) • Kovaltry® (antihemophilic factor [recombinant])

	• Novoeight® (antihemophilic factor [recombinant])
Non-Preferred	• Eloctate® (antihemophilic factor [recombinant], Fc fusion protein) • Helixate® FS (antihemophilic factor [recombinant]) • Nuwiq® (antihemophilic factor [recombinant])

II. EXCEPTION CRITERIA *(Use for Non-Preferred Drug Requests Only)*

A. Eloctate and Nuwiq

Coverage for the non-preferred products, Eloctate, Helixate FS, and Nuwiq, is provided when either of the following criteria is met:

1. Member is currently receiving treatment with the non-preferred product, excluding when the non-preferred product is obtained as samples or via manufacturer's patient assistance programs.
2. Member has had a documented inadequate response or intolerable adverse event with at least three of the preferred products.

B. Helixate FS

Coverage for the non-preferred product, Helixate FS, is provided when the member has failed treatment with the preferred product, Kogenate FS, due to a documented intolerable adverse event and the prescriber has a compelling medical rationale for not expecting the same event to occur with the non-preferred product.

III. CLINICAL CRITERIA (*Use for ALL Drug Requests*)

Must meet all of the clinical criteria listed under the respective diagnosis:

1. Hemophilia A

- Indefinite authorization of Advate, Adynovate, Afstyla, Alphanate, Eloctate, Helixate FS, Hemofil M, Humate-P, Koate, Kogenate FS, Kovaltry, Monoclate-P, 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 to severe disease (see Appendix A)

2. Von Willebrand Disease (vWD)

- Indefinite authorization 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.

3. Acquired Hemophilia A

- Indefinite authorization of Advate, Alphanate, Helixate FS, Hemofil M, Humate P, Koate, Kogenate FS, Monoclate-P, Recombinate or Xyntha may be granted for treatment of acquired hemophilia A.

4. Acquired von Willebrand Syndrome

- Indefinite authorization of Alphanate or Humate-P may be granted for treatment of acquired vWD syndrome.

Reauthorization Criteria:

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria

Appendices

Appendix A: Classification of Hemophilia by Clotting Factor Level (% Activity) and Bleeding Episodes

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, 2N, and 2M vWD

A. Age <2 years
B. Pregnancy
C. Fluid/electrolyte imbalance
D. High risk for cardiovascular or cerebrovascular disease (especially the elderly)
E. Predisposition to thrombus formation

F. Trauma requiring surgery
G. Life-threatening bleed
H. Contraindication or intolerance to desmopressin
I. Severe type 1 vWD

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Indefinite
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Adynovate [package insert]. Westlake Village, CA: Baxalta US Inc.; December 2016.
2. Eloctate [package insert]. Cambridge, MA: Biogen Idec Inc.; January 2017.
3. Helixate FS [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
4. Kogenate FS [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
5. Kogenate FS with BIO-SET [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
6. Kogenate FS with Vial Adapter [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
7. Kovaltry [package insert]. Whippany, NJ: Bayer Healthcare LLC; March 2016.
8. Novoeight [package insert]. Plainsboro, NJ: Novo Nordisk Inc., November 2016.
9. Nuwiq [package insert]. Hoboken, NJ: Octapharma USA, Inc., September 2015.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy- Preferred Product Update (effective 4/1/18)	02/18
Preferred Product Update	12/18