RX.PA.049.CCH ANTIHEMOPHILIC FACTORS

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

Brand	Generic	FDA-Approved Indication(s)	Compendial Indication(s)
Recombinant Factor VIII Concentrates			
Advate	Antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A
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	
Esperoct	Antihemophilic factor [recombinant], glycoPEGylated	Hemophilia A	
Jivi	Antihemophilic factor [recombinant], PEGylated	Hemophilia A	

Human Plasma-Derived Factor VIII Concentrates			
Hemofil M	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

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, and approval by the Medical Policy Committee.

The drugs, listed in the above table, are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:
Must meet all the criteria listed below the respective diagnosis:

1. **Hemophilia A – (Advate, Adynovate, Afstyla, Alphanate, Eloctate, Esperoct, Hemofil M, Humate-P, Jivi, Koate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Recombinate or Xyntha ONLY)**
    - Must have ONE of the following:
        - Mild disease (see Appendix A) AND has had an insufficient response to desmopressin or a documented clinical reason not to use desmopressin (see Appendix B)
        - Moderate-to-severe disease (see Appendix A)

2. **Von Willebrand Disease (vWD) – (Alphanate, Humate-P, or Koate ONLY)**
    - Must have ONE of the following:
        - Type 1, 2A, 2M, or 2N vWD AND the member has had an insufficient response to desmopressin or a documented clinical reason for not using desmopressin (see Appendix B)
        - Type 2B or type 3 vWD

3. Acquired Hemophilia A – (Advate, Alphanate, Hemofil M, Humate P, Koate, Kogenate FS, Recombinate or Xyntha ONLY)

- Must have a diagnosis of acquired hemophilia

4. Acquired von Willebrand Syndrome – (Alphanate or Humate-P ONLY)

- Must have a diagnosis of acquired vWD syndrome

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	N/A

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

HCPCS CODE(S)

HCPCS Code	Brand	Description
J7182	NOVOEIGHT	INJECTION, FACTOR VIII, (ANTIHEMOPHILIC FACTOR, RECOMBINANT), PER IU
J7185	XYNTHA	INJECTION, FACTOR VIII, (ANTIHEMOPHILIC FACTOR, RECOMBINANT), PER IU
J7186	ALPHANATE	INJECTION, ANTIHEMOPHILIC FACTOR VIII/VON WILLEBRAND FACTOR COMPLEX (HUMAN), PER FACTOR VIII IU
J7187	HUMATE-P	INJECTION, VON WILLEBRAND FACTOR COMPLEX, PER IU VWF:RCO
J7190	KOATE	FACTOR VIII (ANTIHEMOPHILIC FACTOR, HUMAN) PER IU
J7192	RECOMBINATE, KOGENATE, ADVATE, HELIXATE FS	FACTOR VIII (ANTIHEMOPHILIC FACTOR, RECOMBINANT), PER IU, NOT OTHERWISE SPECIFIED
J7204	ESPEROCT	INJECTION, FACTOR VIII, ANTIHEMOFILIC FACTOR (RECOMBINANT), GLYCOPEGYLATED-EXEI, PER IU
J7205	ELOCTATE	INJECTION, FACTOR VIII FC FUSION PROTEIN (RECOMBINANT), PER IU
J7207	ADYNOVATE	INJECTION, FACTOR VIII (ANTIHEMOPHILIC FACTOR, RECOMBINANT), PEGYLATED, 1 IU
J7208	JIVI	INJECTION, FACTOR VIII, (ANTIHEMOPHILIC FACTOR, RECOMBINANT), PEGYLATED-AUCL, 1 IU
J7209	NUWIQ	INJECTION, FACTOR VIII, (ANTIHEMOPHILIC FACTOR, RECOMBINANT), 1 IU
J7210	AFSTYLA	INJECTION, FACTOR VIII, (ANTIHEMOPHILIC FACTOR, RECOMBINANT), 1 IU
J7211	KOVALTRY	INJECTION, FACTOR VIII, (ANTIHEMOPHILIC FACTOR, RECOMBINANT), 1 IU

REFERENCES

1. Adynovate [package insert]. Westlake Village, CA: Baxalta US Inc.; December 2016.
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3. Kogenate FS [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
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6. Kovaltry [package insert]. Whippany, NJ: Bayer Healthcare LLC; March 2016.
7. Novoeight [package insert]. Plainsboro, NJ: Novo Nordisk Inc., November 2016.
8. Nuwiq [package insert]. Hoboken, NJ: Octapharma USA, Inc., September 2015.
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10. Recombinate [package insert]. Lexington, MA: Baxalta US Inc; June 2018.
11. Xyntha [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC. December 2020.
12. Afstyla [package insert]. Kankakee, IL: CSL Behring LLC April 2021.
13. Esperoct [package insert]. Plainsboro, NJ: Novo Nordisk Inc. October 2019.
14. Jivi [package insert]. Whippany, NJ. Bayer HealthCare LLC August 2018.
15. Alphanate [package insert]. Los Angeles, CA: Grifols Biologics LLC; March 2021.
16. Humate-P [package insert]. Kankakee, IL: CSL Behring LLC.; June 2020.
17. Koate [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC June 2018.

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
Initial review	3/22