EVH Clinical Guideline 5048.CC for Antihemophilic Factor Products

Guideline Number: EVH_CG_5048.CC	Applicable Codes	
"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc. 		
Original Date: March 2022	**Last Revised Date:** June 2025	**Implementation Date:** October 2025

TABLE OF CONTENTS

STATEMENT **3**
- General Information 3
- Purpose 3
- Scope 5
- Special Note 5

INITIAL REVIEW CRITERIA **6**
- Acquired Hemophilia A *(Advate, Alphanate, Hemofil M, Humate P, Koate, Kogenate FS, Recombinate or Xyntha)* 6
- Hemophilia A *(Advate, Adynovate, Afstyla, Alphanate, Altuviiio, Eloctate, Esperoct, Hemofil M, Humate-P, Jivi, Koate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Recombinate, Wilate or Xyntha)* 6
- Von Willebrand Disease (vWD) *(Alphanate, Humate-P, Koate, or Wilate ONLY)* 6
- Acquired von Willebrand Syndrome *(Alphanate or Humate-P)* 6

REAUTHORIZATION CRITERIA **6**

APPROVAL DURATIONS **7**

APPENDICES **7**
- Appendix 1 - Classification of Hemophilia by Clotting Factor Level (% Activity) and Bleeding Episodes 7
- Appendix 2 - Clinical Reasons for Not Utilizing Desmopressin in Patients with Hemophilia A and Type 1, 2A, 2N, and 2M vWD 7

CODING AND STANDARDS **8**
- Codes 8
- Applicable Lines of Business 9

POLICY HISTORY **9**

LEGAL AND COMPLIANCE **9**
- Guideline Approval 9
  - *Committee* *9*
- Disclaimer 10

REFERENCES **11**

STATEMENT

General Information

- *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.*

- *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.*

Purpose

The purpose of this guideline to define the prior authorization process for the following 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	
Altuviiio	Antihemophilic factor [recombinant], Fc-VWF-XTEN fusion	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
Koate	Antihemophilic factor [human]	Hemophilia A	Acquired Hemophilia A, von Willebrand Disease
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
Wilate	Antihemophilic factor/von Willebrand factor complex [human]	Hemophilia A, von Willebrand Disease	

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

Special Note

Additional uses are included in this policy based on being supported by one or more compendia (e.g., Merative Micromedex®, UpToDate® Lexidrug™, Elsevier Clinical Pharmacology).

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed under the diagnosis-specific sections below.

Acquired Hemophilia A *(Advate, Alphanate, Hemofil M, Humate P, Koate, Kogenate FS, Recombinate or Xyntha)*

- Must have a diagnosis of acquired hemophilia

Hemophilia A *(Advate, Adynovate, Afstyla, Alphanate, Altuviiio, Eloctate, Esperoct, Hemofil M, Humate-P, Jivi, Koate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Recombinate, Wilate or Xyntha)*

- Must have ONE of the following:
  - Mild disease (see **Appendix 1**) AND has had an insufficient response to desmopressin or a documented clinical reason not to use desmopressin (see **Appendix 2**)
  - Moderate-to-severe disease (see **Appendix 1**)

Von Willebrand Disease (vWD) *(Alphanate, Humate-P, Koate, or Wilate 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 2)**
  - Type 2B or type 3 vWD

Acquired von Willebrand Syndrome *(Alphanate or Humate-P)*

- Must have a diagnosis of acquired vWD syndrome

REAUTHORIZATION CRITERIA

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. The request must include updated chart documentation from the prescriber that the member's condition has improved or stabilized based upon the prescriber's assessment while on therapy.

APPROVAL DURATIONS

Initial Authorization	1 year
Reauthorization	1 year

APPENDICES

Appendix 1 - 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
Moderate	1% to 5%	Occasional spontaneous bleeding episodes
Mild	6% to 40%	Severe bleeding with serious injury, trauma, or surgery

Appendix 2 - Clinical Reasons for Not Utilizing Desmopressin in Patients with Hemophilia A and Type 1, 2A, 2N, and 2M vWD

- 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 vWD
- History of seizures

CODING AND STANDARDS

Codes

Code	Brand	Description
J7182	NOVOEIGHT	INJECTION, FACTOR VIII, (ANTIHEMOPHILIC FACTOR, RECOMBINANT), PER IU
J7183	WILATE	INJECTION, VON WILLEBRAND FACTOR COMPLEX (HUMAN), WILATE, 1 I.U. VWF:RCO
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

Code	Brand	Description
J7211	KOVALTRY	INJECTION, FACTOR VIII, (ANTIHEMOPHILIC FACTOR, RECOMBINANT), 1 IU
J7214	ALTUVIIIO	INJECTION, FACTOR VIII,VON WILLEBRAND FACTOR COMPLEX, RECOMBINANT (ALTUVIIIO), PER FACTOR, VIII IU

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
June 2025	• Added Wilate and an exception for desmopressin use to Appendix 2 • Approval duration changed to 1 year from indefinite; reauthorization criteria added
January 2024	• Added Altuviiio
March 2022	• New Guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the *corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.*

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. Kogenate FS [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
4. Kogenate FS with BIO-SET [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
5. Kogenate FS with Vial Adapter [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
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.
9. Advate [package insert]. Lexington, MA: Baxalta US Inc; December 2018.
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.
18. Altuviiio [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; March 2023.
19. Wilate [package insert]. Paramus, NJ: Octapharma USA, Inc; March 2024.