

⊠Kentucky PRMD

Intent:

Name:

Effective Date:

Applies to:

AETNA BETTER HEALTH®
Coverage Policy/Guideline

Recombinate, Xyntha

⊠Illinois

⊠Maryland

8/5/2025

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Advate, Hemofil M, Kogenate FS, Novoeight, Recombinate, and Xyntha under the patient's prescription drug benefit.

⊠ Florida Kids

Advate, Hemofil M, Kogenate FS, Novoeight,

Description:

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.

Table: Factor VIII Concentrates and Covered Uses

| 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 | | | |
| Novoeight | antihemophilic factor [recombinant] | Hemophilia A | Acquired Hemophilia A | | | |
| Recombinate | antihemophilic factor [recombinant] | Hemophilia A | Acquired Hemophilia A | | | |
| Xyntha | antihemophilic factor [recombinant] | Hemophilia A | Acquired Hemophilia A | | | |
| Human Plasma-Derived Factor VIII Concentrate | | | | | | |
| Hemofil M | antihemophilic factor [human] monoclonal antibody purified | Hemophilia A | Acquired Hemophilia A | | | |

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

Applicable Drug List:

Advate Hemofil M Kogenate FS Novoeight Recombinate Xyntha

| | TER HEALTH® olicy/Guideline | * ae | etna | |
|--|--------------------------------|--------------------|-------------------|-----------|
| Name: Advate, Hemofil M, Kogenate FS, Novoeight, Recombinate, Xyntha | | | Page: | 2 of 4 |
| Effective Date: 8/5/2025 | | | Last Review Date: | 6/23/2025 |
| Applies to: | ⊠Illinois | ⊠Florida Kids | ⊠New Jersey | |
| | ⊠Maryland | ⊠Pennsylvania Kids | ⊠Kentucky PRMD | |

Policy/Guideline:

Prescriber Specialty:

Must be prescribed by or in consultation with a hematologist.

Criteria for Initial Approval:

Hemophilia A

Authorization of 12 months of Advate, Hemofil-M, Kogenate FS, Novoeight, Recombinate, or Xyntha may be granted for treatment of hemophilia A when EITHER of the following criteria is met:

- 1. 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).
- 2. Member has moderate or severe disease (see Appendix A).

Acquired Hemophilia A

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

Continuation of Therapy:

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

Appendix A:

Classification of hemophilia by clotting factor level (% activity) & bleeding episodes

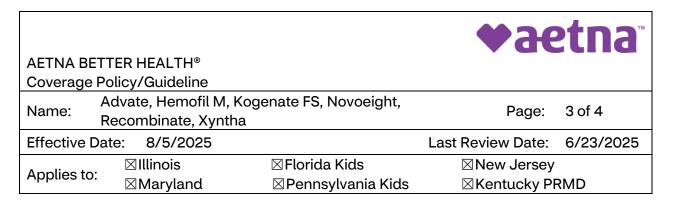
| Severity | Clotting Factor Level % activity* | Bleeding Episodes | |
|----------|--|--|--|
| Severe | Spontaneous bleeding episodes, predominantly muscles Severe bleeding with trauma, injury or surgery | | |
| Moderate | 1% to 5% Occasional spontaneous bleeding episodes Severe bleeding with trauma,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

^{*}Factor assay levels are required to determine the diagnosis and are of value in monitoring treatment response.

Appendix B:

Clinical Reasons For Not Utilizing Desmopressin in Patients with Hemophilia A

- A. Age < 2 years
- B. Pregnancy
- C. Fluid/electrolyte imbalance



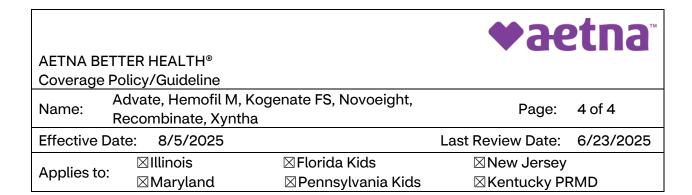
- D. High risk for cardiovascular or cerebrovascular disease (especially the elderly)
- E. Predisposition to thrombus formation
- F. Trauma requiring surgery
- G. Life-threatening bleed
- H. Contraindication or intolerance to desmopressin
- I. Severe type 1 von Willebrand disease
- J. Stimate Nasal Spray is unavailable due to backorder/shortage issues (where applicable)

Approval Duration and Quantity Restrictions:

Approval: 12 months

References:

- Advate [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.
- 2. Jivi [package insert]. Whippany, NJ: Bayer HealthCare LLC; August 2018.
- 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; December 2019.
- 6. Kovaltry [package insert]. Whippany, NJ: Bayer Healthcare LLC; December 2022.
- 7. Novoeight [package insert]. Plainsboro, NJ: Novo Nordisk Inc., July 2020.
- 8. Nuwiq [package insert]. Paramus, NJ: Octapharma USA, Inc., June 2021.
- 9. Recombinate with 5 mL Sterile Water for Injection using BAXAJECT II [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.
- 10. Xyntha [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; July 2022.
- 11. Xyntha Solufuse [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; July 2022.
- 12. Adynovate [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; August 2023.
- 13. Afstyla [package insert]. Kankakee, IL: CSL Behring LLC.; June 2023.
- 14. Eloctate [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; May 2023.
- 15. Hemofil M [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.
- 16. Alphanate [package insert]. Los Angeles, CA: Grifols Biologicals LLC; November 2022.
- 17. Humate-P [package insert]. Kankakee, IL: CSL Behring LLC; June 2020.
- 18. Koate [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; June 2018.
- 19. Koate-DVI [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; August 2012.
- AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed December 9, 2024.
- National Institutes of Health. The diagnosis, evaluation, and management of von Willebrand disease.
 Bethesda, MD: US Dept of Health and Human Services, National Institutes of Health; 2007. NIH publication No. 08-5832.
- 22. Tiede A, Rand J, Budde U, et al. How I treat the acquired von Willebrand syndrome. Blood. 2011;117(25):6777-85.
- 23. Federici A, Budde U, Castaman G, Rand J, Tiede A. Current diagnostic and therapeutic approaches to patients with acquired von Willebrand syndrome: a 2013 update. Semin Thromb Hemost. 2013;39(2):191-201.
- 24. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020;26 Suppl 6:1-158. doi:10.1111/hae.14046.
- 25. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised August 2023. MASAC



Document #290. https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed December 9, 2024.

- 26. National Hemophilia Foundation. MASAC recommendations regarding the treatment of von Willebrand disease. Revised February 2021. MASAC Document #266. https://www.hemophilia.org/sites/default/files/document/files/266.pdf. Accessed December 9, 2024.
- 27. Acquired hemophilia. World Federation of Hemophilia. http://www1.wfh.org/publications/files/pdf-1186.pdf. Accessed December 9, 2024.
- 28. Tiede A, Collins P, Knoebl P, et al. International recommendations on the diagnosis and treatment of acquired hemophilia A. Haematologica. 2020;105(7):1791-1801. doi:10.3324/haematol.2019.230771.
- 29. Franchini M, Mannucci PM. Acquired haemophilia A: a 2013 update. Thromb Haemost. 2013;110(6):1114-20.
- 30. National Hemophilia Foundation. Hemophilia A (Factor VIII Deficiency). Available at: http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=180&contentid=45&rptname=blee ding. Accessed December 9, 2024.
- 31. Stimate [package insert]. King of Prussia, PA: CSL Behring LLC; June 2021.
- 32. Leissinger C, Carcao M, Gill JC, et al. Desmopressin (DDAVP) in the management of patients with congenital bleeding disorders. Haemophilia. 2014;20:158-167.
- 33. Reding MT, NG HJ, Poulsen LH, et al. Safety and efficacy of BAY 94-9027, a prolonged-half-life factor VIII. Journal of thrombosis and Haemostasis. 2017; 15: 411-9.
- 34. Esperoct [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; July 2024.
- 35. Altuviiio [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; September 2024.