



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Advate, Hemofil M, Kogenate FS, Novoeight,
Recombinate, Xyntha

Page: 1 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

Intent:

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.

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

| | | |
|--|--|--|
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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 | <1% | Spontaneous bleeding episodes, predominantly into joints & 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



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- 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

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