



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Koate

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 Koate 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)                      |
|-----------------------------------------------------------------------------------------|-------------------------------|----------------------------|-----------------------------------------------|
| <b>Human Plasma-Derived Factor VIII Concentrates That Contain Von Willebrand Factor</b> |                               |                            |                                               |
| <b>Koate</b>                                                                            | antihemophilic factor [human] | Hemophilia A               | Acquired Hemophilia A, von Willebrand Disease |

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

### Applicable Drug List:

Koate

### 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 Koate 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).

##### Von Willebrand Disease (VWD)

Authorization of 12 months of Koate may be granted for treatment of VWD when ANY of the following criteria is met:



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Page: 2 of 4

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1. 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).
2. Member has type 2B or type 3 VWD.

### Acquired Hemophilia A

Authorization of 12 months of Koate 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) and Bleeding Episodes

| Severity | Clotting Factor Level<br>% activity* | Bleeding Episodes                                                                                                      |
|----------|--------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| Severe   | <1%                                  | Spontaneous bleeding episodes, predominantly into joints and muscles<br>Severe bleeding with trauma, injury or surgery |
| Moderate | 1% to 5%                             | Occasional spontaneous bleeding episodes<br>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 and Type 1, 2A, 2M and 2N 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 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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|                 |                                                                                              |                                                                                                           |                                                                                                     |
|-----------------|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Name:           | Koate                                                                                        | Page:                                                                                                     | 3 of 4                                                                                              |
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AETNA BETTER HEALTH®  
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Name: Koate Page: 4 of 4

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