

Advate[®], Adynovate[®], Afstyl[®], Altuviiio[™], Eloctate[®], Esperoct, Jivi[®], Kogenate FS[®], Kovaltry[®], Obizur[®], Novoeight[®], Nuwiq[®], Recombinate[®], Xyntha[®] (antihemophilic factor [recombinant])

Hemofil M[®], Koate-DVI[®] (antihemophilic factor [plasma-derived])

Alphanate[®], Humate-P[®] (antihemophilic factor/von Willebrand factor complex [Human])

When requesting antihemophilic factor agent, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or an approved compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

Approved Indications

Advate, Adynovate, Afstyl, Altuviiio, Eloctate, Esperoct, Jivi, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha, and Hemofil M are antihemophilic factor agents indicated in patients with hemophilia A (congenital factor VIII deficiency) for:

- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes

Alphanate, Humate-P, and Koate-DVI are antihemophilic factor/von Willebrand factor complex indicated for:

- Control and prevention of bleeding in patients with hemophilia A and von Willebrand Disease.
- Perioperative management in patients with hemophilia A.
- Surgical and/or invasive procedures in patients with von Willebrand Disease in whom desmopressin is either ineffective or contraindicated.

Obizur is an antihemophilic factor (porcine sequence) indicated for the on-demand treatment and control of bleeding episodes in adults with acquired hemophilia A.

Coverage Guidelines

Congenital Hemophilia A (excludes Obizur)

Initial authorization request:

- The request is for treatment or prevention of bleeding episodes or perioperative management of bleeding in individuals with congenital hemophilia A.

- An individual has been screened for antibody inhibitor and has one of the following:
 - o Has no inhibitor to factor VIII; OR
 - o Has low responding inhibitor (less than 5 BU/mL); OR
 - o Has high responding inhibitor (greater than or equal to 5BU/mL) and the requested agent will be used as part of an Immune Tolerance Induction (ITI) regimen.
- *Applies to routine prophylaxis only* - For long-acting product request (Adynovate, Afstylia, Altuviiio, Eloctate, Esperoct, and Jivi), the individual has failed (with at least 3 month-trial), is contraindicated, or is intolerant to TWO recombinant factor VIII products with standard half-life (i.e. Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Recombinate, and Xyntha).
- For Jivi, the individual is 12 years of age or older and has previously been treated for Hemophilia A.

Reauthorization request:

- The request is for treatment or prevention of bleeding episodes or perioperative management of bleeding in individuals with hemophilia A.
- An individual has been screened for antibody inhibitor and has one of the following:
 - o Has no inhibitor to factor VIII; OR
 - o Has low responding inhibitor (less than 5 BU/mL); OR
 - o Has high responding inhibitor (greater than or equal to 5BU/mL) and the requested agent will be used as part of an Immune Tolerance Induction (ITI) regimen.

Acquired Hemophilia A (Obizur only)

- The request is for treatment or prevention of bleeding episodes in individuals with acquired hemophilia A.
- The individual is 18 years of age or older.

Von Willebrand disease (Alphanate, Humate-P, Koate-DVI only)

- The request is for treatment or prevention of bleeding episodes or perioperative management in individuals with von Willebrand disease.

Approval duration (initial and renewal): 12 months

Dosing Recommendations

For intravenous use only

Congenital Hemophilia A

For treatment of bleeding episodes and perioperative management

The recommended dose is:

Required dose (IU) = body weight (kg) x desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)

OR

Estimated increment of factor VIII (IU/dL or % of normal) = [Total Dose (IU)/body weight (kg)] x 2 (IU/dL per IU/kg)

For routine prophylaxis

Advate

The recommended dose is 20 to 40 IU/kg every other day (3 to 4 times weekly) OR Use every third day dosing regimen targeted to maintain FVIII trough levels greater than or equal to 1%.

Adynovate

The recommended dose is 40-50 IU per kg body weight 2 times a week. Start dose of 55 IU/kg 2 times a week patients less than 12 years of age with a maximum of 70 IU/kg.

Afstyla

For adults and adolescents (12 years of age and up): the recommended starting regimen is 20 to 50 IU/kg administered 2 to 3 times weekly.

For children (less than 12 years of age) the recommended starting regimen is 30 to 50 IU/kg administered 2 to 3 times weekly.

Eloctate

The recommended dose is 50 IU/kg every 4 days.

For children less than 6 years of age: the recommended dose is 50 IU/kg twice weekly.

Adjust dose based on patient response with dosing in the range of 25-65 IU/kg at 3-5 day intervals.

Jivi

The recommended initial regimen is 30-40 IU/kg twice weekly. The regimen may be adjusted to 45-60 IU/kg every 5 days based on the bleeding episodes.

Kogenate FS

For adults: the recommended dose is 25 units/kg 3 times per week.

For children: the recommended dose is 25 units/kg every other day.

Kovaltry

For adults and adolescents: the recommended dose is 20-40 IU/kg 2 or 3 times per week.

For children (12 years of age and under): the recommended dose is 25-50 IU/kg 2 times per week, 3 times per week, or every other day.

Obizur

The recommended initial dose is 200 units/kg. Titrate dose and frequency of administration based on factor VIII recovery levels and individual clinical response.

Novoeight

For adults and adolescents (12 years of age and up): the recommended dose is 20-50 IU/kg 3 times per week OR 20-40 IU/kg every other day

For children less than 12 years of age: the recommended dose is 25-60 IU/kg 3 times per week OR 25-50 IU/kg every other day

Nuwiq

For adults and adolescents (12 years of age and up): the recommended dose is 30-40 IU/kg every other day

For children less than 12 years of age: the recommended dose is 30-50 IU/kg 3 times per week or every other day

Xyntha

For adults and adolescents (12 years of age and up): the recommended dose is 30 IU/kg administered 3 times weekly.

For children less than 12 years of age: the recommended dose is 25 IU/kg administered every other day.

Esperoct*On-demand treatment:*

For adults and adolescents (12 years of age and up): the recommended dose is 40 IU/kg for minor/moderate bleeds and 50 IU/kg for major bleeds.

For children less than 12 years of age: the recommended dose is 65 IU/kg for minor, moderate and major bleeds.

Perioperative management:

For adults and adolescents (12 years of age and up): the recommended pre-operative dose is 50 IU/kg.

For children less than 12 years of age: the recommended pre-operative dose is 65 IU/kg.

Routine prophylaxis:

For adults and adolescents (12 years of age and up): the recommended dose is 50 IU/kg every 4 days.

For children less than 12 years of age: the recommended dose is 65 IU/kg twice weekly.

Altuviiio

On-demand treatment and perioperative management: a single dose of 50 IU/kg.

Routine prophylaxis:

The recommended dose is 50 IU/kg once weekly.

Von Willebrand Disease**Alphanate**

For adults: the recommended pre-operative dose is 60 IU VWF:RCo/kg with subsequent doses of 40-60 IU VWF:RCo/kg at 8 to 12 hour intervals post-operative as clinically needed.

For pediatric: the recommended pre-operative dose is 75 IU VWF:RCo/kg with subsequent doses of 50-75 IU VWF:RCo/kg at 8 to 12 hour intervals post-operative as clinically needed.

Humate-P

For treatment of bleeding episodes: the recommended dose is 40-80 IU VWF: RCo/kg every 8-12 hours.

References

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2. Adynovate prescribing information. Westlake Village, CA; Baxalta US Inc. August 2023.
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4. Eloctate prescribing information. Waltham, MA; Bioverativ Therapeutics Inc. December 2020.
5. Hemofil M prescribing information. Westlake Village, CA; Baxalta US Inc. June 2018.
6. Humate-P prescribing information. Kankakee, IL; CSL Behring LLC. June 2020.
7. Jivi prescribing information. Whippany, NJ; Bayer HealthCare LLC. August 2018.
8. Koate-DVI prescribing information. Research Triangle Park, NC; Grifols Therapeutics Inc. August 2012.
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24. Altuviiiio prescribing information. Waltham, MA; Bioverativ Therapeutics Inc. February 2023.
25. National hemophilia Foundation for all bleeding disorders. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. MASAC Document #276. Revised May 2023.