

Factor VIII Products

(Advate[®], Adynovate[®], Afstyl[®], Altuviii[™], Eloctate[®], Esperoct, Jivi[®], Kovaltry[®], 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 a Factor VIII product, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Advate, Adynovate, Afstyl, Altuviii, Eloctate, Esperoct, Jivi, 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.

Coverage Guidelines

Hemophilia A (Congenital Factor VIII Deficiency)

Initial authorization request:

- The request is for one of the following:
 - On-demand treatment and control of bleeding episodes; OR
 - Routine prophylaxis to reduce the frequency of bleeding episodes; OR
 - Perioperative management of bleeding;
- The requested product is prescribed by or in consultation with a hemophilia specialist;

- The 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 5 BU/mL) and the requested agent will be used as part of an Immune Tolerance Induction (ITI) regimen.
- For Jivi, the individual is 7 years of age or older and has previously been treated for Hemophilia A.

Reauthorization request:

- The request is for on-demand treatment and control of bleeding episodes, routine prophylaxis or perioperative management of bleeding in individuals with hemophilia A.
- The 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 5 BU/mL) and the requested agent will be used as part of an Immune Tolerance Induction (ITI) regimen.

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; AND
- The requested product is prescribed by or in consultation with a hemophilia specialist.

Approval duration (initial and renewal): 12 months

Dosing Recommendations

For intravenous use only

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

Adults and adolescents (12 years of age and older)

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.

Children (7 to < 12 years of age)

The recommended initial dosage regimen is 60 IU/kg twice weekly. Adjust the dose based on the patient's clinical response and/or recovery.

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.

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.

Altuviiro

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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4. Elocate prescribing information. Waltham, MA; Bioverativ Therapeutics Inc. May 2023.

5. Hemofil M prescribing information. Westlake Village, CA; Baxalta US Inc. February 2025.
6. Humate-P prescribing information. Kankakee, IL; CSL Behring LLC. June 2020.
7. Jivi prescribing information. Whippany, NJ; Bayer HealthCare LLC. May 2025.
8. Koate-DVI prescribing information. Research Triangle Park, NC; Grifols Therapeutics Inc. January 2022.
9. Kovaltry prescribing information. Whippany, NJ; Bayer HealthCare LLC. December 2022.
10. Novoeight prescribing information. Plainsboro, NJ; Novo Nordisk Inc. July 2020.
11. Nuwiq prescribing information. Hoboken, NJ; Octapharma USA, Inc. December 2024.
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