

Factor IX Products

(Alprolix[®], BeneFIX[®], Idelvion[®], Ixinity[®], Rebinyn[®], Rixubis[®]
[coagulation factor IX {recombinant}]
AlphaNine SD[®] [coagulation factor IX {plasma-derived}]
Profilnine[®] [factor IX complex {plasma-derived}])

When requesting a Factor IX product, the individual requiring treatment must be diagnosed with one of the following approved indications or an approved compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Coagulation Factor IX (recombinant and plasma-derived) and Factor IX Complex (plasma-derived) are indicated in patients with hemophilia B (congenital Factor IX deficiency) for:

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

Approved Off-label Compendial Uses

Factor II Deficiency (Profilnine only)

Factor X Deficiency (Profilnine only)

Coverage Guidelines

Hemophilia B

Initial authorization request:

- The request is for treatment or prevention of bleeding episodes or perioperative management of bleeding in individuals with congenital hemophilia B.
- The requested product is prescribed by or in consultation with a hemophilia specialist.

Reauthorization request:

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

Factor II Deficiency (*Profilnine only*)

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

Factor X Deficiency (*Profilnine only*)

- 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

AlphaNine SD and Profilnine

Required units = body weight (kg) x desired factor IX increase (IU/dL or % of normal) x 1.0 IU/kg

Alprolix

On-demand treatment and control of bleeding episodes:

Initial Dose: Type of Bleeding	Target Circulating FIX required (IU/dL)	Dosing Interval
Minor and moderate	30-60	Repeat every 48 hours as needed
Major	80-100	Repeat dose after 6-10 hours, then every 24 hours for 3 days, then every 48 hours until healing is achieved

Perioperative management:

For minor surgery: a single infusion to reach FIX level of 50-80 IU/dL may be sufficient. Repeat as needed after 24-48 hours until bleeding stops and healing is achieved.

For major surgery: initial infusion to reach FIX level of 60-100 IU/dL. Consider a repeat dose after 6-10 hours and then every 24 hours for the first 3 days, then every 48 hours until bleeding stops and healing is achieved.

Routine prophylaxis:

For adults and adolescents ≥12 years of age: start at 50 IU/kg once weekly or 100 IU/kg once every 10 days.

For children <12 years of age: start at 60 IU/kg once weekly.

BeneFIX

On-demand treatment and control of bleeding episodes:

Required units = body weight (kg) x desired factor IX increase (IU/dL or % of normal) x reciprocal of observed recovery (IU/kg per IU/dL)

Routine prophylaxis:

For long term prophylaxis against bleeding, the recommended regimen is 100 IU/kg once weekly.

Ixinity

On-demand treatment and control of bleeding episodes and perioperative management of bleeding:

Required units = body weight (kg) x desired factor IX increase (IU/dL or % of normal) x reciprocal of observed recovery (IU/kg per IU/dL)

Routine prophylaxis:

For adults and adolescents ≥12 years of age: The recommended regimen is 40 to 70 IU/kg twice weekly.

For children <12 years of age: The recommended regimen is 35 to 75 IU/kg twice weekly.

Idelvion

On-demand treatment and control of bleeding episodes and perioperative management:

Required units = body weight (kg) x desired factor IX increase (IU/dL or % of normal) x reciprocal of observed recovery (IU/kg per IU/dL)

Routine prophylaxis:

For adults and adolescents ≥12 years of age: 25-40 IU/kg every 7 days. Patients who are well-controlled on this regimen may be switched to a 14-day interval at 50-75 IU/kg.

For children <12 years of age: 40-55 IU/kg every 7 days

Rebinyn

On-demand treatment and control of bleeding episodes and perioperative management:

For minor and moderate bleeds/minor surgery: 40 IU/kg

For major bleeds/surgery: 80 IU/kg

Routine prophylaxis:

The recommended dose is 40 IU/kg once weekly.

Rixubis

On-demand treatment and control of bleeding episodes and perioperative management:

Required units = body weight (kg) x desired factor IX increase (IU/dL or % of normal) x reciprocal of observed recovery (IU/kg per IU/dL)

Routine prophylaxis:

For adults and adolescents ≥12 years of age: 40-60 IU/kg twice weekly

For children <12 years of age: 60-80 IU/kg twice weekly

References

1. Alprolix prescribing information. Waltham, MA; Bioverativ Therapeutics Inc. May 2023.
2. BeneFIX prescribing information. Philadelphia, PA; Wyeth Pharmaceuticals Inc. November 2022.
3. Idelvion prescribing information. Kankakee IL; CSL Behring LLC. June 2023.

4. Ixinity prescribing information. Berwyn PA; Aptevio Bio Therapeutics LLC. March 2024.
5. Rebinyn prescribing information. Plainsboro, NJ; Novo Nordisk Inc. August 2022.
6. Rixubis prescribing information. Westlake Village, CA; Baxalta US Inc. March 2025.
7. AlphaNine SD prescribing information. Los Angeles, CA; Grifols Biologicals Inc. November 2022.
8. Profilnine prescribing information. Los Angeles, CA; Grifols Biologicals Inc. June 2018.
9. Menegatti M, Peyvandi F. Treatment of rare factor deficiencies other than hemophilia. *Blood*. 2019;133(5):415-424.
10. 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.
11. World Federation of Hemophilia. WFH Guidelines for the Management of Hemophilia. 3rd edition. Haemophilia. 2020;00:1-158.
12. Coagulation Factor IX (recombinant [Albumin Fusion Protein]) (Idelvion®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. [Updated; April 15, 2024; Accessed April 23, 2024].
13. Coagulation Factor IX (human) (AlphaNine SD®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. [Updated; April 15, 2024; Accessed April 23, 2024].
14. Coagulation Factor IX complex (human) [Factors II, IX, X] (Profilnine®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. [Updated; April 6, 2024; Accessed April 23, 2024].
15. Sidonio RF, Malec L. Hemophilia B (Factor IX Deficiency). *Hematol Oncol Clin North Am*. 2021;35(6):1143-1155.
16. Mancuso ME, Mahlangu JN, Pipe SW. The changing treatment landscape in haemophilia: from standard half-life clotting factor concentrates to gene editing. *Lancet*. 2021;397:630-640.
17. Croteau SE. Hemophilia A/B. *Hematol Oncol Clin N Am*. 2022;36:797-812.
18. National Bleeding Disorders Foundation. Medical and Scientific Advisory Council (MASAC) recommendations concerning products licensed for the treatment of hemophilia selected disorders of the coagulation system (endorsed on October 2, 2024). MASAC document #290. Available at: <https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf>. Accessed on February 19, 2025.
19. Rezende SM, Neumann I, Angchairsuksiri P, et al. International Society on Thrombosis and Haemostasis clinical practice guideline for the treatment of congenital hemophilia A and B based on the Grading of Recommendations Assessment, Development, and Evaluation methodology. *J Thromb Haemost*. 2024;22:2629-2652.