

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

The individual must meet both of the following criteria for approval:

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

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: 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

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3. Rebinyn® intravenous infusion [prescribing information]. Plainsboro, NJ: Novo Nordisk; August 2022.
4. BeneFIX® intravenous infusion [prescribing information]. Philadelphia, PA: Wyeth/Pfizer; November 2022.

5. Ixinity® intravenous infusion [prescribing information]. Chicago, IL: Medexus; March 2024.
6. Rixubis® intravenous infusion [prescribing information]. Cambridge, MA: Baxalta/Takeda; March 2025.
7. AlphaNine® SD intravenous infusion [prescribing information]. Los Angeles, CA: Grifols; November 2022.
8. Profilnine® intravenous infusion [prescribing information]. Los Angeles, CA: Grifols; November 2022.
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12. Chowdary P, Carcao M, Kenet G, Pipe SW. *Haemophilia*. 2025;405:736-750.
13. 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 9, 2026.
14. Rezende SM, Neumann I, Angchaisuksiri 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.