

**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 Factor IX agent, the individual requiring treatment must be diagnosed with an approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

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

Coverage Guidelines

Initial authorization request:

- The request is for treatment or prevention of bleeding episodes or perioperative management of bleeding in individuals with congenital hemophilia B.
- *Applies to routine prophylaxis only* - For long acting product request (i.e., Alprolix, Idelvion, Rebinyn), the individual has failed (with at least 3 month-trial), is contraindicated, or is intolerant to TWO recombinant factor IX products with standard half-life (i.e. BeneFix, Ixinity, and Rixubis).

Reauthorization request:

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

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 2023.
7. AlphaNine SD prescribing information. Los Angeles, CA; Grifols Biologicals Inc. March 2021.
8. Profilnine prescribing information. Los Angeles, CA; Grifols Biologicals Inc. June 2018.
9. 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.
10. World Federation of Hemophilia. WFH Guidelines for the Management of Hemophilia. 3rd edition. Haemophilia. 2020;00:1-158.
11. 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].
12. Coagulation Factor IX (human) (AlphaNine SD®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. [Updated; April 15, 2024; Accessed April 23, 2024].
13. 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].