Reference number(s)
1944-A

Specialty Guideline Management Factor IX Products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rebinyn	coagulation factor IX [recombinant], glycoPEGylated
Idelvion	coagulation factor IX [recombinant], albumin fusion protein
Alprolix	coagulation factor IX [recombinant], Fc fusion protein
Benefix	coagulation factor IX [recombinant]
Ixinity	coagulation factor IX [recombinant]
Rixubis	coagulation factor IX [recombinant]
Alphanine SD	coagulation factor IX [human])

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1-7]

Hemophilia B

All other indications are considered experimental/investigational and not medically necessary.

Reference number(s)
1944-A

Prescriber Specialties

Must be prescribed by or in consultation with a hematologist.

Coverage Criteria

Hemophilia B[1-9]

Authorization of 12 months may be granted for treatment of hemophilia B.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

References

1. Alprolix [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; May 2023.
2. BeneFIX [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; November 2022.
3. Ixinity [package insert]. Chicago, IL: Medexus Pharma, Inc.; March 2024.
4. Rixubis [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2025.
5. AlphaNine SD [package insert]. Los Angeles, CA: Grifols Biologicals LLC; November 2022.
6. Idelvion [package insert]. Kankakee, IL: CSL Behring LLC; June 2023.
7. Rebinyn [package insert]. DK-2880 Bagsvaerd, Denmark: Novo Nordisk A/S; August 2022.
8. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020;26 Suppl 6:1-158. Doi:10.1111/hae.14046.
9. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised October 2024. MASAC Document #290. https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed December 2, 2025.