

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Factor IX Agents under the patient's prescription drug benefit.

Description:

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 Indication Hemophilia B

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

Applicable Drug List:

Alphanine SD Alprolix Benefix Idelvion Ixinity Rebinyn Rixbubis

Policy/Guideline:

Prescriber Specialty:

Must be prescribed by or in consultation with a hematologist.

Criteria for Initial Approval:

Hemophilia B

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 criteria for initial approval when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

Approval Duration and Quantity Restrictions:

Approval: 12 months



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Coverage Policy/Guideline

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Effective Date	e: 4/21/2025		Last Review Date:	3/25/2025
Applies to:	⊠Illinois ⊠Maryland	⊠Florida Kids ⊠Pennsylvania Kids	⊠New Jersey □Virginia	

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 2023.
- 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 5, 2024.