

Reference number(s)
1944-A

## SPECIALTY GUIDELINE MANAGEMENT

**REBINYN (coagulation factor IX [recombinant], glycoPEGylated)**

**IDELVION (coagulation factor IX [recombinant], albumin fusion protein)**

**ALPROLIX (coagulation factor IX [recombinant], Fc fusion protein)**

**BENEFIX, IXINITY, RIXUBIS (coagulation factor IX [recombinant])**

**ALPHANINE SD (coagulation factor IX [human])**

### POLICY

#### I. 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 Indication

Hemophilia B

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

#### II. PRESCRIBER SPECIALTIES

Must be prescribed by or in consultation with a hematologist.

#### III. CRITERIA FOR INITIAL APPROVAL

**Hemophilia B**

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

#### IV. CONTINUATION OF THERAPY

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

#### V. REFERENCES

<b>Reference number(s)</b>
1944-A

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.; November 2022.
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 August 2023. MASAC Document #280. <https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf>. Accessed December 5, 2023.