

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, MONONINE (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. CRITERIA FOR INITIAL APPROVAL

**Hemophilia B**

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

#### III. CONTINUATION OF THERAPY

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

#### IV. REFERENCES

1. Alprolix [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; October 2020.
2. BeneFIX [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; June 2020.
3. Ixinity [package insert]. Seattle, WA: Aptevo BioTherapeutics LLC, September 2020.
4. Rixubis [package insert]. Lexington, MA: Baxalta US Inc.; June 2020.
5. AlphaNine SD [package insert]. Los Angeles, CA: Grifols Biologicals LLC; June 2018.

Reference number(s)
1944-A

6. Mononine [package insert]. Kankakee, IL: CSL Behring LLC; December 2018.
7. Idelvion [package insert]. Kankakee, IL: CSL Behring LLC; July 2020.
8. Rebinyn [package insert]. DK-2880 Bagsvaerd, Denmark: Novo Nordisk A/S; June 2020.
9. 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.
10. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised August 2020. MASAC Document #263. [https://www.hemophilia.org/sites/default/files/document/files/263\\_treatment.pdf](https://www.hemophilia.org/sites/default/files/document/files/263_treatment.pdf). Accessed November 20, 2020.