

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. 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

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1. Alprolix [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; October 2020.
2. BeneFIX [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; September 2021.
3. Ixinity [package insert]. Seattle, WA: Aptevo BioTherapeutics LLC, February 2021.
4. Rixubis [package insert]. Lexington, MA: Baxalta US Inc.; June 2020.
5. AlphaNine SD [package insert]. Los Angeles, CA: Grifols Biologicals LLC; February 2021.
6. Mononine [package insert]. Kankakee, IL: CSL Behring LLC; December 2020.
7. Idelvion [package insert]. Kankakee, IL: CSL Behring LLC; July 2021.
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. Accessed December 7, 2021.