

<b>Reference number(s)</b>
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 are not a covered benefit.

#### **II. CRITERIA FOR INITIAL APPROVAL**

**Hemophilia B**

Indefinite authorization may be granted for treatment of hemophilia B.

#### **III. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

#### **IV. REFERENCES**

1. Alprolix [package insert]. Cambridge, MA: Biogen Idec Inc.; June 2018.
2. BeneFix [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; June 2016.
3. Ixinity [package insert]. Berwyn, PA: Aptevo BioTherapeutics LLC, April 2018.
4. Rixubis [package insert]. Lexington, MA: Baxalta US Inc.; May 2018.
5. AlphaNine SD [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; March 2017.
6. Mononine [package insert]. Kankakee, IL: CSL Behring LLC; April 2016.

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7. Idelvion [package insert]. Kankakee, IL: CSL Behring LLC; May 2018
8. Rebinyn [package insert]. DK-2880 Bagsvaerd, Denmark: Novo Nordisk A/S; May 2017.
9. Srivastava A, Brewer A, Street A, et al. Guidelines for the management of hemophilia. *Haemophilia: The Official Journal Of The World Federation Of Hemophilia* [serial online]. January 2013;19(1):e1-e47. Available from: MEDLINE Complete, Ipswich, MA. Accessed December 18, 2018.
10. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised April 2018. MASAC Document # 253. Accessed December 18, 2018.