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 are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Hemophilia B
Authorization of 12 months 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.; July 2016.
2. BeneFix [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; August 2015.
3. Ixinity [package insert]. Berwyn, PA: Aptevo BioTherapeutics LLC, August 2016.
4. Rixubis [package insert]. Westlake Village, CA: Baxalta US Inc.; March 2016.
5. AlphaNine SD [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; January 2013.
6. Mononine [package insert]. Kankakee, IL: CSL Behring LLC; April 2014.
7. Idelvion [package insert]. Kankakee, IL: CSL Behring LLC; March 2016

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 9, 2017.
10. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised August 2017. MASAC Document # 250. Accessed December 8, 2017.