Reference number(s)
4852-A

STANDARD MEDICARE PART B 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 Indications
Hemophilia B

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

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 be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with the requested medication
B. The requested medication is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy (e.g., reduced frequency or severity of bleeds)

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for the factor IX products (Rebinyn, Idelvion, Alprolix, Benefix, Ixinity, Rixubis, Alphanine SD).
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for the factor IX products are covered.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VI. REFERENCES

1. Alprolix [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; October 2020.
2. BeneFIX [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; November 2022.
3. Ixinity [package insert]. Chicago, IL: Medexus Pharma, Inc.; May 2022.
4. Rixubis [package insert]. Lexington, MA: Baxalta US Inc.; June 2020.
5. AlphaNine SD [package insert]. Los Angeles, CA: Grifols Biologicals LLC; March 2021.
6. Idelvion [package insert]. Kankakee, IL: CSL Behring LLC; July 2021.
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 other bleeding disorders. Revised March 2022. MASAC Document #272. https://www.hemophilia.org/sites/default/files/document/files/272_Treatment.pdf. Accessed December 2, 2022.