

PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Hemophilia – Recombinant Factor IX Products Preferred Specialty Management Policy
Standard Half-Life Products

- BeneFIX[®] (coagulation Factor IX [recombinant] injection – Wyeth/Pfizer)
- Ixinity[®] (coagulation Factor IX [recombinant] injection – Medexus)
- Rixubis[®] (coagulation Factor IX [recombinant] injection – Baxalta/Takeda)

Extended Half-Life Products

- Alprolix[®] (coagulation Factor IX [recombinant] Fc fusion protein injection – Bioverativ/Sanofi)
- Idelvion[®] (coagulation Factor IX [recombinant] albumin fusion protein injection – CSL Behring)
- Rebinyn[®] (coagulation Factor IX [recombinant] glycoPEGylated injection – NovoNordisk)

REVIEW DATE: 10/04/2023; effective 01/01/2024

OVERVIEW

All of the Factor IX products are used for **hemophilia B**. Alprolix,¹ Idelvion,² Rebinyn,³ BeneFIX,⁴ Ixinity,⁵ and Rixubis⁶ are recombinant Factor IX products. Alprolix, Idelvion, and Rebinyn differ because they are modified agents that have an extended dosing interval in various clinical scenarios (e.g., routine prophylaxis).^{1-3,7} Most products are indicated in children and adults for control and prevention of bleeding episodes, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Ixinity is only indicated for use in patients who are ≥ 12 years of age.⁵

POLICY STATEMENT

This Preferred Specialty Management Policy has been developed to encourage the use of Preferred Products. The Policy is divided between standard half-life products and extended half-life products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Hemophilia – Factor IX Products Prior Authorization Policy* criteria. The program also directs the patient to try at least one Preferred Product prior to the use of Non-Preferred Product(s). Requests for Non-Preferred Product(s) will also be reviewed using the exception criteria (below). All approvals are provided for 1 year in duration. If the patient meets the standard *Hemophilia – Factor IX Products Prior Authorization Policy* criteria but has not tried a Preferred Product, a Preferred Product will be authorized.

Automation: None.

Hemophilia – Standard Half-Life Recombinant Factor IX Products Preferred Specialty Management Program

Preferred Products: BeneFIX
Non-Preferred Products: Rixubis, Ixinity

Hemophilia – Extended Half-Life Recombinant Factor IX Products Preferred Specialty Management Program

Preferred Products: Alprolix, Idelvion
Non-Preferred Products: Rebinyn

10/04/2023

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I. Hemophilia – Standard Half-Life Recombinant Factor IX Products Preferred Specialty Management Program

RECOMMENDED EXCEPTION CRITERIA

II. Hemophilia – Extended Half-Life Recombinant Factor IX Products Preferred Specialty Management Program

RECOMMENDED EXCEPTION CRITERIA

REFERENCES

1. Alprolix® intravenous injection [prescribing information]. Waltham, MA: Bioverativ/Sanofi; May 2023.
2. Idelvion® intravenous injection [prescribing information]. Kankakee, IL: CSL Behring; June 2023.
3. Rebinyn® intravenous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; August 2022.
4. BeneFIX® intravenous injection [prescribing information]. Philadelphia, PA: Wyeth/Pfizer; November 2022.
5. Ixinity® intravenous injection [prescribing information]. Chicago, IL: Medexus; November 2022.
6. Rixubis® intravenous injection [prescribing information]. Lexington, MA: Baxalta/Takeda; May 2023.
7. National Hemophilia Foundation. Hemophilia B. An overview of symptoms, genetics, and treatments to help you understand hemophilia B. Available at: <https://www.hemophilia.org/bleeding-disorders-a-z/types/hemophilia-b>. Accessed on September 17, 2023.