POLICY Document for PROFILNINE (factor IX complex [human])

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
HEMOPHILIA B

PREFERRED PRODUCTS: ALPROLIX, BENEFIX, INDELVION

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the Factor IX products specified in this policy. Coverage for targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Factor IX Products

	Product(s)
Preferred*	• **Alprolix** (coagulation factor IX [recombinant], Fc fusion protein) • **Benefix** (coagulation factor IX [recombinant]) • **Idelvion** (coagulation factor IX [recombinant], albumin fusion protein)
Targeted	• **AlphaNine SD** (coagulation factor IX [human]) • **Ixinity** (coagulation factor IX [recombinant])

	• **Profilnine SD** (factor IX complex) • **Rebinyn** (coagulation factor IX [recombinant], glycoPEGylated) • **Rixubis** (coagulation factor IX [recombinant])

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Member has a documented inadequate response, contraindication, or intolerable adverse event to all preferred products.

Section 2: Clinical Criteria

Specialty Guideline Management Profilnine

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Profilnine	factor IX complex [human]

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[1]

Hemophilia B

Compendial Uses

- Bleeding due to low levels of liver-dependent coagulation factors[2]

- Factor II deficiency[3]

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

Must be prescribed by or in consultation with a hematologist.

Coverage Criteria

Hemophilia B[1]

Authorization of 12 months may be granted for treatment of hemophilia B.

Bleeding Due to Low Levels of Liver-dependent Coagulation Factors[2]

Authorization of 12 months may be granted for treatment of bleeding due to low levels of liver-dependent coagulation factors.

Factor II Deficiency[3]

Authorization of 12 months may be granted for treatment of factor II deficiency.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in coverage criteria section when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

REFERENCES:

SECTION 1

1. AlphaNine SD [package insert]. Los Angeles, CA: Grifols Biologicals Inc; November 2022.
2. Alprolix [package insert]. Cambridge, MA: Biogen Idec Inc.; October 2020.
3. Benefix [package insert]. Philadelphia, PA: Wyeth Pharmaceutical LLC; September 2021.
4. Idelvion [package insert]. Kankakee, IL: CSL Behring LLC; June 2023.
5. Ixinity [package insert]. Chicago, IL: Medexus Pharma, Inc; March 2024.
6. Profilnine SD [package insert]. Los Angeles, CA: Grifols Biologicals Inc; August 2010.
7. Rebinyn [package insert]. DK-2880 Bagsvaerd, Denmark: Novo Nordisk A/S; August 2022
8. Rixubis [package insert]. Lexington, MA. Baxalta US Inc.; June 2020

SECTION 2

1. Profilnine [package insert]. Los Angeles, CA: Grifols Biologicals, LLC; June 2023.

2. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically www.micromedexsolutions.com [available with subscription]. Accessed December 5, 2024.
3. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised October 2024. MASAC Document #290. https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed December 5, 2024.