

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 Indications¹

Hemophilia B

Compendial Uses

- Bleeding due to low levels of liver-dependent coagulation factors²
- Factor II deficiency³

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 B¹

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

Bleeding Due to Low Levels of Liver-dependent Coagulation Factors²

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

Factor II Deficiency³

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

1. Profilnine [package insert]. Los Angeles, CA: Grifols Biologicals, LLC; November 2022.
2. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically www.micromedexsolutions.com [available with subscription]. Accessed December 2, 2025.
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 2, 2025.