

<b>Reference number(s)</b>
1949-A

## SPECIALTY GUIDELINE MANAGEMENT

### PROFILNINE (factor IX complex [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.

A. FDA-Approved Indication  
Hemophilia B

B. Compendial Uses  
1. Bleeding due to low levels of liver-dependent coagulation factors  
2. Factor II deficiency

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

##### II. PRESCRIBER SPECIALTIES

Must be prescribed by or in consultation with a hematologist.

##### III. CRITERIA FOR INITIAL APPROVAL

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

B. **Bleeding Due to Low Levels of Liver-dependent Coagulation Factors**  
Authorization of 12 months may be granted for treatment of bleeding due to low levels of liver-dependent coagulation factors.

C. **Factor II Deficiency**  
Authorization of 12 months may be granted for treatment of factor II deficiency.

##### IV. CONTINUATION OF THERAPY

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

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## V. REFERENCES

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](http://www.micromedexsolutions.com) [available with subscription]. Accessed December 5, 2023.
3. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised August 2023. MASAC Document #280. <https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf>. Accessed December 5, 2023.