

**Profilnine (factor IX complex [human])**  
**Effective 01/01/2026**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical Benefit</b> <b>Pharmacy Benefit</b>	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
<b>Exceptions</b>	N/A		

**Overview**

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 Indication**

1. Hemophilia 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.

**Coverage Guidelines**

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

**OR**

When the following diagnosis-specific criteria are met:

**Hemophilia B**

1. Member has a diagnosis of Hemophilia B.
2. The requested medication is prescribed by or in consultation with a hematologist.

**Bleeding Due to Low Levels of Liver-dependent Coagulation Factors**

1. Member has a diagnosis of bleeding due to low levels of liver-dependent coagulation factors.
2. The requested medication is prescribed by or in consultation with a hematologist.

**Factor II Deficiency**

1. Member has a diagnosis of Factor II deficiency.
2. The requested medication is prescribed by or in consultation with a hematologist.

### **Continuation of Therapy**

Requests for reauthorization will be approved when the following criteria are met:

1. Member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

### **Limitations**

1. Initial approvals and reauthorizations will be granted for 12 months.

### **References**

1. 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](https://www.hemophilia.org/sites/default/files/document/files/272_Treatment.pdf). Accessed December 1, 2022.
2. Profilnine (factor IX complex) [prescribing information]. Los Angeles, CA: Grifols Biologicals, LLC; November 2022.

### **Review History**

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024

05/14/2025 – Reviewed at May P&T. No changes. Effective 06/01/2025.

10/08/2025 – Reviewed at October P&T. Updated policy to indicate it no longer applies to the medical benefit. Effective 01/01/2026.

