Reference number(s)
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. 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.

III. CONTINUATION OF THERAPY

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

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IV. REFERENCES

1. Profilnine [package insert]. Los Angeles, CA: Grifols Biologicals, LLC; June 2018.
2. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically www.micromedexsolutions.com [available with subscription]. Accessed November 25, 2020.

3. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised August 2020. MASAC Document #263. https://www.hemophilia.org/sites/default/files/document/files/263_treatment.pdf. Accessed November 20, 2020.