

Reference number(s)
1941-A
1949-A

## SPECIALTY GUIDELINE MANAGEMENT

### BEBULIN, 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 X deficiency (Bebulin only)
3. Factor II deficiency (Profilnine only)

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

##### II. CRITERIA FOR INITIAL APPROVAL

- 1. Hemophilia B**  
Indefinite authorization may be granted for treatment of hemophilia B.
- 2. Bleeding Due to Low Levels of Liver-dependent Coagulation Factors**  
Indefinite authorization may be granted for treatment of bleeding due to low levels of liver-dependent coagulation factors.
- 3. Factor X Deficiency**  
Indefinite authorization of Bebulin may be granted for treatment of factor X deficiency.
- 4. Factor II Deficiency**  
Indefinite authorization of Profilnine may be granted for treatment of factor II deficiency.

##### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

##### IV. REFERENCES

1. Bebulin [package insert]. Westlake Village, CA: Baxalta US Inc.; September 2015.

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2. Profilnine [package insert]. Los Angeles, CA: Grifols Biologicals, LLC; June 2018.
3. 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 4, 2019.
4. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised April 2018. MASAC Document # 253. Accessed December 3, 2019.
5. Brown DL, Kouides PA. Diagnosis and treatment of inherited factor X deficiency. *Haemophilia*. 2008;14:1176-1182.