

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^{1,2}
Hemophilia B
- B. Compendial Uses
 - 1. Bleeding due to low levels of liver-dependent coagulation factors^{3,4}
 - 2. Factor X deficiency^{3,5-7} (Bebulin only)
 - 3. Factor II deficiency^{3,5,6} (Profilnine only)

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

II. CRITERIA FOR INITIAL APPROVAL

- 1. **Hemophilia B**^{1,2}
Indefinite authorization may be granted for treatment of hemophilia B.
- 2. **Bleeding Due to Low Levels of Liver-dependent Coagulation Factors**^{3,4}
Indefinite authorization may be granted for treatment of bleeding due to low levels of liver-dependent coagulation factors.
- 3. **Factor X Deficiency**^{3,5-7}
Indefinite authorization of Bebulin may be granted for treatment of factor X deficiency.
- 4. **Factor II Deficiency**^{5,6}
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, Inc.; March 2017.
3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed December 11, 2018.
4. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hemophilia Agents; November 2006.
5. 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 18, 2018.
6. Clinical Consult. CVS Caremark. Clinical Programs Review. Focus on Bleeding Disorder Programs; June 2014.
7. Brown DL, Kouides PA. Diagnosis and treatment of inherited factor X deficiency. *Haemophilia*. 2008;14:1176-1182.

DOCUMENT HISTORY

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