## 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. <u>FDA-Approved Indication</u> 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 are not a covered benefit.

#### **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: Baxter Healthcare Corporation; July 2012.

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- 2. Profilnine [package insert]. Los Angeles, CA: Grifols Biologicals, Inc.; May 2014.
- 3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. <u>www.micromedexsolutions.com</u> [available with subscription]. Accessed December 11, 2017.
- 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 August 2017. MASAC Document # 250. Accessed December 8, 2017.
- 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.

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