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\(^{3,5-7}\) (Bebulin only)
   3. Factor II deficiency\(^ {3,5,6}\) (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