Clinical Policy: Factor IX Complex (Human - Bebulin, Profilnine)
Reference Number: CP.PHAR.219
Effective Date: 05/16
Last Review Date: 05/17

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for factor IX complex* (Bebulin®, Profilnine®).

*Factor IX complex products (containing factors IX, II, X and VII) should not be confused with factor IX products.

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Bebulin and Profilnine are medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Congenital Hemophilia B (must meet all):
      1. Prescribed by or in consultation with a hematologist;
      2. Diagnosis of congenital hemophilia B (factor IX deficiency);
      3. Request is for control and prevention of bleeding episodes;
      4. If Bebulin is prescribed, age ≥ 18 years;
      5. If Profilnine is prescribed, age ≥ 16 years.

   Approval duration: 3 months

   B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval
   A. Congenital Hemophilia B (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
      2. Member is responding positively to therapy.

   Approval duration: 3 months

   B. Other diagnoses/indications (1 or 2):
      1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
         Approval duration: Duration of request or 6 months (whichever is less); or

      2. Refer to CP.PHAR.57 - Global Biopharm Policy.

Background
Description/Mechanism of Action:
Bebulin and Profilnine contain coagulation factors IX, II, X and low levels of factor VII. Factor IX is a vitamin K-dependent coagulation factor which is synthesized in the liver. Factor IX is activated by factor XIa in the intrinsic coagulation pathway. Activated factor IX (IXa), in combination with factor VII, activates factor X to Xa, resulting ultimately in the conversion of prothrombin to thrombin and the formation of a fibrin clot. The infusion of exogenous factor IX to replace the deficiency present in hemophilia B temporarily restores hemostasis. Hemophilia B is an X-linked recessively inherited disorder of blood coagulation characterized by insufficient or abnormal synthesis of the clotting protein factor IX.

**Formulations (from human plasma):**
Solution Reconstituted, Intravenous:
- Bebulin: 200-1200 (units of factor IX activity stated on each vial)
- Profilnine: 500; 1000; 1500 (units of factor IX activity)

**FDA Approved Indications:**
Bebulin is a factor IX concentrate/intravenous formulation indicated for:
- Prevention and control of bleeding episodes in adult patients with hemophilia B (congenital factor IX deficiency or Christmas disease).
  Limitations of use: Bebulin is not indicated for use in the treatment of factor VII deficiency. No clinical studies have been conducted to show benefit from this product for treating deficiencies other than factor IX deficiency.

Profilnine is a factor IX concentrate/intravenous formulation indicated for:
- Prevention and control of bleeding in patients with factor IX deficiency (hemophilia B).
  Limitations of use: Profilnine contains non-therapeutic levels of factor VII and is not indicated for use in the treatment of factor VII deficiency.

**Coding Implications**
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J7194</td>
<td>Factor IX complex, per IU</td>
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<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>Approval Date</th>
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<tbody>
<tr>
<td>Policy split from CP.PHAR.12.Blood Factors and converted to new template. Removed requests for documentation. Added age requirement per PIs. Neither drug is approved for prophylaxis so the “history of 2 or more episodes of bleeding into joints” is removed; approval period for non-</td>
<td>04/16</td>
<td>05/16</td>
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Reviews, Revisions, and Approvals

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<td>prophylactic use is edited to provide 3 months on initial approval and one 3-month re-auth. Removed denial based on inhibitor titer of ≥5 BU/mL. Reviewed by specialist.</td>
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<td>Safety information removed. Wording, approval periods, and use of “congenital” versus “acquired hemophilia” descriptions made consistent across all blood factor policies. Efficacy statement added to renewal criteria. Reviewed by specialist- hematology/internal medicine.</td>
<td>04/17</td>
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References


Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.
This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at [http://www.cms.gov](http://www.cms.gov) for additional information.

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