Clinical Policy: Factor XIII (Human - Corifact)
Reference Number: ERX.SPMN.203
Effective Date: 01/17

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

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that factor XIII (Corifact®) is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Congenital Factor XIII Deficiency (must meet all):
      1. Prescribed by or in consultation with a hematologist;
      2. Diagnosis of congenital factor XIII (FXIII) deficiency;
      3. Prescribed agent will be used for one of the following:
         a. Routine prophylactic treatment;
         b. Perioperative management of surgical bleeding;
         c. Acute bleeding.

      Approval duration: 3 months (surgical or acute bleeding)  
                              6 months (prophylaxis)

   B. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy.

II. Continued Approval
   A. Congenital Factor XIII Deficiency (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met 
         all initial approval criteria.

      Approval duration: 3 months (surgical or acute bleeding)  
                              6 months (prophylaxis)

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports 
         positive response to therapy; or
      2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

Background
Description/Mechanism of Action:
Factor XIII (FXIII) is an endogenous plasma glycoprotein found in platelets, monocytes and 
macrophages that is converted to activated factor XIII (FXIIIa) in the presence of calcium ions. 
Once activated, FXIIIa cross-links fibrin and cross-links plasmin inhibitor to protect and 
strengthen the hemostatic platelet plug.
FORMULATIONS:
Kit, Intravenous:
Corifact (FXIII, concentrate from human plasma)

FDA Approved Indications:
Corifact is indicated for adult and pediatric patients with congenital FXIII deficiency for:
- Routine prophylactic treatment;
- Perioperative management of surgical bleeding.

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>J7180</td>
<td>Injection, factor XIII (antihemophilic factor, human), 1 IU</td>
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Reviews, Revisions, and Approvals
Policy created. | Date | Approval Date |
---------------|------|---------------|
|               | 12/16| 01/17         |

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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