Clinical Policy: Factor XIII, Human (Corifact)
Reference Number: ERX.SPA.190
Effective Date: 01.11.17
Last Review Date: 02.18

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

Description
Factor XIII, human (Corifact®) is a plasma-derived factor XIII concentrate.

FDA Approved Indication(s)
Corifact is indicated for adult and pediatric patients with congenital factor XIII deficiency for:
- Routine prophylactic treatment
- Peri-operative management of surgical bleeding

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Corifact is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Congenital Factor XIII Deficiency (must meet all):
      1. Diagnosis of congenital factor XIII deficiency;
      2. Prescribed by or in consultation with a hematologist;
      3. Corifact will be used for one of the following (a, b, or c):
         a. Routine prophylactic treatment;
         b. Perioperative management of surgical bleeding;
         c. Acute bleeding.
      Approval duration: 3 months (surgical or acute bleeding) or 6 months (prophylaxis)

   B. Other diagnoses/indications
      1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III
         (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. Congenital Factor XIII Deficiency (must meet all):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or
         member has previously met initial approval criteria;
      2. Member is responding positively to therapy.
      Approval duration: 3 months (surgical or acute bleeding) or 6 months (prophylaxis)

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions
         and documentation supports positive response to therapy.
         Approval duration: Duration of request or 6 months (whichever is less); or
      2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III
         (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient
documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or
evidence of coverage documents.

IV. Appendices/General Information
V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>Routine prophylaxis</td>
<td>40 IU/kg IV every 28 days</td>
<td>Individualized</td>
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<td>Adjust dose ± 5 IU/kg to maintain 5% to 20% trough level of FXIII activity.</td>
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<tr>
<td>Peri-operative management and management of acute bleeding episodes</td>
<td>Dosing is individualized and depends on the time since the patient’s last prophylactic dose.</td>
<td>Individualized</td>
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<td>- If the patient’s last dose was within the past 7 days, then an additional dose may not be needed.</td>
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<td>- If the last dose was 8-21 days prior, then an additional partial or full dose may be needed based on Factor XIII activity level.</td>
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<td>- If the last dose was 21-28 days prior, then a full prophylactic dose can be given.</td>
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</table>

VI. Product Availability
Vial: 1000-1600 units/vial

VII. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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</thead>
<tbody>
<tr>
<td>Policy created</td>
<td>12.01.16</td>
<td>01.17</td>
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<tr>
<td>4Q17 Annual Review</td>
<td>10.11.17</td>
<td>11.17</td>
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<tr>
<td>No significant changes. References reviewed and updated.</td>
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<td>1Q18 annual review:</td>
<td>11.28.17</td>
<td>02.18</td>
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<tr>
<td>Added efficacy statement to renewal criteria.</td>
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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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