Clinical Policy: Factor XIII (Human - Corifact)

Reference Number: PA.CP.PHAR.221
Effective Date: 01/18
Last Review Date: 01/19

Coding Implications
Revision Log

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;
- Perioperative management of surgical bleeding.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that 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 deficiency;
3. Request is for one of the following uses (a, b, or c):
   a. Control and prevention of bleeding;
   b. Perioperative management;
   c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

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

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Congenital Factor XIII Deficiency (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy.

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

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:

Factor XIII is an endogenous plasma glycoprotein found in platelets, monocytes and macrophages that is converted to activated factor XIII in the presence of calcium ions. Once activated, factor XIII cross-links fibrin and plasmin inhibitor to protect and strengthen the hemostatic platelet plug.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): patients with known anaphylactic or severe systemic reactions to human plasma-derived products
- Boxed warning(s): none reported

IV. Dosage and Administration

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

V. Product Availability

Single-use vial: 1,000-1,600 units/vial

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.

HCPCS Codes	Description
J7180	Injection, factor XIII (antihemophilic factor, human), 1 IU

Reviews, Revisions, and Approvals	Date	Approval Date
References reviewed and updated.	02/18	
1Q 2019 annual review: references reviewed and updated.	01/19	

References
1. Corifact Prescribing Information. Kankalee, IL: CSL Behring LLC; September 2017. Available at http://www.corifact.com. Accessed November 8, 2018.
2. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.
3. Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations. Accessed September 26, 2018.