Clinical Policy: Factor XIII (Human - Corifact)

Reference Number: PA.CP.PHAR.221
Effective Date: 01/2018
Last Review Date: 01/2024

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
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & 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. Diagnosis of congenital factor XIII deficiency;
2. Prescribed by or in consultation with a hematologist;
3. Request is for one of the following uses (a, b, or c):
   a. Control and prevention of acute 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 Therapy

A. Congenital Factor XIII Deficiency (must meet all)**:**
1. Currently receiving medication via PA Health & 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 PA Health & 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

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

Appendix D: General Information

- Serious bleeding episodes include bleeds in the following site: intracranial; neck/throat; gastrointestinal; joints (hemarthrosis); muscles (especially deep compartments such as the iliopsoas, calf, forearm); or mucous membranes of the mouth, nose and genitourinary tract.
- Spontaneous bleed is defined as a bleeding episode that occurs without apparent cause and is not the result of trauma.

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

VI. References

1. Corifact Prescribing Information. Kankalee, IL: CSL Behring LLC; December 2019. Available at https://labeling.cslbehring.com/pi/us/corifact/en/corifact-prescribing-information.pdf. Accessed October 27, 2023.
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 Bleeding Disorders Foundation (formerly National Hemophilia Foundation): Database of treatment guidelines. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations. Accessed November 8, 2022.

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
References reviewed and updated.	02/2018
1Q 2019 annual review: references reviewed and updated.	01/2019
1Q 2020 annual review: references reviewed and updated.	01/2020
Added appendix D: general information	07/2020
1Q 2021 annual review: references reviewed and updated.	01/2021
1Q 2022 annual review: no significant changes; references reviewed and updated.	01/2022
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023
1Q 2024 annual review: no significant changes; updated sites of serious bleeds per WFH guideline in Appendix D; references reviewed and updated.	01/2024