Clinical Policy: Factor XIII, Human (Corifact)

Reference Number: CP.PHAR.221
Effective Date: 05.01.16
Last Review Date: 02.18
Line of Business: Medicaid

Coding Implications
Revision Log

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 a human factor XIII concentrate/intravenous formulation 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 (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 Centene Corporation® 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. 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 (acute bleeding episodes/surgery)
6 months (routine prophylaxis)

B. Other diagnoses/indications

1. Refer to CP.PMN.53 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 Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy.

Approval duration: 3 months (acute bleeding episodes/surgery)
6 months (routine prophylaxis)

B. Other diagnoses/indications (must meet 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.PMN.53 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 – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
N/A

V. 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.	N/A
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 patient's 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.	N/A

VI. Product Availability

Vial: 1000-1600 units/vial

VII. References

1. Corifact Prescribing Information. Kankalee, IL: CSL Behring LLC; July 2016. Available at http://labeling.cslbehring.com/PI/US/Corifact/EN/Corifact-Prescribing-Information.pdf. Accessed November 28, 2017.
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 November 28, 2017.

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	P&T Approval Date
Policy split from CP.PHAR.12.Blood Factors and converted to new template. Use is edited to include routine prophylaxis per PI, with approval period for non-prophylactic use edited to provide 3 months on initial approval and one 3-month re-auth; prophylactic approval is 6 months/6 months. Added indication for acute bleeding. Reviewed by specialist.	04.01.16	05.16
Safety information removed. Wording for uses, approval periods, and specification as "congenital" versus "acquired" made consistent across all blood factor policies. Efficacy statement added to renewal criteria. Reviewed by specialist- hematology/internal medicine.	04.01.17	05.17
1Q18 annual review: - No significant changes -Converted to new template - References reviewed and updated.	11.28.17	02.18

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.

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.