

## Clinical Policy: Factor XIII, Human (Corifact)

Reference Number: CP.PHAR.221

Effective Date: 05.01.16

Last Review Date: 05.22

Line of Business: Commercial, HIM, 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<sup>®</sup>) 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 health plans affiliated with Centene Corporation<sup>®</sup> 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 of acute bleeding;
  - b. Perioperative management;
  - c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
4. For routine prophylaxis requests, member meets one of the following (a, b, or c):
  - a. Member has previously used factor XIII for routine prophylaxis;
  - b. Member has severe hemophilia (defined as factor level of < 1%);
  - c. Member has experienced at least one life-threatening or serious spontaneous bleed (see Appendix D).

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

##### B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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#### II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy.

**Approval duration: 3 months (surgical/acute bleeding) or 6 months (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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

#### 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.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

#### IV. 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*

- Life-threatening bleeding episodes include, but are not limited to, bleeds in the following sites: intracranial, neck/throat, or gastrointestinal.
- Serious bleeding episodes include bleeds in the following site: joints (hemarthrosis).
- Spontaneous bleed is defined as a bleeding episode that occurs without apparent cause and is not the result of trauma.
- May 2016: coverage for acute bleed was added to clinical policy based on specialist feedback.

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**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Routine prophylaxis	40 IU/kg IV every 28 days  Adjust dose $\pm$ 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. <ul style="list-style-type: none"> <li>• If the last dose was within the past 7 days, then an additional dose may not be needed.</li> <li>• 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.</li> <li>• If the last dose was 21-28 days prior, then a full prophylactic dose can be given.</li> </ul>	Individualized

**VI. Product Availability**

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

**VII. References**

1. Corifact Prescribing Information. Kankalee, IL: CSL Behring LLC; December 2019. Available at <http://www.corifact.com>. Accessed November 23, 2021.
2. Srivastava A, Santagostino E, Dougall A, et al. WFH guidelines for the management of hemophilia. *Haemophilia*. 2020;26(suppl 6):1-158.
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 December 1, 2020.

**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
1Q18 annual review: - No significant changes -Converted to new template	11.28.17	02.18

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
- References reviewed and updated.		
1Q 2019 annual review: added HIM-Medical Benefit; no significant changes; references reviewed and updated.	09.26.18	02.19
1Q 2020 annual review: no significant changes; added HIM line of business; references reviewed and updated.	11.28.19	02.20
Added routine prophylaxis-specific requirement for severe hemophilia classification or at least one life-threatening or serious spontaneous bleed for classification of non-severe hemophilia; added requirement for prescriber attestation of not partaking in contact sports; added Commercial line of business.	05.27.20	08.20
Removed requirement for prescriber attestation of not partaking in contact sports.	10.01.20	11.20
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	12.01.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.23.21	02.22
Clarified requirement for coverage of factor XIII for routine prophylaxis: the requirement for factor XIII activity level or documentation of bleed history only applies to requests for new starts to routine prophylactic therapy. Consolidated language re: covered indications to now include control of acute bleeds, perioperative management, and routine prophylaxis.	03.03.22	05.22

**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,

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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.

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**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.

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