

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

Reference Number: ERX.SPA.190

Effective Date: 01.11.17

Last Review Date: 05.22

Line of Business: Commercial, Medicaid

[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.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions<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 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/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**

*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.

**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. Kankakee, IL: CSL Behring LLC; December 2019. Available at: [www.corifact.com](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.

- 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q18 annual review: Added efficacy statement to renewal criteria.	11.28.17	02.18
1Q 2019 annual review: no significant changes; references reviewed and updated.	09.26.18	02.19
1Q 2020 annual review: no significant changes; 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.	08.27.20	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 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.

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.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2017 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.