Clinical Policy: Factor XIII (Human - Corifact)

Reference Number: PA.CP.PHAR.221
Effective Date: 01/18
Last Review Date: 05/17

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for factor XIII (Corifact®).

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. Control and prevention of bleeding;
   b. Perioperative management;
   c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

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

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

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 (bleeding episodes/surgery)
6 months (routine 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.PHAR.57 - Global Biopharm Policy.

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.

Formulations (from human plasma):
Solution Reconstituted, Intravenous [preservative free]

- Corifact: 1000-1600 units

FDA Approved Indications:
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.

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

1. Corifact Prescribing Information. Kankalee, IL: CSL Behring LLC; March 2015. Available at http://labeling.cslbehring.com/PI/US/Corifact/EN/Corifact-Prescribing-Information.pdf. Accessed April 26, 2017.
2. Factor XIII, concentrate from human plasma: Drug Information (Lexicomp). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at uptodate.com. Accessed April 26, 2017.
3. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.
4. 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 April 28, 2017.