

SPECIALTY GUIDELINE MANAGEMENT

CORIFACT (factor XIII concentrate [human])

POLICY

A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

- Congenital Factor XIII Deficiency
 - Corifact is indicated for routine prophylactic treatment and peri-operative management of surgical bleeding in adult and pediatric patients with congenital factor XIII deficiency.

Compendial Uses

- Acquired Factor XIII Deficiency

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- Laboratory documentation of specific factor XIII assay (e.g., an ammonia release assay, such as a Berichrom assay, or an enzyme-linked immunosorbent assay [ELISA])

C. CRITERIA FOR APPROVAL

1. Congenital Factor XIII Deficiency

Indefinite authorization may be granted to members who are prescribed Corifact for congenital factor XIII deficiency confirmed by specific factor XIII assay(s).

2. Acquired Factor XIII Deficiency

Authorization of 12 months may be granted to members who are prescribed Corifact for acquired factor XIII deficiency confirmed by specific factor XIII assay(s).

D. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

E. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

REFERENCES

1. Corifact [package insert]. Kankakee, IL: CSL Behring LLC; January 2013.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed January, 4th 2016.
3. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised August 2015. MASAC Document # 237. <https://www.hemophilia.org/sites/default/files/document/files/230Text2014-09.pdf>. Accessed December 3, 2014.
4. Fadoo Z, Merchant Q, Rehman KA. New developments in the management of congenital Factor XIII deficiency. *J Blood Med.* 2013;4:65-73.
5. Kohler HP, Ichinose A, Seitz R, et al. Diagnosis and classification of factor XIII deficiencies. *J Thromb Haemost.* 2011;9(7):1404-6.

6. Hsieh L, Nugent D. Factor XIII deficiency. *Haemophilia*. 2008;14:1190-1200.