Reference number(s)
4851-A

STANDARD MEDICARE PART B MANAGEMENT

CORIFACT (factor XIII concentrate [human])

POLICY

I. 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.

A. FDA-Approved Indication

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

B. Compendial Use

Acquired factor XIII deficiency

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Factor XIII Deficiency
Authorization of 12 months may be granted for treatment of factor XIII deficiency.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with the requested medication
B. The requested medication is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy (e.g., reduced frequency or severity of bleeds)

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Corifact.
2. The available compendium

a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
b. Micromedex DrugDex
c. American Hospital Formulary Service- Drug Information (AHFS-DI)
d. Lexi-Drugs
e. Clinical Pharmacology

3. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders.
4. Guideline for the diagnosis and management of the rare coagulation disorders: a United Kingdom Haemophilia Centre Doctors' Organization guideline on behalf of the British Committee for Standards in Haematology.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Corifact are covered in addition to acquired factor XIII deficiency.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Corifact to treat acquired factor XIII deficiency can be found in the Guideline for the Diagnosis and Management of Rare Coagulation Disorders published by the United Kingdom Haemophilia Centre Doctors' Organization. Acquired factor XIII deficiency has been reported in patients with cardiac surgery, inflammatory bowel disease and Henoch-Schonlein purpura and is rarely associated with de novo FXIII inhibitors. Corifact is listed as an appropriate treatment for acquired factor XIII deficiency, which follows the same recommendations as congenital factor XIII deficiency.

VI. REFERENCES

1. Corifact [package insert]. Kankakee, IL: CSL Behring LLC; September 2020.
2. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised April 2022. MASAC Document #272. https://www.hemophilia.org/sites/default/files/document/files/272_Treatment.pdf. Accessed September 26, 2022.
3. Mumford AD, Ackroyd S, Alikhan R, et al. Guideline for the diagnosis and management of the rare coagulation disorders: a United Kingdom Haemophilia Centre Doctors' Organization guideline on behalf of the British Committee for Standards in Haematology. *Br J Haematol*. 2014;167(3):304-26.
4. AHFS DI (Adult and Pediatric) [database online]. Bethesda, MD. American Society of Health System Pharmacists, Inc. Electronic version. Updated March 28, 2022. Available with subscription. URL: http://online.lexi.com/lco. Accessed September 26, 2022.