PRIOR AUTHORIZATION POLICY

POLICY: Hematology – Corifact Prior Authorization Policy
- Corifact® (Factor XIII Concentrate [human] intravenous infusion – CSL Behring)

REVIEW DATE: 12/04/2024

OVERVIEW
Corifact, a Factor XIII concentrate, is indicated in congenital Factor XIII deficiency in adult and pediatric patients for:[1]
- **Peri-operative management** of surgical bleeding.
- **Routine prophylactic** treatment.

Disease Overview
Congenital Factor XIII deficiency is caused by defects in both Factor XIIIA and Factor XIIIB genes.[2,3] However, most cases are due to genetic alterations on the Factor XIIIA gene. The estimated prevalence of Factor XIIIA deficiency is one case in 2 million patients. Clinical symptoms include delayed wound healing, bleeding of soft and subcutaneous tissue, recurrent spontaneous miscarriage, and central nervous system (CNS) bleeding, which may be life-threatening. If patients have severe Factor XIII deficiency, early manifestations include bleeding from the umbilical cord or CNS. Prospective data showed that a level of 30% Factor XIII clotting activity is an adequate therapeutic target for most patients. Treatment of Factor XIII deficiency involves use of fresh frozen plasma, cryoprecipitate, Corifact, or Tretten® (coagulation Factor XIIIA-Subunit [recombinant] intravenous infusion).

Guidelines
The National Bleeding Disorders Foundation Medical and Scientific Advisory Council has guidelines for the treatment of hemophilia and other bleeding disorders (revised October 2024).[4] Corifact is recommended in patients who have Factor XIII deficiency.

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Corifact. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Corifact as well as the monitoring required for adverse events and long-term efficacy, approval requires Corifact to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Corifact is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Congenital Factor XIII Deficiency.** Approve for 1 year if the agent is prescribed by or in consultation with a hematologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Corifact is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Corifact® intravenous infusion [prescribing information]. Kankakee, IL: CSL Behring; September 2020.
2. Mangla A, Hamad H, Killeen RB, et al. Factor XIII Deficiency. [Updated 2024 Feb 12]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK557467/.
3. Pelcovits A, Schiffman F, Niroula R. Factor XIII deficiency: a review of clinical presentation and management. *Hematol Oncol Clin North Am*. 2021;35(6):1171-1180.
4. National Bleeding Disorders Foundation. MASAC (Medical and Scientific Advisory Council) recommendations concerning products licensed for the treatment of hemophilia and selected disorders of the coagulation system (October 2024). MASAC Document #290. Available at: https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed on November 27, 2024.