

Corifact® (factor XIII concentrate [human])

Tretten® (coagulation factor XIII A-subunit [recombinant])

When requesting Corifact or Tretten, the individual requiring treatment must be diagnosed with one of the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

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

Tretten is indicated for routine prophylaxis of bleeding in patients with congenital factor XIII-A subunit deficiency.

Coverage Guidelines

Corifact

- The request is for routine prophylaxis of bleeding or perioperative management of surgical bleeding in individuals with congenital Factor XIII deficiency.

Tretten

- The request is for routine prophylaxis of bleeding in individuals with congenital Factor XIII deficiency.
- The individual has factor XIII A-subunit deficiency.

Approval duration (initial): 3 months

Approval duration (renewal): 12 months

Dosing Recommendations

For intravenous use only

Corifact

The recommended dose is 40 IU per kg. Dose adjustment can be made +/- 5 IU per kg to maintain 5% to 20% trough level of FXIII activity. For routine prophylaxis, dose is administered every 28 days. For peri-operative management of surgical bleeding, dose should be individualized based on the patient's Factor XIII activity level, type of surgery, and clinical response.

Tretten

The recommended dose is 35 IU per kg once monthly to achieve a target trough level of FXIII activity at or above 10%. Dose adjustment can be considered if adequate coverage is not achieved with the recommended 35 IU/kg dose.

References

1. Corifact prescribing information. Kankakee, IL; CSL Behring LLC. September 2020.
2. Tretten prescribing information. Plainsboro, NJ; Novo Nordisk Inc. June 2020.
3. Factor XIII A-subunit (recombinant) (Tretten®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. [Updated; March 26, 2024; Accessed August 2, 2024].
4. Factor XIII concentrate (human) (Corifact®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. [Updated; July 23, 2024; Accessed August 2, 2024].

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