

## PRIOR AUTHORIZATION POLICY

**POLICY:** Hematology – Tretten Prior Authorization Policy

- Tretten® (coagulation Factor XIII A-Subunit [recombinant] intravenous infusion – NovoNordisk)

**REVIEW DATE:** 12/04/2024

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### OVERVIEW

Tretten, a coagulation Factor XIII A-Subunit, is indicated for routine prophylaxis of bleeding in congenital factor XIII A-subunit deficiency.<sup>1</sup> The agent is not indicated for use in patients with congenital Factor XIII B-subunit deficiency.

### Disease Overview

Congenital Factor XIII deficiency is caused by defects in both Factor XIII<sub>A</sub> and Factor XIII<sub>B</sub> genes.<sup>2,3</sup> However, most cases are due to genetic alterations on the Factor XIII<sub>A</sub> gene. The estimated prevalence of Factor XIII<sub>A</sub> deficiency is one case in 1 to 2 million people. 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® (Factor XIII concentration intravenous infusion), or Tretten.

### 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).<sup>4</sup> Tretten is recommended in patients who have factor XIII deficiency who lack the factor XIII-A subunit. It will not work in patients who only lack factor XIII-B subunit.

### POLICY STATEMENT

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

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tretten is recommended for patients who meet the following criteria:

12/04/2024

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### **FDA-Approved Indication**

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

### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Tretten is not recommended in the following situations:

1. **Congenital Factor XIII B-Subunit Deficiency.** Tretten will not work in patients who only lack Factor XIII-B subunit.<sup>1,2</sup>
2. 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. Tretten® intravenous infusion [prescribing information]. Plainsboro, NJ: Novo Nordisk; June 2020.
2. Mangla A, Hamad H, Killeen RB, Kumar A. Factor XIII Deficiency. 2024 Feb 12. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. PMID: 32491399.
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.