

# Specialty Guideline Management

## Tretten

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tretten	coagulation Factor XIII A-Subunit [recombinant]

### 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 Indications<sup>1</sup>

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

Tretten is not for use in patients with congenital factor XIII B-subunit deficiency.

All other indications are considered experimental/investigational and not medically necessary.

### Coverage Criteria

#### Congenital Factor XIII A-Subunit Deficiency<sup>1-2</sup>

Authorization of 12 months may be granted for prophylaxis of bleeding in members with congenital factor XIII A-subunit deficiency.

Reference number(s)
2985-A

# Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

## References

1. Tretten [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; June 2020.
2. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised April 2024. MASAC Document #284. <https://www.bleeding.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf>. Accessed October 16, 2024.