Reference number(s)
5002-A

Standard Medicare Part B 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[1]

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

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

Coverage Criteria

Congenital Factor XIII A-Subunit Deficiency[1-2]

Authorization of 12 months may be granted for prophylactic treatment of congenital factor XIII A-subunit deficiency.

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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:

- The member is currently receiving therapy with the requested medication.
- Tretten is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy (e.g., reduced frequency or severity of bleeds).

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Tretten.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service-Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- MASAC recommendations concerning products licensed for the treatment of hemophilia and selected disorders of the coagulation system.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Tretten are covered.

Explanation of Rationale

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

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 October 2024. MASAC Document #290. https://www.bleeding.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed October 10, 2025.

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