Clinical Policy: Factor XIII A-Subunit (Recombinant - Tretten)

Reference Number: PA.CP.PHAR.222
Effective Date: 01/2018
Last Review Date: 01/2025

Description
Factor XIII A-subunit, recombinant (Tretten®) is a recombinant factor XIII concentrate.

FDA Approved Indication(s)
Tretten is indicated for routine prophylaxis of bleeding in patients with congenital factor XIII A-subunit deficiency.

Limitation(s) of use: Tretten is not for use in patients with congenital factor XIII B-subunit deficiency.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Tretten is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Congenital Factor XIII A-Subunit Deficiency (must meet all):

1. Diagnosis of congenital factor XIII A-subunit deficiency;
2. Prescribed by or in consultation with a hematologist;
3. Request is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Congenital Factor XIII A-Subunit Deficiency (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy.

Approval duration: 6 months

B. Other diagnoses/indications (1, 2 or 3)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.PHARM.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53
3. Member does not have congenital factor XIII B-subunit deficiency.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53;

B. Congenital factor XIII B-subunit deficiency.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to the active substance or to any of the excipients
- Boxed warning(s): none reported

Appendix D: General Information

- Serious bleeding episodes include bleeds in the following sites: intracranial; neck/throat; gastrointestinal; joints (hemarthrosis); muscles (especially deep compartments such as the iliopsoas, calf, forearm); or mucous membranes of the mouth, nose and genitourinary tract.
- Spontaneous bleed is defined as a bleeding episode that occurs without apparent cause and is not the result of trauma.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Routine bleeding prophylaxis	35 IU/kg IV once monthly to achieve a target trough level of Factor XIII activity ≥ 10%. Consider dose adjustment if adequate coverage is not achieved with the 35 IU/kg dose.	Individualized

VI. Product Availability

Powder for reconstitution in single-use vial: 2,000 to 3,125 IU (*the actual amount of Tretten in international units is stated on each carton and vial; may vary for each vial*)

VII. References

1. Tretten Prescribing Information. Plainsboro, NJ: Novo Nordisk; June 2020. Available at http://www.novo-pi.com/tretten.pdf. Accessed October 29, 2024.
2. Srivastava A, Santagostino E, Dougall A, et al. WFH guidelines for the management of hemophilia. *Haemophilia.* 2020;26(suppl 6):1-158.
3. Medical and Scientific Advisory Council (MASAC) of the National Bleeding Disorders Foundation (formerly National Hemophilia Foundation): Database of treatment guidelines. Available at https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents. Accessed November 18, 2024.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7181	Injection, factor XIII A-subunit, (recombinant), per IU

Reviews, Revisions, and Approvals	Date
Referenced reviewed and updated.	02/2018
1Q 2019 annual review: references reviewed and updated.	01/2019
1Q 2020 annual review: references reviewed and updated.	01/2020
Added Appendix D: General Information	07/2020
1Q 2021 annual review: enhanced existing requirement for A-subunit disease by excluding coverage for B-subunit disease in section II B; references reviewed and updated.	01/2021
1Q 2022 annual review: enhanced existing requirement for A-subunit disease by excluding coverage for B-subunit disease in section III; references reviewed and updated.	01/2022
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023
1Q 2024 annual review: updated sites of serious bleeds per WFH guideline in Appendix D; references reviewed and updated.	01/2024
1Q 2025 annual review: no significant changes; references reviewed and updated.	01/2025