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

Reference Number: PA.CP.PHAR.222
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

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
It is the policy of Pennsylvania Health and 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. Prescribed by or in consultation with a hematologist;
2. Diagnosis of congenital factor XIII A-subunit deficiency;
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 Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy.

Approval duration: 6 months

B. Other diagnoses/indications (1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

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

2. Refer to PA.CP.PMN.53

Background
Description/Mechanism of Action:
Factor XIII is the terminal enzyme in the blood coagulation cascade. When activated by thrombin at the site of vessel wall injury, factor XIII plays an important role in the maintenance of hemostasis through crosslinking of fibrin and other proteins in the fibrin clot. The A-subunit is involved, along with thrombin, in the activation of factor XIII.

III. 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

IV. 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

V. Product Availability

Powder for reconstitution in single-use vial: nominally 2,500 IU/vial (2,000 – 3,125 IU)

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	Approval Date
Referenced reviewed and updated.	02/18	
1Q 2019 annual review: references reviewed and updated.	01/19	

References

1. Tretten Prescribing Information. Plainsboro, NJ: Novo Nordisk; November 2016. Available at http://www.novo-pi.com/tretten.pdf. Accessed November 8, 2018.
2. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. *Haemophilia.* Jan 2013; 19(1): e1-47.
3. Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations. Accessed September 26, 2018.