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

Reference Number: LA.PHAR.222
Effective Date: **Revision Log**
Last Review Date: 06.21
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

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

Prior authorization is required. 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 Louisiana Healthcare Connections 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;**
4. **For routine prophylaxis requests, member meets one of the following (a or b):**
   a. **Member has severe hemophilia (defined as factor level of < 1%);**
   b. **Member has experienced at least one life-threatening or serious spontaneous bleed (*see Appendix D*).**

Approval duration: 6 months

B. Other diagnoses/indications

1. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

II. Continued Therapy

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

1. **Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;**
2. **Member is responding positively to therapy.**

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.**
   Approval duration: Duration of request or 6 months (whichever is less); or
2. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

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 – LA.PMN.53 for Medicaid, or evidence of coverage documents;**
B. **Member does not have 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

- **Life-threatening bleeding episodes include, but are not limited to, bleeds in the following sites: intracranial, neck/throat, or gastrointestinal.**
- **Serious bleeding episodes include bleeds in the following site: joints (hemarthrosis).**
- **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%.	Individualized

Indication	Dosing Regimen	Maximum Dose
	Consider dose adjustment if adequate coverage is not achieved with the 35 IU/kg dose.	

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 December 1, 2020.
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 December 1, 2020.

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
Converted corporate to local policy	06.2021

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any

external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.