

# Hemophilia Products – Coagulation Factor XIII A-subunit: Tretten® (Intravenous)

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## I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 3 months (90 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

*Note: The cumulative amount of medication the member has on-hand will be taken into account for authorizations. Up to 5 'on-hand' doses for the treatment of acute bleeding episodes will be permitted at the time of the authorization request.*

## II. Dosing Limits

**Max Units (per dose and over time) [HCPCS Unit]:**

- 4,025 billable units per 28-day supply

## III. Initial Approval Criteria <sup>1-3,7</sup>

| Hemophilia Management Program                                                                                                                                                                                                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Requirements for half-life study and inhibitor tests are a part of the hemophilia management program. This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. |

Prior authorization validity is provided in the following conditions:

### **Congenital Factor XIII A-subunit deficiency † Φ**

- Diagnosis of congenital factor XIII A-subunit deficiency has been confirmed by blood coagulation testing; **AND**
- Used for routine prophylaxis of bleeding

| Hemophilia Management Program                                                                                                                                                                                                                        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• If the request is for routine prophylaxis and the requested dose exceeds dosing limits under part II, a half-life study should be performed to determine the appropriate dose and dosing interval.</li></ul> |

- For members with a BMI  $\geq 30$ , a half-life study should be performed to determine the appropriate dose and dosing interval.
- For minimally treated members (< 50 exposure days to factor products) previously receiving a different factor product, inhibitor testing is required at baseline, then at every comprehensive care visit (yearly for the mild and moderate members, semi-annually for the severe members)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

#### IV. Dispensing Requirements for Rendering Providers (Hemophilia Management Program)

- Prescriptions cannot be filled without an expressed need from the member, caregiver, or prescribing practitioner. Auto-filling is not allowed.
- Monthly, rendering provider must submit for authorization of dispensing quantity before delivering factor product. Information submitted must include:
  - Original prescription information, requested amount to be dispensed, vial sizes available to be ordered from the manufacturer, and member clinical history (including member product inventory and bleed history)
  - Factor dose should not exceed +1% of the prescribed dose and a maximum of three vials may be dispensed per dose. If unable to provide factor dosing within the required threshold, below the required threshold, the lowest possible dose able to be achieved above +1% should be dispensed. Prescribed dose should not be increased to meet assay management requirements.
- The cumulative amount of medication(s) the member has on-hand should be taken into account when dispensing factor product. Members should not have more than 5 extra doses on-hand for the treatment of acute bleeding episodes.
- Dispensing requirements for rendering providers are a part of the hemophilia management program. This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide.

#### V. Renewal Criteria <sup>1-3,7</sup>

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of allergic-anaphylactic reactions (anaphylaxis, wheezing, rash, urticaria, tightness of the chest, hypotension, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (i.e., weight gain, half-life study results, increase in breakthrough bleeding when member is fully adherent to therapy, etc.); **AND**

- The cumulative amount of medication(s) the member has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**

### **Routine prophylaxis of bleeding**

- Member has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

## **VI. Dosage/Administration <sup>1-3</sup>**

| Indication                                                                                  | Dose                                                                                                                                                                     |
|---------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Routine prophylaxis of bleeding in members with congenital factor XIII A-subunit deficiency | Administer 35 international units (IU) per kilogram body weight once monthly to achieve a target trough level of FXIII activity at or above 10% using a validated assay. |

## **VII. Billing Code/Availability Information**

HCPCS Code & NDC:

| Drug    | Manufacturer | HCPCS Code | 1 Billable Unit Equiv. | Vial Size      | NDC           |
|---------|--------------|------------|------------------------|----------------|---------------|
| Tretten | Novo Nordisk | J7181      | 1 IU                   | 2,000-3,125 IU | 00169-7013-xx |

## **VIII. References**

1. Tretten [package insert]. Bagsvaerd, Denmark; Novo Nordisk; June 2020. Accessed April 2026.
2. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised October 2, 2024. National Hemophilia Foundation. MASAC Document #290. Available at: <http://www.bleeding.org>. Accessed April 2026.
3. Guidelines for the Management of Hemophilia. 3<sup>rd</sup> Edition. World Federation of Hemophilia 2020. Available at: <https://www1.wfh.org/publications/files/pdf-1863.pdf>.
4. Graham A, Jaworski K. Pharmacokinetic analysis of anti-hemophilic factor in the obese patient. Haemophilia. 2014 Mar;20(2):226-9.
5. Croteau SE, Neufeld EJ. Transition considerations for extended half-life factor products. Haemophilia. 2015 May;21(3):285-8.
6. Mingot-Castellano ME, Diaz-Canales D, Tamayo-Bermejo R, Heiniger-Mazo AI. Application of Pharmacokinetics Programs in Optimization of Haemostatic Treatment in Severe Hemophilia a Patients: Changes in Consumption, Clinical Outcomes and Quality of Life. Blood. 2014 December; 124 (21).
7. MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B with and without Inhibitors. Revised April 27, 2022. National Hemophilia Foundation. MASAC Document #267. Available at: <http://www.bleeding.org>. Accessed April 2026.

8. Rayment R, Chalmers E, Forsyth K, et al. Guidelines on the use of prophylactic factor replacement for children and adults with Haemophilia A and B. *B J Haem*:190;5,Sep 2020. <https://doi.org/10.1111/bjh.16704>.
9. Palmetto GBA. Local Coverage Article: Billing and Coding: Guidance for Anti-Inhibitor Coagulant Complex (AICC) National Coverage Determination (NCD) 110.3 (A56065). Centers for Medicare & Medicaid Services Inc. Updated on 11/14/2022 with effective date 11/24/2022. Accessed April 2026.

## Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

| Factor                     | Conclusion            |
|----------------------------|-----------------------|
| Indication                 | Yes: Consider for PA  |
| Safety and efficacy        | No: PA not a priority |
| Potential for misuse/abuse | No: PA not a priority |
| Cost of drug               | Yes: Consider for PA  |

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description                              |
|--------|-------------------------------------------------|
| D68.2  | Hereditary deficiency of other clotting factors |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

| Medicare Part B Covered Diagnosis Codes |                          |              |
|-----------------------------------------|--------------------------|--------------|
| Jurisdiction                            | NCD/LCA/LCD Document (s) | Contractor   |
| J,M                                     | A56065                   | Palmetto GBA |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |                                                                                             |                                                   |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------|---------------------------------------------------|
| Jurisdiction                                                  | Applicable State/US Territory                                                               | Contractor                                        |
| E (1)                                                         | CA, HI, NV, AS, GU, CNMI                                                                    | Noridian Healthcare Solutions, LLC                |
| F (2 & 3)                                                     | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ                                                      | Noridian Healthcare Solutions, LLC                |
| 5                                                             | KS, NE, IA, MO                                                                              | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6                                                             | MN, WI, IL                                                                                  | National Government Services, Inc. (NGS)          |
| H (4 & 7)                                                     | LA, AR, MS, TX, OK, CO, NM                                                                  | Novitas Solutions, Inc.                           |
| 8                                                             | MI, IN                                                                                      | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9)                                                         | FL, PR, VI                                                                                  | First Coast Service Options, Inc.                 |
| J (10)                                                        | TN, GA, AL                                                                                  | Palmetto GBA                                      |
| M (11)                                                        | NC, SC, WV, VA (excluding below)                                                            | Palmetto GBA                                      |
| L (12)                                                        | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                           |
| K (13 & 14)                                                   | NY, CT, MA, RI, VT, ME, NH                                                                  | National Government Services, Inc. (NGS)          |
| 15                                                            | KY, OH                                                                                      | CGS Administrators, LLC                           |