Hemophilia Products – Coagulation Factor XIII A-subunit: Tretten®
(Intravenous)
Effective date: 10/1/2019
Review date: 1/29/2020, 7/15/2021
Revision date: 1/29/2020, 7/15/2021
Scope: Medicaid*, Commercial*, Medicare-Medicaid Plan (MMP)
*(Medication only available on the Medical Benefit)

I. Length of Authorization

Unless otherwise specified*, the initial authorization will be provided for 3 months and may be renewed for a period of 12 months.

* Initial and renewal authorization periods may vary by specific covered indication

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]: N/A

B. Max Units (per dose and over time) [Medical Benefit]:

- 4,025 billable units per 28 day supply

III. Initial Approval Criteria

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.

A. Tretten

Coverage is provided in the following conditions:

- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

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

- 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.
- For members with a BMI ≥ 30, a half-life study should be performed to determine the appropriate dose and dosing interval.
- For minimally treated patients (< 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 patients, semi-annually for the severe patients).

† FDA Approved Indication(s) ☐ Orphan Drug

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

- Prescriptions cannot be filled without an expressed need from the patient, 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 patient clinical history (including patient 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 patient has on-hand should be taken into account when dispensing factor product. Patients should not have more than 5 extra doses on-hand for the treatment of acute bleeding episodes.
- Dispensing requirements for renderings 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

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, 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 patient is fully adherent to therapy, etc.); AND
• The cumulative amount of medication(s) the patient 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

Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episode

• Renewals will be approved for a 12 month authorization period; AND
• Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

VI. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
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<tbody>
<tr>
<td>Routine prophylaxis for bleeding</td>
<td>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.</td>
</tr>
<tr>
<td>Congenital factor XIII A-subunit deficiency</td>
<td></td>
</tr>
</tbody>
</table>

VII. Billing Code/Availability Information

HCPCS & NDC:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Manufacturer</th>
<th>J-Code</th>
<th>1 Billable Unit Equiv.</th>
<th>Vial Size</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tretten</td>
<td>Novo Nordisk</td>
<td>J7181</td>
<td>1 IU</td>
<td>Unassigned size</td>
<td>00169-7013</td>
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</table>

VIII. References


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D68.2</td>
<td>Hereditary deficiency of other clotting factors</td>
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</table>

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

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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): H, L  
NCD/LCD Document (s): L35111  

Jurisdiction(s): N  
NCD/LCD Document (s): L33684  

Medicare Part B Administrative Contractor (MAC) Jurisdictions

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
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<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>Jurisdiction</td>
<td>Applicable State/US Territory</td>
<td>Contractor</td>
</tr>
<tr>
<td>--------------</td>
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</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>H (4 &amp; 7)</td>
<td>LA, AR, MS, TX, OK, CO, NM</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>8</td>
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<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>N (9)</td>
<td>FL, PR, VI</td>
<td>First Coast Service Options, Inc.</td>
</tr>
<tr>
<td>J (10)</td>
<td>TN, GA, AL</td>
<td>Palmetto GBA, LLC</td>
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<tr>
<td>M (11)</td>
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<tr>
<td>L (12)</td>
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<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>K (13 &amp; 14)</td>
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<td>National Government Services, Inc. (NGS)</td>
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<tr>
<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
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