SPECIALTY GUIDELINE MANAGEMENT

TRETTEN (coagulation factor XIII A-subunit [recombinant])

POLICY

A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

- Congenital Factor XIII A-Subunit Deficiency
  - Tretten is indicated for routine prophylaxis of bleeding in patients with congenital factor XIII A-subunit deficiency.

Tretten is not approved for use in patients with congenital Factor XIII B-subunit deficiency.

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- Laboratory documentation of the following (where applicable):
  - Specific factor XIII assay (e.g., enzyme-linked immunosorbent assay [ELISA])
  - Genotyping
  - Factor XIII assay prior to and following administration of a test dose of Tretten

C. CRITERIA FOR APPROVAL

1. Congenital Factor XIII A-Subunit Deficiency

a. Indefinite authorization may be granted to members who are prescribed Tretten for congenital factor XIII A-subunit deficiency confirmed by EITHER of the following:
   i. Specific Factor XIII assay(s) AND genotyping; OR
   ii. An increase in factor XIII activity following administration of a test dose of Tretten

b. Authorization of 1 month may be granted to members for administration of a test dose of Tretten.

D. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

E. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

REFERENCES

1. Tretten [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; April 2014.
2. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised August 2015. MASAC Document # 237. https://www.hemophilia.org/sites/default/files/document/files/230Text2014-09.pdf. Accessed December 3, 2014.
3. Fadoo Z, Merchant Q, Rehman KA. New developments in the management of congenital Factor XIII deficiency. *J Blood Med.* 2013;4:65-73.
4. Kohler HP, Ichinose A, Seitz R, et al. Diagnosis and classification of factor XIII deficiencies. *J Thromb Haemost.* 2011;9(7):1404-6.
5. Hsieh L, Nugent D. Factor XIII deficiency. *Haemophilia.* 2008;14:1190-1200.
6. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Factor XIII Agents; January 2014.