SPECIALTY GUIDELINE MANAGEMENT

TRETENN (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