

SPECIALTY GUIDELINE MANAGEMENT

TRETTEEN (coagulation Factor XIII A-Subunit [recombinant])

POLICY

I. 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

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

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

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Congenital Factor XIII A-Subunit Deficiency

Authorization of 12 months may be granted for prophylaxis of bleeding in members with congenital factor XIII A-subunit deficiency.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

IV. REFERENCES

1. Tretten [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; June 2020.
2. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised March 2022. MASAC Document #272. https://www.hemophilia.org/sites/default/files/document/files/272_Treatment.pdf. Accessed October 4, 2022.