



# Coagulation Factor XIII A-Subunit, recombinant (Tretten®) COMMERCIAL POLICY

Policy Type: PA/SP

Pharmacy Coverage Policy: COMM335

## Description

Coagulation Factor XIII A-Subunit, Recombinant (Tretten) works by replacing the missing coagulation factor XIII A-subunit in people with congenital Factor XIII A-subunit deficiency. It helps maintain the body's FXIII activity levels, helping to make clots stronger and less likely to dissolve.

## Length of Authorization

- Initial: 12 months
- Renewal: 12 months

## Quantity limits

Product Name	Dosage Form	Indication/FDA Labeled Dosing	Quantity Limit
Coagulation Factor XIII A-Subunit, Recombinant (Tretten)	2000-3125 units/vial	<b>Factor XIII A-subunit deficiency:</b> <b>Routine prophylaxis</b> 35 IU/kg once monthly to achieve a target trough level of FXIII activity at or above 10%	4,025 IU/28 days

For medical unit guidance, please see appendix

## Initial Evaluation

- I. **Coagulation Factor XIII A-Subunit, Recombinant (Tretten)** may be considered medically necessary when the following criteria below are met:
  - A. Treatment is prescribed by, or in consultation with a hematologist; **AND**
  - B. A diagnosis of **congenital Factor XIII A-subunit deficiency** when the following are met:
    1. Diagnosis confirmed by blood coagulation testing; **AND**
    2. Used for routine prophylaxis of bleeding
- II. Coagulation Factor XIII A-Subunit, Recombinant (Tretten) is considered investigational when used for all other conditions.

## Renewal Evaluation

- I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
- II. 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.) as verified by a Moda Health pharmacist; **AND**
- III. Used for routine prophylaxis to reduce the frequency of bleeding episodes; **AND**
- IV. Prescriber attestation that the patient has demonstrated a clinical benefit with therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

## Supporting Evidence

- I. Coagulation Factor XIII A-Subunit, Recombinant (Tretten) is indicated for the prevention of bleeding episodes in patients with congenital Factor XIII A-subunit deficiency.
- II. For routine prophylaxis, Coagulation Factor XIII A-Subunit, Recombinant (Tretten) should be administered once monthly. The starting dose is 35 international units (IU) per kg body weight with a target of achieving a trough level of FXIII activity at or above 10%. Dose adjustments may be necessary if adequate coverage is not achieved with the recommended 35 IU/kg dose.

## Investigational or Not Medically Necessary Uses

- I. There is no evidence to support the use of coagulation Factor XIII A-Subunit, Recombinant (Tretten) in any other condition.

## References

1. Tretten [package insert]. Bagsvaerd, Denmark; Novo Nordisk; June 2020. Accessed January 2026.

## Appendix

HCPSC Code:	Medication:	Unit Conversion:
J7180	Factor XIII concentrate, human (Corifact)	1 IU = 1 billing unit (1:1 conversion)*

\*Current billing unit conversion as of 01/2026. This is subject to change pending new information.

## Policy Implementation/Update:

Action and Summary of Changes	Date
New Policy	01/2026