Reference number(s)
4036-A

JURISDICTION SPECIFIC MEDICARE PART B

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

POLICY

I. COVERED USES

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

Routine prophylaxis for bleeding in patients with congenital factor XIII A-subunit deficiency

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available in a legible format with patient identification information (e.g., complete name and dates of service and signature of physician or non-physician practitioner responsible for and providing care to the member, upon request, for all submissions:

A. The submitted medical record must support the use of the selected ICD-10-CM codes. The submitted CPT/HCPCS code must describe the service performed.
B. The medical record documentation shows the patient has a congenital factor XIII A-subunit deficiency.
C. The medical record documentation must support the medical necessity of the services as stated in this policy.

III. CRITERIA FOR APPROVAL

Congenital Factor XIII A-Subunit Deficiency
Authorization of 12 months may be granted for prophylactic treatment of documented congenital factor XIII A-subunit deficiency.

IV. REFERENCES

1. Hemophilia Factor Products LCD (L35111) Version R16. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed July 1, 2020.
2. Billing and Coding: Hemophilia Factor Products (A56433) Version R2. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed July 1, 2020.
3. Tretten [package insert]. Plainsboro, NJ: Novo Nordisk, Inc.; June 2020.

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