

JURISDICTION SPECIFIC MEDICARE PART B

COAGADEX (coagulation factor X [human])

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.

Coagadex is indicated in adults and children with hereditary factor X deficiency for:

- A. Routine prophylaxis to reduce the frequency of bleeding episodes
- B. On-demand treatment and control of bleeding episodes
- C. Perioperative management of bleeding in patients with mild and moderate hereditary factor X 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 must support the medical necessity of the services as stated in this policy and the member has a factor X deficiency.

III. CRITERIA FOR APPROVAL

Hereditary Factor X Deficiency

- A. Authorization of 12 months may be granted for prophylaxis to reduce the frequency of bleeding episodes due to hereditary factor X deficiency.
- B. Authorization of 12 months may be granted for on-demand treatment and control of bleeding episodes due to hereditary factor X deficiency.
- C. Authorization of 1 month may be granted for perioperative management of bleeding in members with mild or moderate hereditary factor X 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.

Reference number(s)
4027-A

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. Coagadex [package insert]. Durham, NC: BPL USA, Inc.; September 2018.