

# 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

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1. Hemophilia Factor Products LCD (L35111) Version R16. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed October 25, 2021.
2. Billing and Coding: Hemophilia Factor Products (A56433) Version R7. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed October 25, 2021.
3. Coagadex [package insert]. Durham, NC: BPL USA, Inc.; September 2018.