SPECIALTY GUIDELINE MANAGEMENT

COAGADEX (coagulation Factor X [human])

POLICY

A. 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**
- Hereditary Factor X deficiency
  - Coagadex is a plasma-derived human blood coagulation Factor indicated in adults and children (aged 12 years and above) with hereditary Factor X deficiency for:
    - On-demand treatment and control of bleeding episodes
    - Perioperative management of bleeding in patients with mild hereditary Factor X deficiency.

*Limitation of Use:*
Perioperative management of bleeding in major surgery in patients with moderate and severe hereditary Factor X deficiency has not been studied.

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
- Baseline factor X assay level (% activity) in members with mild hereditary Factor X deficiency who are requesting Coagadex for perioperative management of bleeding.

C. CRITERIA FOR APPROVAL

1. Hereditary Factor X Deficiency
   a. Authorization for up to 12 months may be granted to members 12 years old or older who are requesting Coagadex for on-demand treatment and control of bleeding episodes.
   b. Authorization of 1 month may be granted to members 12 years old or older with mild hereditary Factor X deficiency (i.e., baseline Factor X assay level ≥ 5%) who are requesting Coagadex for perioperative management of bleeding.

D. CONTINUATION OF THERAPY
All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

E. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

REFERENCES