SPECIALTY GUIDELINE MANAGEMENT

COAGADEX (coagulation Factor X [human])

POLICY

I. 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 Indications
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.

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

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Hereditary Factor X Deficiency
A. Indefinite authorization may be granted for prophylaxis to reduce the frequency of bleeding episodes
B. Indefinite authorization may be granted for on-demand treatment and control of bleeding episodes.
C. Authorization of 1 month may be granted for perioperative management of bleeding in members with mild or moderate hereditary Factor X deficiency (i.e., baseline Factor X assay level ≥ 1%).

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES
