

## 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  $\geq 5\%$ ) 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

1. Coagadex [package insert]. Durham, NC: Bio Products Laboratory USA, Inc.; October 2015.
2. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised April 2015. MASAC Document # 235. Accessed October 22, 2015.
3. Mumford AD, Ackroyd S, Alikhan R, et al. Guideline for the diagnosis and management of the rare coagulation disorders: a United Kingdom Haemophilia Centre Doctors' Organization guideline on behalf of the British Committee for Standards in Haematology. *Br J Haematol.* 2014;167(3):304-26.
4. Brown DL, Kouides PA. Diagnosis and treatment of inherited factor X deficiency. *Haemophilia.* 2008;14(6):1176-82.