

## 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 Indication

Coagadex is indicated in adults and children (aged 12 years and above) with hereditary Factor X deficiency for:

- A. On-demand treatment and control of bleeding episodes
- B. 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.

##### II. CRITERIA FOR INITIAL APPROVAL

##### **Hereditary Factor X Deficiency**

- A. Indefinite authorization may be granted for on-demand treatment and control of bleeding episodes.
- B. Authorization of 1 month may be granted for perioperative management of bleeding in members with mild disease (i.e., baseline Factor X assay level  $\geq 5\%$ ).

##### III. CONTINUATION OF THERAPY

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

##### IV. 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 October 2016. MASAC Document # 246. Accessed December 1, 2016.
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.