POLICY: Hematology – Coagadex® (coagulation Factor X [human] injection for intravenous use – BPL)

APPROVAL DATE: 09/11/2019

OVERVIEW
Coagadex, a plasma-derived coagulation Factor X product, is indicated for use in adults and children with hereditary Factor X deficiency for: 1) routine prophylaxis to reduce the frequency of bleeding episodes; 2) on-demand treatment and control of bleeding episodes; and 3) perioperative management of bleeding in patients with mild and moderate hereditary Factor X deficiency.¹

Disease Overview
Factor X deficiency, a rare autosomal recessive inherited bleeding disorder that affects approximately 1 in 500,000 to 1,000,000 patients worldwide.²,³ The Factor X protein has a key role in activating the enzymes that are key in clot formation. In this condition, blood does not clot properly. Patients experience easy bruising, nose or mouth bleeds and bleeding after trauma or surgery. Among patients with severe Factor X deficiency, umbilical cord bleeding can be one of the first signs; however, bleeding may present at any time. Serious bleeds include spontaneous head bleeds, spinal cord bleeds, and gastrointestinal bleeds. Women who have the condition may experience heavy menstrual bleeding or have menorrhagia. During pregnancy, women may miscarry during the first trimester or have other complications during labor and delivery. However, Factor X deficiency has an equal prevalence in men and women. It is recommended to maintain trough levels of around 20% to 30%. Other treatments include fresh frozen plasma, prothrombin complex concentrates, and Corifact.

Guidelines
The National Hemophilia Foundation Medical and Scientific Advisory Council has guidelines for the treatment of hemophilia and other bleeding disorders (revised April 2018).⁴ Coagadex is recommended in patients who have Factor X deficiency.⁵

Dosing Considerations
Dosing of clotting factor concentrates is highly individualized. MASAC provides recommendations regarding doses of clotting factor concentrate in the home (2016).⁵ The number of required doses varies greatly and is dependent on the severity of the disorder and the prescribed regimen. Per MASAC guidance, patients on prophylaxis should also have a minimum of one major dose and two minor doses on hand for breakthrough bleeding in addition to the prophylactic doses used monthly. The guidance also notes that an adequate supply of clotting factor concentrate is needed to accommodate weekends and holidays. Therefore, maximum doses in this policy allow for prophylactic dosing plus three days of acute bleeding or perioperative management per 28 days. Doses exceeding this quantity will be reviewed on a case-by-case basis by a clinician.

POLICY STATEMENT
Prior authorization is recommended for medical benefit coverage Coagadex. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the criteria and dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). Because of the specialized skills required for evaluation and diagnosis of patients treated with Coagadex, as well as the monitoring required for adverse events and long-term
efficacy, the agent is required to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**RECOMMENDED AUTHORIZATION CRITERIA**

Coverage of Coagadex is recommended for patients who meet criteria:

**FDA-Approved Indication**

1. **Hereditary Factor X Deficiency.** Approve for 1 year if the agent is prescribed by or in consultation with a hematologist.

   **Dosing.** Approve up to 600 IU/kg by intravenous infusion no more frequently than once every 28 days.

**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

1. **Other Indications.** Coverage is not recommended for circumstances not listed in the Authorization Criteria. Criteria will be updated as new published data are available.

**REFERENCES**


**HISTORY**

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