PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/09/2020

OVERVIEW

Coagadex, a plasma-derived coagulation Factor X product, is indicated for use in adults and children with hereditary Factor X deficiency for:[1]

- **On-demand treatment and control** of bleeding episodes.
- **Perioperative management** of bleeding in patients with mild and moderate hereditary Factor X deficiency.
- **Routine prophylaxis** to reduce the frequency of bleeding episodes.

Disease Overview

Factor X deficiency, a rare autosomal recessive inherited bleeding disorder the affects approximately 1 in 500,000 to 1,000,000 patients worldwide.[2] The Factor X protein has a key role to assist 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 Coagadex.

Guidelines

The National Hemophilia Foundation Medical and Scientific Advisory Council has guidelines for the treatment of hemophilia and other bleeding disorders (revised February 2020).[3] Coagadex is recommended in patients who have Factor X deficiency.[3]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Coagadex. All approvals are provided for the duration noted below. 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, approval requires Coagadex to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Coagadex is recommended in those who meet the following 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Coagadex is recommended in those who meet the following criteria:

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

REFERENCES

1. Coagadex® injection for intravenous use [prescribing information]. Plainsboro, NJ: Noro Nordisk; November 2018.
2. Menegatti M, Peyvandi F. Treatment of rare factor deficiencies other than hemophilia. *Blood*. 2019;133(5):415-424.
3. National Hemophilia Foundation. MASAC (Medical and Scientific Advisory Council) recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders (Revised February 2020). MASAC Document #259. Adopted March 16, 2020. Available at: https://www.hemophilia.org/sites/default/files/document/files/259_treatment.pdf. Accessed on September 4, 2020.