Reference number(s)
4849-A

STANDARD MEDICARE PART B 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, moderate, and severe hereditary Factor X deficiency.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Hereditary Factor X Deficiency
A. Authorization of 12 months may be granted for treatment of hereditary Factor X deficiency when used in either of the following settings:
   1. Prophylaxis to reduce the frequency of bleeding episodes
   2. 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, moderate, or severe hereditary Factor X deficiency.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

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

B. All other indications
Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with the requested medication
2. The requested medication is being used to treat an indication enumerated in Section II
3. The member is receiving benefit from therapy (e.g., reduced frequency or severity of bleeds).

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Coagadex.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. MASAC recommendations concerning products licensed for the treatment of hemophilia and selected disorders of the coagulation system.
4. 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.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Coagadex are covered.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer’s prescribing information.

VI. REFERENCES

1. Coagadex [package insert]. Durham, NC: Bio Products Laboratory USA, Inc.; April 2023.
2. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised August 2023. MASAC Document #280. https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-280-masac-recommendations-concerning-products-licensed-for-the-treatment-of-hemophilia-and-selected-disorders-of-the-coagulation-system. Accessed October 4, 2023.
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.