Reference number(s)
4849-A

Standard Medicare Part B Management Coagadex

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Coagadex	coagulation factor X [human]

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[1]

Coagadex is indicated in adults and children with hereditary Factor X deficiency for:

- Routine prophylaxis to reduce the frequency of bleeding episodes.
- On-demand treatment and control of bleeding episodes.
- 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 listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Coverage Criteria

Hereditary Factor X Deficiency[1-4]

Authorization of 12 months may be granted for treatment of hereditary Factor X deficiency when used in either of the following settings:

- Prophylaxis to reduce the frequency of bleeding episodes
- On-demand treatment and control of bleeding episodes

Authorization of 1 month may be granted for perioperative management of bleeding in members with mild, moderate, or severe hereditary Factor X deficiency.

Continuation of Therapy

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

Perioperative Management of Bleeding

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

All Other Indications

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy (e.g., reduced frequency or severity of bleeds).

Summary of Evidence

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

- The prescribing information for Coagadex.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service-Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

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- MASAC recommendations concerning products licensed for the treatment of hemophilia and selected disorders of the coagulation system.
- 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.

Explanation of Rationale

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

References

1. Coagadex [package insert]. Durham, NC: Bio Products Laboratory USA, Inc.; May 2024.
2. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised October 2024. MASAC Document #290. https://www.bleeding.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed October 10, 2025.
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.

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