Drug Coverage Policy

Effective Date..... 3/1/2026
Coverage Policy Number.....IP0554
Policy Title.....Hematology - Coagadex

Hematology -Coagadex

- Coagadex® (coagulation Factor X [human] intravenous infusion – BPL)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

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

- **On-demand treatment and control** of bleeding episodes.
- **Perioperative management** of bleeding in patients with mild, moderate, and severe 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, affects approximately 1 in 500,000 to 1,000,000 patients worldwide.[2-7] 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 Bleeding Disorders Foundation Medical and Scientific Advisory Council (MASAC) has guidelines for the treatment of hemophilia and other bleeding disorders (revised October 2024).[8] Coagadex is recommended in patients who have Factor X deficiency.

Dosing Considerations
Dosing of clotting factor concentrates is highly individualized. MASAC provides recommendations regarding doses of clotting factor concentrate in the home (2016).[9] 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.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage Coagadex. Approval is required for those who meet the **Criteria** and **Dosing** for the listed indication. 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). 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, the agent is required to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Coagadex is considered medically necessary when the following criteria are met:

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. Up to 600 IU/kg by intravenous infusion no more frequently than once every 28 days

Conditions Not Covered

Coagadex for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J7175	Injection, Factor X, (human), 1 IU

References

1. Coagadex® intravenous infusion [prescribing information]. Fort Lee, NJ: BPL/Kedrion; May 2024.
2. Escobar MA, Kavakli K. Plasma-derived human factor X concentrate for the treatment of patients with hereditary factor X deficiency. *Hemophilia*. 2024;30(1):59-67.
3. Payne J, Batsuli G, Leavitt AD, et al. A review of the pharmacokinetics, efficacy, safety of high-purity factor X for the prophylactic treatment of hereditary factor X deficiency. *Haemophilia*. 2022;28(4):523-531.
4. Menegatti M, Peyvandi F. Treatment of rare factor deficiencies other than hemophilia. *Blood*. 2019;133(5):415-424.
5. Peyvandi F, Auerswald G, Austin SK, et al. Diagnosis, therapeutic advances, and key recommendations for the management of factor X deficiency. *Blood Rev*. 2021 Nov;50:100833.
6. Menegatti M, Peyvandi F. Clinical, laboratory aspects and management of Factor X deficiency. *Semin Thromb Hemost.* 2025;51(2):138-144.
7. Branchford B, Clark K, Stanford RH, et al. Hereditary factor X deficiency in America survey: impact on quality of and burden of disease in patients and caregivers. *Blood Coagul Fibrinolysis*. 2024;35(3):73-81.

8. National Bleeding Disorders Foundation. MASAC (Medical and Scientific Advisory Council) recommendations concerning products licensed for the treatment of hemophilia and selected disorders of the coagulation system (October 2024). MASAC Document #290. Available at: https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed on December 7, 2025.
9. MASAC (Medical and Scientific Advisory Council) recommendations regarding doses of clotting factor concentrate used in the home. MASAC Document #242. Adopted on June 7, 2016. Available at: https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/MASAC-Recommendations-Regarding-Doses-of-Clotting-Factor-Concentrate-in-the-Home. Accessed on December 7, 2025.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	Updated coverage policy title.	5/1/2024
Annual Revision	No criteria changes.	3/1/2025
Annual Revision	**Hereditary Factor X Deficiency.** **Removed** "Documentation of **ONE** of the following: Routine prophylaxis to reduce the frequency of bleeding episodes; Treatment of bleeding episodes; Perioperative management of bleeding in individuals with mild, moderate, and severe hereditary Factor X deficiency	3/1/2026

The policy effective date is in force until updated or retired.