



## Drug Coverage Policy

Effective Date ..... 3/1/2025

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 and have discretion in making individual coverage determinations. 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.

## Medical Necessity Criteria

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

1. **Hereditary Factor X Deficiency.** Individual meets **BOTH** of the following criteria:
  - A. Documentation of **ONE** of the following:
    - i. Routine prophylaxis to reduce the frequency of bleeding episodes
    - ii. Treatment of bleeding episodes
    - iii. Perioperative management of bleeding in individuals with mild, moderate, and severe hereditary Factor X deficiency
  - B. Medication is prescribed by, or in consultation with, hematologist

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

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

## Reauthorization Criteria

Continuation of Coagadex is considered medically necessary for treatment of Hereditary Factor X Deficiency when the above medical necessity criteria are met AND there is documentation of beneficial response.

## Authorization Duration

Initial approval duration: up to 12 months

Reauthorization approval duration: up to 12 months

## Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

## 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

## Background

### 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 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, 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).<sup>8</sup> 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).<sup>9</sup> 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.

## References

1. Coagadex® intravenous infusion [prescribing information]. Durham, NC: BPL; April 2023.
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*. 2024 Aug 29. [Online ahead of print].
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 November 27, 2024.
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 November 27, 2024.

## 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

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

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