

Coagadex® (coagulation factor X [Human])

When requesting Coagadex, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Coagadex is a plasma-derived human blood coagulation factor 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

Coverage Guidelines

Factor X Deficiency (Hereditary)

The individual must meet the following criteria for authorization:

- The request is for treatment of one of the following:
 - o Routine prophylaxis; OR
 - o On demand treatment and control of bleeding episodes; OR
 - o Perioperative management of bleeding;
- Coagadex is prescribed by or in consultation with a hematologist.

Approval duration: 12 months

Dosing Recommendations

For intravenous use only

For prophylaxis of bleeding episodes:

For less than 12 years of age: the recommended initial dose is 40 IU/kg twice weekly.

For 12 years of age or older: the recommended initial dose is 25 IU/kg twice weekly.

For treatment of bleeding episodes:

For less than 12 years of age: the recommended initial dose is 30 IU/kg, repeat at intervals of 24 hours until the bleed stops.

For 12 years of age or older: the recommended initial dose is 25 IU/kg, repeated at intervals of 24 hours until the bleed stops.

For perioperative management:

For less than 12 years of age: the recommended initial dose is to use a factor of 0.6 to calculate the required dose.

Dose (IU) = body weight (kg) x desired factor X rise (IU/dL or % of normal) x 0.6

For 12 years of age or older: the recommended initial dose is to use a factor of 0.5 to calculate the required dose.

Dose (IU) = body weight (kg) x desired factor X rise (IU/dL or % of normal) x 0.5

For pre-surgery: raise plasma Factor X levels to 70-90 IU/dL.

For post-surgery: maintain plasma Factor X levels at ≥ 50 IU/dL until the patient is no longer at risk of bleeding due to surgery.

References

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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 August 8, 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 August 11, 2025.