

Coagadex (coagulation Factor X [human])
Effective 01/01/2026

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange		Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit			<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.			
Contact Information	Medical Benefit Pharmacy Benefit		Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A			

Overview

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 and moderate hereditary Factor X deficiency.

Limitation of Use:

Perioperative management of bleeding in major surgery in patients with severe hereditary Factor X deficiency has not been studied.

All other indications are considered experimental/investigational and not medically necessary.

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when the following criteria is met:

1. Member has a diagnosis of hereditary Factor X deficiency.
2. The requested medication is being used for at least one of the following:
 - a. Reduce the frequency of bleeding episodes
 - b. On-demand treatment and control of bleeding episodes
 - c. Perioperative management of bleeding in members with mild or moderate hereditary Factor X deficiency (i.e., baseline Factor X assay level $\geq 1\%$).

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. **Perioperative management of bleeding**
 - a. Initial criteria are met.

2. All other indications

- a. Member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

Limitations

1. Initial approvals and reauthorizations will be granted for the following:
 - a. Prophylaxis to reduce the frequency of bleeding episodes – 12 months
 - b. On-demand treatment and control of bleeding episodes – 12 months
 - c. Perioperative management of bleeding in members with mild or moderate hereditary Factor X deficiency – 1 month

References

1. Brown DL, Kouides PA. Diagnosis and treatment of inherited factor X deficiency. *Haemophilia*. 2008;14(6):1176-82.
2. Coagadex (coagulation factor X [human] lyophilized powder for solution) [prescribing information]. Fort Lee, NJ: Kedrion Biopharm, Inc.; May 2024.
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. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised April 2022. MASAC Document #272. https://www.hemophilia.org/sites/default/files/document/files/272_Treatment.pdf. Accessed September 26, 2022.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024

05/14/2025 – Reviewed at May P&T. Administrative update – updated Limitations section to clarify approval lengths. Effective 06/01/2025.

10/08/2025 – Reviewed and updated for October P&T. Updated to policy to indicate it no longer applies to the medical benefit. Effective 01/01/2026.

