

**Coagadex (coagulation Factor X [human])**  
**Effective 01/01/2024**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Contact Information</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<b>Exceptions</b>	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 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 to reduce the frequency of bleeding episodes OR for on-demand treatment and control of bleeding episodes OR for 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
**1. Perioperative management of bleeding**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

## 2. All other indications

Reauthorization may be granted for continued treatment in members when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

### Limitations

1. Initial approvals 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
2. Reauthorization for all indications will be granted for 12 months.

### References

1. Coagadex [package insert]. Durham, NC: Bio Products Laboratory USA, Inc.; November 2020.
2. 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](https://www.hemophilia.org/sites/default/files/document/files/272_Treatment.pdf). Accessed September 26, 2022.
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.

### Review History

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

