

Policy Type: PA/SP

Pharmacy Coverage Policy: COMM090

**Description**

Coagulation Factor X, human is a plasma-derived human blood coagulation factor that works by temporarily replacing the missing Factor X needed for effective hemostasis.

**Length of Authorization**

- Initial: 12 months (for on-demand treatment and prophylaxis); one month (for perioperative)
- Renewal: 12 months (for prophylaxis); 6 months (for on-demand)

**Quantity limits**

Product Name	Dosage Form	Indication/FDA Labeled Dosing	Quantity Limit
Coagulation Factor X, human (Coagadex)	250 IU/vial, 500 IU/vial	<p><b>Factor X deficiency:</b></p> <p><b>On-demand treatment</b>                      &lt;12 years: 30 IU/kg/dose                      &gt;12 years: 25 IU/kg/dose                      Repeat every 24 hours until bleeding stops.                      Max of 60 IU/kg/day</p> <p><b>Routine prophylaxis</b>                      &lt;12 years: 40 IU/kg IV twice weekly initially                      &gt;12 years: 25 IU/kg IV twice weekly initially                      Max of 60 IU/kg/day</p> <p><b>Perioperative management</b>                      Max of 60 IU/kg/day</p>	<p><b>On-demand Treatment:</b> Amount requested OR a max of 60 IU/kg/day (<i>whichever value is lower</i>) and no more than 5 on-demand doses on hand</p> <p><b>Routine Prophylaxis:</b>                      480 IU/kg every 28 days</p> <p><b>Perioperative Management:</b>                      Amount requested OR a max of 60 IU/kg/day (<i>whichever value is lower</i>)                      Up to the number of doses requested for 28 days</p>

*For medical unit guidance, please see appendix*

**Initial Evaluation**

- I. **Coagulation Factor X, human (Coagadex)** may be considered medically necessary when the following criteria below are met:
  - A. Treatment is prescribed by, or in consultation with a hematologist; **AND**
  - B. A diagnosis of **hereditary Factor X deficiency** when the following are met:
    1. Used for on-demand treatment and control of bleeding episodes; **OR**
    2. Used for routine prophylaxis to reduce the frequency of bleeding episodes; **AND**
      - i. Member must have severe factor X deficiency (factor X level of <1%); **OR**
      - ii. Member has at least two documented episodes of spontaneous bleeding into joints; **OR**
    3. Used for perioperative management of surgical bleeding in patients with mild (Factor X level 6-10%) and moderate (Factor X level 1-5%) deficiency

- II. Coagulation Factor X, human (Coagadex) is considered investigational when used for all other conditions.

**Renewal Evaluation**

- I. Member has received a previous prior authorization approval for this agent; **AND**
- II. Any increases in dose must be supported by an acceptable clinical rationale (i.e. weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.) as verified by a Moda Health pharmacist; **AND**
- III. Used for on-demand treatment and control of bleeding episodes; **OR**
- IV. Used for routine prophylaxis to reduce the frequency of bleeding episodes; **AND**
  - Documentation of clinical benefit, including decreased incidence of bleeding episodes or stability of bleeding episodes relative to baseline

**Supporting Evidence**

- I. Perioperative management of bleeding in major surgery in patients with severe hereditary Factor X deficiency has not been studied.
- II. Dose and duration of the treatment depend on the severity of the Factor X deficiency, location and extent of the bleeding, the patient’s age (<12 years or >12 years) and on the patient’s clinical condition.
- III. The dose and frequency is based on the individual clinical response. With a max dose of 60 IU/kg daily.

**Investigational or Not Medically Necessary Uses**

- I. There is no evidence to support the use of coagulation Factor X, human (Coagadex) in any other condition.

**References**

1. Coagadex [Prescribing Information]. Durham, NC: Bio Products Laboratory USA, Inc. September 2018.
2. Brown DL, Kouides PA. Diagnosis and treatment of inherited factor X deficiency. Hemophilia. 2008 Nov;14(6):1176-82.
3. National Hemophilia Foundation for all Bleeding Disorders. Factor X. Available from: <https://www.hemophilia.org/Bleeding-Disorders/Types-of-Bleeding-Disorders/Other-Factor-Deficiencies/Factor-X>.
4. UpToDate, Inc. Rare inherited coagulation disorders. [database online]. Mannucci PM. Last updated September 18, 2018. Available from: [http://www.uptodate-com/contents/rare-inherited-coagulation-disorders?source=search\\_result&search=factor+x+deficiency&selectedTitle=1%7E10](http://www.uptodate-com/contents/rare-inherited-coagulation-disorders?source=search_result&search=factor+x+deficiency&selectedTitle=1%7E10)

**Appendix**

Medication:	Unit Conversion:
Coagulation Factor X, human (Coagadex)	1 IU = 1 billing unit (1:1 conversion)*

*\*Current billing unit conversion as of 11/2025. This is subject to change pending new information.*

**Policy Implementation/Update:**

Action and Summary of Changes	Date
Added appendix table regarding medical billing units. Updated formatting to align with current standards. Removed the requirement to not have more than 5 doses for on demand treatment on hand.	11/2025
Removed age requirement as now also approved in patients less than 12 years of age. Addition of agent to be prescribed by hematologist, limited to only allow 5 doses on hand in on demand treatment setting, added requirement of severe factor X deficiency or at least two spontaneous bleeds into joints for prophylaxis use, limited perioperative use to mild or moderate deficiency as per label. Updated initial approval duration from one month to now six months. Addition of renewal criteria.	11/2019
Previous Reviews	01/2016