

PHARMACY COVERAGE GUIDELINE

COAGADEX® (coagulation factor X [Human]) Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for initial therapy:** Coagadex (coagulation factor X [Human]) and/or generic equivalent (if available) is considered **medically necessary** and will be approved when **ALL** the following criteria are met:
1. Prescriber is a physician specializing in the patient’s diagnosis or is in consultation with a Hematologist
 2. Individual has a confirmed diagnosis of hereditary Factor X deficiency and **ONE** of the following:
 - 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, moderate, and severe deficiency
 3. Individual baseline Factor X level is below the lower limit of the reference range or not detectable

ORIGINAL EFFECTIVE DATE: 08/15/2024 | ARCHIVE DATE: | LAST REVIEW DATE: | LAST CRITERIA REVISION DATE:

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4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
5. Individual is not currently taking any other drugs which cause severe adverse reactions or any significant drug interactions requiring discontinuation

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Coagadex (coagulation factor X [Human]) and/or generic equivalent (if available) is considered **medically necessary** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Hematologist
2. Individual has a confirmed diagnosis of hereditary Factor X deficiency and **ONE** of the following:
 - 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, moderate, and severe deficiency
3. Individual's condition has responded while on therapy with response defined as adequate Factor X levels have been achieved and maintained
4. Individual has been adherent with the medication
5. **If available:** Individual has failure after adequate trial, contraindication per FDA label or intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
6. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use such as a hypersensitivity or allergic reaction
7. Individual is not currently taking any other drugs which cause severe adverse reactions or any significant drug interactions requiring discontinuation

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

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Description:

Coagadex (coagulation factor X [Human]) is approved for on-demand treatment and control of bleeding episodes in individuals with hereditary factor X deficiency, routine prophylaxis to reduce the frequency of bleeding episodes, and for perioperative management of bleeding in individuals with mild, moderate, and severe hereditary Factor X deficiency. Factor X deficiency is a rare bleeding disorder that can vary in severity. Common signs and symptoms of deficiency include nosebleeds, easy bruising, bleeding under the skin, bleeding of the gums, hematuria, and prolonged or excessive bleeding following surgery or trauma. Coagadex (coagulation factor X [Human]) replaces the deficient Factor X needed for hemostasis.

Factor X deficiency is typically managed with plasma-derived factor concentrate or a 4-factor or 3-factor prothrombin complex concentrate (PCC). PCC carries a prothrombotic risk and as such is not used for less severe bleeding. If factor concentrate or PCC is not available, fresh frozen plasma (FFP) may be used.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
[MedWatch Forms for FDA Safety Reporting | FDA](#)

Resources:

Coagadex (coagulation factor X [Human]) product information, revised by Bio Products Laboratory Limited 04-2023. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed June 04, 2024.

Mannucci PM. Rare inherited coagulation disorders. In: UpToDate, Editor(s) (Ed), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through May 2024. Topic last updated February 02, 2024. Accessed June 15, 2024.

Menegatti M, Peyvandi F. Treatment of rare factor deficiencies other than hemophilia. Blood 2019;133(5):415-424. Accessed June 16, 2024.