Hemophilia Products – Factor X: Coagadex®
(Intravenous)

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I. Length of Authorization

Perioperative management of surgical bleeding:

- Initial: Prior authorization validity will be provided initially for 1 month (30 days).
- Renewal: Prior authorization validity may NOT be renewed.

Control and prevention of acute bleeding episodes:

- Initial: Prior authorization validity will be provided initially for 3 months (90 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

Routine prophylaxis:

- Initial: Prior authorization validity will be provided initially for 3 months (90 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

Note: The cumulative amount of medication the member has on-hand will be taken into account for authorizations. Up to 5 'on-hand' doses for the treatment of acute bleeding episodes will be permitted at the time of the authorization request.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 23,000 billable units per 28 day supply

III. Initial Approval Criteria [1-3,8,11]

Hemophilia Management Program
Requirements for half-life study and inhibitor tests are a part of the hemophilia management program. This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide.

Prior authorization validity is provided in the following conditions:

Hereditary Factor X deficiency † Φ

- Diagnosis of congenital factor X deficiency has been confirmed by blood coagulation testing; **AND**
- Used as treatment in one of the following:
  - On-demand treatment and control of bleeding episodes; **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
    - Used as primary prophylaxis in members with severe factor X deficiency (factor X level of <1%); **OR**
    - Used as secondary prophylaxis in members with at least TWO documented episodes of spontaneous bleeding into joints; **OR**
  - Perioperative management of surgical bleeding in members with mild, moderate, and severe deficiency

Hemophilia Management Program
• If the request is for prophylaxis and the requested dose exceeds dosing limits under part II, a half-life study should be performed to determine the appropriate dose and dosing interval. • For members with a BMI ≥ 30, a half-life study should be performed to determine the appropriate dose and dosing interval. • For minimally treated members (< 50 exposure days to factor products) previously receiving a different factor product, inhibitor testing is required at baseline, then at every comprehensive care visit (yearly for the mild and moderate members, semi-annually for the severe members)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Dispensing Requirements for Rendering Providers (Hemophilia Management Program)

– Prescriptions cannot be filled without an expressed need from the **member, caregiver or prescribing practitioner. Auto-filling is not allowed.**

– Monthly, rendering provider must submit for authorization of dispensing quantity before delivering factor product. Information submitted must include:
  - Original prescription information, requested amount to be dispensed, vial sizes available to be ordered from the manufacturer, and member clinical history (including member product inventory and bleed history)
  - Factor dose should not exceed +1% of the prescribed dose and a maximum of three vials may be dispensed per dose. If unable to provide factor dosing within the required threshold, below the required threshold, the lowest possible dose able to be achieved above +1% should be dispensed. Prescribed dose should not be increased to meet assay management requirements.

- The cumulative amount of medication(s) the member has on-hand should be taken into account when dispensing factor product. Members should not have more than 5 extra doses on-hand for the treatment of acute bleeding episodes.
- Dispensing requirements for rendering providers are a part of the hemophilia management program. This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide.

V. Renewal Criteria [1-3,8]

Prior authorization validity can be renewed based upon the following criteria:

- Member continues to meet indication-specific relevant criteria identified in section III; **AND**
- Duration of authorization has not been exceeded *(refer to Section I)*; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: allergic type hypersensitivity reactions (including anaphylaxis, angioedema, and infusion site inflammation, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc.; **AND**
- 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 member is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the member has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**

Routine prophylaxis to reduce the frequency of bleeding episodes

- Member has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

VI. Dosage/Administration [1]

Indication	Dose
On-demand treatment and control of bleeding episodes due to Factor X deficiency	– Children (<12 years of age): 30 IU/kg at first sign of bleeding, repeat every 24 hours until bleeding stops. – Adults and adolescents (≥12 years of age): 25 IU/kg at first sign of bleeding, repeat every 24 hours until bleeding stops. *Do not administer more than 60 IU/kg daily.
Perioperative management of bleeding in members with mild, moderate, and severe Factor X deficiency	Pre-surgery: Calculate the dose to raise plasma Factor X levels to 70-90 IU/dL using the formula: – Children (<12 years of age): Dose (IU) = Body Weight (kg) x Desired Factor X Rise (IU/dL or % of normal) x 0.6 (The dosing formula is based on observed recovery of 1.7 IU/dL per IU/kg).

Indication	Dose
	– Adults and adolescents (≥12 years of age): Dose (IU) = Body Weight (kg) x Desired Factor X Rise (IU/dL or % of normal) x 0.5 (The dosing formula is based on observed recovery of 2 IU/dL per IU/kg). Post-surgery: Repeat dose as necessary to maintain plasma Factor X levels at a minimum of 50 IU/dL until the member is no longer at risk of bleeding due to surgery * Do not administer more than 60 IU/kg daily.
Prophylaxis of bleeding episodes	– Children (<12 years of age): 40 IU/kg twice weekly – Adults and adolescents (≥12 years of age): 25 IU/kg twice weekly Monitor trough blood levels of Factor X targeting ≥5 IU/dL and adjust dosage to clinical response and trough levels. Do not exceed a peak level of 120 IU/dL. * Do not administer more than 60 IU/kg daily.

VII. Billing Code/Availability Information

HCPCS Code & NDC:

Drug	Manufacturer	HCPCS Code	1 Billable Unit Equiv.	Vial Size	NDC
Coagadex	Bio Products Laboratory	J7175	1 IU	250 units	64208-7752-xx
				500 units	64208-7753-xx

VIII. References

1. Coagadex [package insert]. Durham, NC; Bio Products Laboratory; May 2024; Accessed May 2026.
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3. Guidelines for the Management of Hemophilia. 3rd Edition. World Federation of Hemophilia. 2020. Available at: https://www1.wfh.org/publications/files/pdf-1863.pdf.
4. Annual Review of Factor Replacement Products. Oklahoma Health Care Authority Review Board. Updated December 2020.
5. Graham A, Jaworski K. Pharmacokinetic analysis of anti-hemophilic factor in the obese patient. Haemophilia. 2014 Mar;20(2):226-9.
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7. Mingot-Castellano ME, Diaz-Canales D, Tamayo-Bermejo R, Heiniger-Mazo AI. Application of Pharmacokinetics Programs in Optimization of Haemostatic Treatment in Severe Hemophilia a Patients: Changes in Consumption, Clinical Outcomes and Quality of Life. Blood. 2014 December; 124 (21).

8. MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B with and without Inhibitors. Revised April 27, 2022. National Hemophilia Foundation. MASAC Document #267; April 2022. Available at: http://www.bleeding.org. Accessed May 2026.
9. Brown DL, Kouides PA. Diagnosis and treatment of inherited factor X deficiency. Haemophilia. 2008 Nov;14(6):1176-82.
10. Rayment R, Chalmers E, Forsyth K, et al. Guidelines on the use of prophylactic factor replacement for children and adults with Haemophilia A and B. Br J Haematol. 2020 Sep;190(5):684-695. doi: 10.1111/bjh.16704.
11. Lewandowska, MD. (2026). Hemophilia A and B: Routine management including prophylaxis. In Shapiro AD, Tirnauer JS (Eds.), UptoDate. Last updated: March 02, 2026. Accessed May 01, 2026. Available from https://www.uptodate.com/contents/hemophilia-a-and-b-routine-management-including-prophylaxis
12. Palmetto GBA. Local Coverage Article: Billing and Coding: Guidance for Anti-Inhibitor Coagulant Complex (AICC) National Coverage Determination (NCD) 110.3 (A56065). Centers for Medicare & Medicaid Services Inc. Updated on 11/14/2022 with effective date 11/24/2022. Accessed May 2026.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D68.2	Hereditary deficiency of other clotting factors

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local

Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
J,M	A56065	Palmetto GBA

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC