

Hemophilia Products – Factor X: Coagadex (Intravenous)

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I. Length of Authorization

Unless otherwise specified*, the initial authorization will be provided for 3 months and may be renewed for a period of 6 months thereafter.

Note: The cumulative amount of medication the patient 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.

** Initial and renewal authorization periods may vary by specific covered indication*

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC unit]:

- Coagadex 250 IU vial: 36 vials per 7 days
- Coagadex 500 IU vial: 18 vials per 7 days

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

- 36,800 billable units per 28 day supply

III. Initial Approval Criteria ^{1,2,3,8}

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.

Coverage is provided in the following conditions:

Universal Criteria

- Diagnosis of congenital factor X deficiency has been confirmed by blood coagulation testing: **AND**

Hereditary Factor X deficiency †

- Used for on-demand treatment and control of bleeding episodes; **OR**
- Used for routine prophylaxis to reduce the frequency of bleeding episodes:
 - Patient must have severe factor X deficiency (factor X level of <1%); **OR**
 - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
- Used for perioperative management of surgical bleeding in patients with mild and moderate deficiency (**Authorizations valid for 1 month*)

Hemophilia Management Program
<ul style="list-style-type: none">• 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 patients (< 50 exposure days to factor products) previously receiving a different factor product, inhibitor testing is required at, then at every comprehensive care visit (yearly for the mild and moderate patients, semi-annually for the severe patients)

† FDA Approved Indication(s)

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

- Prescriptions cannot be filled without an expressed need from the patient, 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 patient clinical history (including patient 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 patient has on-hand should be taken into account when dispensing factor product. Patients should not have more than 5 extra doses on-hand for the treatment of acute bleeding episodes.
- Dispensing requirements for renderings 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 ^{1,2,3,8}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash); thromboembolic events (thromboembolism, pulmonary embolism); and development of neutralizing antibodies (inhibitors); **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 patient is fully adherent to therapy, etc.) ; **AND**
- The cumulative amount of medication(s) the patient 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**

Treatment of acute bleeding episodes/Treatment of Spontaneous and trauma-induced bleeding episodes/On-demand treatment of bleeding episodes

- Renewals will be approved for a 6 month authorization period

Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 6 month authorization period

VI. Dosage/Administration¹⁻³

Indication	Dose
On-demand treatment and control of bleeding episodes due to Factor X deficiency	<ul style="list-style-type: none"> – Children (Less than 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 or older): 25 IU/kg at first sign of bleeding, repeat every 24 hours until bleeding stops. <p>*Do not administer more than 60 IU/kg daily.</p>
Perioperative management of bleeding in patients with mild Factor X deficiency	<p><u>Pre-surgery:</u></p> <p>Calculate the dose to raise plasma Factor X levels to 70-90 IU/dL using the formula:</p> <ul style="list-style-type: none"> • For children <12 years of age: Dose (IU) = Body Weight (kg) x Desired Factor X Rise (IU/dL) x 0.6 (The dosing formula is based on observed recovery of 1.7 IU/dL per IU/kg). • For adults & adolescents ≥12 years of age: Dose (IU) = Body Weight (kg) x Desired Factor X Rise (IU/dL) x 0.5 (The dosing formula is based on observed recovery of 2 IU/dL per IU/kg).

Indication	Dose
	<u>Post-surgery:</u> Repeat dose as necessary to maintain plasma Factor X levels at a minimum of 50 IU/dL until the patient is no longer at risk of bleeding due to surgery * Do not administer more than 60 IU/kg daily.
Prophylaxis of bleeding episodes	– Children (Less than 12 years of age): 40 IU/kg twice weekly – Adults and adolescents (12 years of age or older): 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	J-Code	1 Billable Unit Equiv.	Vial Size	NDC
Coagadex	Bio Products Laboratory	J7175	1 IU	250 units	– 64208-7752
				500 units	– 64208-7753

VIII. References

1. Coagadex [package insert]. Durham, NC; Bio Products Laboratory; September 2018; Accessed January 2020.
2. MASAC RECOMMENDATIONS CONCERNING PRODUCTS LICENSED FOR THE TREATMENT OF HEMOPHILIA AND OTHER BLEEDING DISORDERS. 2016 National Hemophilia Foundation. MASAC Document #249; October 2016. Available at: <http://www.hemophilia.org>. Accessed January 2019.
3. Guidelines for the Management of Hemophilia. 2nd Edition. World Federation of Hemophilia. 2013. Available at: <https://www1.wfh.org/publication/files/pdf-1472.pdf>. Accessed January 2019.
4. Annual Review of Factor Replacement Products. Oklahoma Health Care Authority Review Board. Updated April 2016. Access January 2019.
5. Graham A1, Jaworski K. Pharmacokinetic analysis of anti-hemophilic factor in the obese patient. Haemophilia. 2014 Mar;20(2):226-9.
6. Croteau SE1, Neufeld EJ. Transition considerations for extended half-life factor products. Haemophilia. 2015 May;21(3):285-8.
7. Mingot-Castellano, et al. 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. 2016 National Hemophilia Foundation. MASAC Document #241; February 2016. Available at: <http://www.hemophilia.org>. Accessed January 2019.

9. Brown DL, Kouides PA. Diagnosis and treatment of inherited factor X deficiency. Haemophilia. 2008 Nov;14(6):1176-82
10. 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 10/24/2019 with effective date 10/31/2019. Accessed January 2020.
11. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Hemophilia Factor Products (A56433). Centers for Medicare & Medicaid Services Inc. Updated on 11/08/2019 with effective date 11/14/2019. Accessed January 2020

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)

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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): J,M	NCD/LCD Document (s): A56065
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56065&bc=gAAAAAAAAAAAA	

Jurisdiction(s): H,L	NCD/LCD Document (s): A56433
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56433&bc=gAAAAAAAAAAAA	

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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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