Hemophilia Products – Factor X: Coagadex

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I. Length of Authorization

- Initial and renewal authorization periods vary by specific covered indication
- Unless otherwise specified, the initial authorization will be provided for 3 months and may be renewed.

The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. 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.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

N/A

B. Max Units (per dose and over time) [Medical Benefit]:

34,500 billable units per 90 day supply

III. Initial Approval Criteria

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.

A. Coagadex

Coverage is provided in the following conditions:

Hereditary Factor X deficiency †

- Diagnosis of congenital factor X deficiency has been confirmed by blood coagulation testing; **AND**
    - Used for on-demand treatment and control of bleeding episodes; **OR**
    - Used for perioperative management of surgical bleeding in patients with mild deficiency
        - Authorization is valid for 1 month

Hemophilia Management Program
• 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

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria 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.).
- 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.
- Patient meets the disease specific criteria below:

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 3 month authorization period

VI. Dosage/Administration

Coagadex

Indication	Dose
On-demand treatment and control of bleeding episodes due to Factor X deficiency	Infuse 25 IU/kg when the first sign of bleeding occurs. Repeat at intervals of 24 hours until the bleed stops. Do not administer more than 60 IU/kg daily.
Perioperative management of bleeding in patients with mild Factor X deficiency	Do not administer more than 60 IU/kg daily. Pre-surgery: Calculate the dose to raise plasma Factor X levels to 70-90 IU/dL using the formula: Dose (IU) = Body Weight (kg) x Desired Factor X Rise (IU/dL) x 0.5 The dosing formula is based on the 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 patient is no longer at risk of bleeding due to surgery

VII. Billing Code/Availability Information

Jcode & NDC:

Drug	Manufacturer	J-Code	1 Billable Unit Equiv.	Vial Size	NDC
Coagadex	Bio Products Laboratory	J7175	1 IU	250 units	64208-7752-01

				500 units	64208-7753-01

VIII. References

1. Coagadex [package insert]. Durham, NC; Bio Products Laboratory; October 2015; Accessed June 2017.
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 June 2017.
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 June 2017.
4. First Coast Service Options, Inc. Local Coverage Determination (LCD): Hemophilia Clotting Factors (L33684). Centers for Medicare & Medicaid Services, Inc. Updated on 01/03/2017 with effective date 01/01/2017. Accessed June 2017.
5. Novitas Solutions, Inc. Local Coverage Determination (LCD): Hemophilia Clotting Factors (L35111). Centers for Medicare & Medicaid Services, Inc. Updated on 01/06/2017 with effective date 01/01/2017. Accessed June 2017.
6. Annual Review of Factor Replacement Products. Oklahoma Health Care Authority Review Board. Updated April 2016. Access June 2016.
7. Graham A1, Jaworski K. Pharmacokinetic analysis of anti-hemophilic factor in the obese patient. Haemophilia. 2014 Mar;20(2):226-9.
8. Croteau SE1, Neufeld EJ. Transition considerations for extended half-life factor products. Haemophilia. 2015 May;21(3):285-8.
9. 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).
10. MASAC RECOMMENDATION CONCERNING PROPHYLAXIS. 2016 National Hemophilia Foundation. MASAC Document #241; February 2016. Available at: http://www.hemophilia.org. Accessed August 2017.

Appendix 1 – Covered Diagnosis Codes

Coagadex

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): H,L	**NCD/LCD Document (s):** L35111
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35111&bc=gAAAAAAAAAAAAA==	

Jurisdiction(s): N	**NCD/LCD Document (s):** L33684
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33684&bc=gAAAAAAAAAAAAA==	

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	Cahaba Government Benefit Administrators, 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