Neighborhood Health Plan OF RHODE ISLAND™
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Hemophilia Products – Factor X: Coagadex
(Intravenous)

Effective date: 10/1/2019
Review date: 1/29/2020, 7/15/2021, 6/16/2022, 6/22/2023, 12/07/2023, 01/04/2024, 08/14/2024
Scope: Medicaid*, Commercial, Medicare-Medicaid Plan (MMP)
***(Medication only available on the Medical Benefit)**

I. Length of Authorization

Unless otherwise specified*, the initial authorization will be provided for 3 months and may be renewed.

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) [Pharmacy Benefit]:

- Coagadex 250 IU vial: 92 vials per 28 days
- Coagadex 500 IU vial: 46 vials per 28 days

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

- 23,000 billable units per 28-day supply

III. Summary of Evidence

Coagadex is a plasma derives human blood coagulation factor indicated for hereditary Factor X deficiency for routine prophylaxis to reduce the frequency of bleeding episodes, on-demand treatment/control of bleeding episodes, perioperative management of bleeding in patients with mild, moderate and severe hereditary Factor X deficiency. In a multicenter, open-label, non-randomized trial, nine children were enrolled with FX deficiency to evaluate the use of Coagadex in routine prophylaxis of bleeding episodes. Patients were given Coagadex 40-50 IU/kg, and then underwent 30 min post dose incremental recovery assessment. After the six months, patients excelled at the investigators assessment, meaning no minor or major bleeds occurred. To evaluate safety and efficacy of on-demand treatment and control of bleeding episodes, a multicenter, open-label, non-clinical trial was used in 16 subjects with Factor X deficiency. Subjects received a dose of 25 IU/kg to treat spontaneous, traumatic and hemorrhagic bleeding episodes. Efficacy was evaluated through the investigator using a bleed-specific ordinal rating scale and then scores were reviewed by a Data Review Committee. With four treatment failures, Coagadex was considered good (7%) or excellent (98%) in treating bleeding episodes. Common side effects include hypersensitivity reactions, development of neutralizing antibodies, and a risk of transmitting infectious diseases such as Creutzfeldt-Jakob disease.

IV. 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:

- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

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 for patients with severe factor X deficiency (factor X level of <1%); **OR**
    - Used as second prophylaxis in patients with at least TWO documented episodes of spontaneous bleeding into joints; **OR**
  - Perioperative management of surgical bleeding in patients with mild deficiency *(*Authorizations valid for 1 month)*

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 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) **Φ** Orphan Drug

V. 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.

VI. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section IV; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, 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 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**

On-demand treatment of bleeding episodes and control of bleeding episodes

- Renewals will be approved for a 6 month authorization period

Perioperative management of surgical bleeding

- Coverage may NOT be renewed

Routine prophylaxis to reduce the frequency of bleeding episodes

- Renewals will be approved for a 6 month authorization period; **AND**

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

VII. Dosage/Administration

Coagadex

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 patients with mild and moderate 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: 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). 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). 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
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.

VIII. 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
				500 units	– 64208-7753

IX. References

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13. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Hemophilia Factor Products (A56433). Centers for Medicare & Medicaid Services Inc. Updated on 09/29/2023 with effective date 10/01/2023. Accessed May 2024.
14. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Hemophilia Factor Products (A56482). Centers for Medicare & Medicaid Services Inc. Updated on 09/29/2023 with effective date 10/01/2023. Accessed May 2024.

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
H,L	A56433	Novitas Solutions, Inc.
N	A56482	First Coast Service Options, Inc.

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

Policy Rationale:

Coagadex was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Coagadex according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.