Neighborhood Health Plan OF RHODE ISLAND™
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Hemophilia Products – Factor XIII: Corifact®
(Intravenous)

Effective date: 10/1/2019
Review date: 01/29/2020, 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]:

- Corifact 1000-1600 IU vial: 5 vials per 28-day supply

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

- 4,600 billable units per 28 day supply

III. Summary of Evidence

Corifact is a Factor XIII concentrate indicated for congenital Factor XIII deficiency for routine prophylactic treatment and peri-operative management of surgical bleeding. A trial was conducted in 41 subjects who received routine prophylactic treatment (40 U/kg every 28 days for 52 weeks) for congenital FXIII deficiency to compare the incidence of bleeding in Corifact treated subjects to historical control with FXIII deficiency. Efficacy was measured based on incidence of spontaneous bleeding episodes during treatment. None of the spontaneous bleeding episodes required treatment with a FXIII-containing product, resulting in an annualized bleeding rate of 0 episodes per subject per year, compared to 2.5 episodes per year with on-demand treatment. The results indicate that routine prophylactic treatment with Corifact in subjects with congenital FXIII deficiency was effective in preventing spontaneous bleeding episodes, with none of the episodes requiring treatment with a FXIII-containing product. The prophylactic administration of Corifact maintained FXIII activity levels within the desired range in the majority of subjects, with minimal dose adjustments needed. Pre-operative administration of Corifact in elective surgeries was associated with no significant post-operative bleeding. Common adverse reactions include joint inflammation, hypersensitivity, rash, pruritus, erythema, hematoma, arthralgia, headache, elevated thrombin-antithrombin levels, and increased blood lactate dehydrogenase.

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. Corifact

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

Congenital Factor XIII deficiency † Φ

- Diagnosis of congenital factor XIII deficiency has been confirmed by blood coagulation testing; **AND**
  - Used for routine prophylactic treatment, **OR**
  - Used for perioperative management of surgical bleeding *(*Authorizations valid for 1 month)*

Hemophilia Management Program
• If the request is for routine 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 baseline, then at every comprehensive care visit (yearly for the mild and moderate patients, semi-annually for the severe patients)

† FDA Approved Indication(s) ‡ Compendia Recommended 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-anaphylaxis and hypersensitivity reactions (e.g., urticaria, rash, tightness of the chest, wheezing, hypotension), 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**

Routine prophylactic treatment

- Renewals will be approved for a 12-month authorization; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

Perioperative management of surgical bleeding

- Coverage may NOT be renewed

VII. Dosage/Administration

Indication	Dose
Routine prophylaxis for bleeding in patients with Congenital factor XIII deficiency	40 International Units (IU) per kg body weight at a rate not to exceed 4 mL per minute, given every 28 days. Adjust dose ±5 IU per kg to maintain 5% to 20% trough level of FXIII activity.

Perioperative management in patients with Congenital factor XIII deficiency	Dosing should be individualized based on the patient's FXIII activity level, type of surgery, and clinical response. Monitor patient's FXIII activity levels during and after surgery. Dose adjustment will need to be made depending on when last prophylactic dose was given. ▪ Within 7 days – Additional dose may not be needed ▪ 8-21 days - Additional partial or full dose may be needed based on FXIII activity level ▪ 21-28 days - Full prophylactic dose

VIII. Billing Code/Availability Information

HCPCS & NDC:

Drug	Manufacturer	J-Code	1 Billable Unit Equiv.	Vial Size	NDC
Corifact	CSL Behring LLC	J7180	1 IU	Unassigned size	63833-0518-xx

IX. References

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2. MASAC Recommendations Concerning Products Licensed For The Treatment Of Hemophilia And Selected Disorders of the Coagulation System. Revised April 11, 2024. National Hemophilia Foundation. MASAC Document #284; April 2024. Available at: http://www.bleeding.org. Accessed May 2024.
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. Accessed May 2024.
4. Annual Review of Factor Replacement Products. Oklahoma Health Care Authority Review Board. Updated April 2016. Accessed May 2023.
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 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 2024.
9. 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. B J Haem:190;5,Sep2020. https://doi.org/10.1111/bjh.16704. Accessed May 2023.

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 11/14/2022 with effective date 11/24/2022. Accessed May 2024.
11. 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.
12. 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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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 LLC
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:

Corifact 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 Corifact 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.