Neighborhood Health Plan OF RHODE ISLAND™
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Hemophilia Products – Factor VIII/VWF Complex: Alphanate, Humate-P, Wilate
(Intravenous)

Effective date: 01/01/2020

Review date: 10/02/2019, 12/18/19, 1/22/20, 5/3/2021, 6/24/2021, 6/16/2022, 6/22/2023, 12/07/2023, 01/04/2024, 05/15/2024

Scope: Medicaid, Exchange*, 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]:

N/A

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

- Alphate: 55,200 billable units per 28 day supply
- Humate-P: 55,200 billable units per 28 day supply
- Wilate: 55,200 billable units per 90 day supply

III. Summary of Evidence

Clinical trials support the efficacy and safety of von Willebrand factor therapies in managing bleeding symptoms and preventing bleeding complications in patients with VWD. These therapies provide exogenous von Willebrand factor activity, enhancing platelet adhesion and stabilizing clot formation, thereby reducing the frequency and severity of bleeding episodes. Adverse reactions reported include respiratory distress, pruritus, rash, urticaria, and others.

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. Alphanate, Humate-P ONLY

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.

Hemophilia A (congenital factor VIII deficiency) †

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Used as treatment in one of the following:
  - Treatment and control of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management *(*Authorization is valid for 1 month)*; **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
    - Patient must have severe hemophilia A (factor VIII level of <1%); **OR**
  - Patient has at least two documented episodes of spontaneous bleeding into joints

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)

von Willebrand disease (vWD) † Φ

- Diagnosis of von Willebrand disease has been confirmed by blood coagulation and von Willebrand factor testing; **AND**
- Used as treatment in one of the following:
  - Spontaneous and trauma-induced bleeding episodes; **OR**
  - Surgical bleeding prophylaxis during major or minor procedures in patients with vWD in whom desmopressin is either ineffective or contraindicated *(*Authorization valid for 1 month)* ; **AND**

- Alphanate is not indicated for patients with severe (type 3) vWD undergoing major surgery OR treatment of spontaneous/trauma-induced bleeding episodes

Hemophilia Management Program
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)

B. **Wilate**

Hemophilia A (congenital factor VIII deficiency) †

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Used as treatment in one of the following:
    - Control and prevention of bleeding episodes (episodic treatment of acute hemorrhage); **OR**
    - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
        - Patient must have severe hemophilia A (factor VIII level of <1%); **OR**
        - Patient has at least two documented episodes of spontaneous bleeding into joints

von Willebrand disease (vWD) † Φ

- Diagnosis of von Willebrand disease has been confirmed by blood coagulation and von Willebrand factor testing; **AND**
- Used as treatment in one of the following:
    - Perioperative management of bleeding*(*Authorization valid for 1 month)*; **OR**
    - Used as treatment of spontaneous and trauma-induced bleeding episodes in at least one of the following:
        - Patients with severe vWD; **OR**
        - Patients mild or moderate vWD in whom the use of desmopressin is known or suspected to be ineffective or contraindicated; OR
    - Routine prophylaxis to reduce the frequency of bleeding episodes; **AND**
        - Patient is at least 6 years of age
        -

Hemophilia Management Program
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 III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include : anaphylaxis and hypersensitivity reactions (e.g., angioedema, urticaria, tachycardia, chest tightness, hypotension, rash, nausea, vomiting, paresthesia, restlessness, wheezing, dyspnea, 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**

Treatment and control 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

Perioperative management of surgical bleeding/Surgical bleeding prophylaxis

- Coverage may NOT be renewed

Routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12 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

Alphanate

Indication	Dose
Control and prevention of bleeding Congenital Hemophilia A	The expected in vivo peak increase in FVIII level expressed as IU/dL (or % normal) can be estimated using the following formulas: Dosage (international units) = body weight (kg) x desired FVIII rise (IU/dL or % normal) x 0.5 (IU/kg per IU/dL) Minor FVIII:C levels should be brought to 30% of normal (15 IU FVIII/kg twice daily) until hemorrhage stops and healing has been achieved (1-2 days). Moderate FVIII:C levels should be brought to 50% (25 IU FVIII/Kg twice daily). Treatment should continue until healing has been achieved (2-7 days, on average). Major FVIII:C levels should be brought to 80-100% for at least 3-5 days (40-50 IU FVIII/kg twice daily). Following this treatment period, FVIII levels should be maintained at 50% (25 IU FVIII/kg twice daily) until healing has been achieved. Major hemorrhages may require treatment for up to 10 days. Intracranial hemorrhages may require prophylaxis therapy for up to 6 months.
Perioperative management Congenital Hemophilia A	Prior to surgery, the levels of FVIII:C should be brought to 80-100% of normal (40-50 IU FVIII/kg). For the next 7-10 days, or until healing has been achieved, the patient should be maintained at 60-100% of normal (30-50 IU FVIII/kg twice daily).
Control and prevention of bleeding and perioperative management von Willebrand Disease (VWD)	The ratio of VWF:RCo to FVIII in Alphanate varies by lot, so with each new lot, check the IU VWF:RCo/Vial to ensure accurate dosing. Minor *Pre-operative/pre-procedure dose (Target FVIII:C Activity – 40-50 IU/dL):* Adults: 60 IU VWF:RCo/kg body weight. Pediatrics: 75 IU VWF:RCo/kg body weight. *Maintenance dose (Target FVIII:C Activity – 40-50 IU/dL):* Adults: 40- 60 IU VWF:RCo/kg body weight at 8 to 12 hour intervals as clinically needed for 1-3 days.

Indication	Dose
	Pediatrics: 50-75 IU VWF:RCo/kg body weight at 8 to 12 hour intervals as clinically needed for 1-3 days. Major *Pre-operative/pre-procedure dose (Target FVIII:C Activity – 100 IU/dL):* Adults: 60 IU VWF:RCo/kg body weight. Pediatrics: 75 IU VWF:RCo/kg body weight. *Maintenance dose (Target FVIII:C Activity – 100 IU/dL):* Adults: 40-60 IU VWF:RCo/kg body weight at 8 to 12 hour intervals as clinically needed for at least 3-7 days. Pediatrics: 50- 75 IU VWF:RCo/kg body weight at 8 to 12 hour intervals as clinically needed for at least 3-7 days.

Humate-P

Indication	Dose
Control and prevention of bleeding Congenital Hemophilia A	One International Unit (IU) of Factor VIII (FVIII) activity per kg body weight will increase the circulating FVIII level by approximately 2.0 International Units (IU)/dL. Minor Loading Dose: Adminster 15 IU FVIII:C/kg intravenously to achieve a FVIII:C plasma level of approximately 30% of normal; one infusion may be sufficient. If needed, half of the loading dose may be given once or twice daily for 1-2 days. Moderate Loading Dose: Adminster 25 IU FVIII:C/kg intravenously to achieve a FVIII:C plasma level of approximately 50% of normal, followed by 15 IU FVIII:C/kg every 8-12 hours for the first 1-2 days to maintain the FVIII:C plasma level at 30% of normal. Continue the same dose once or twice daily for up to 7 days or until adequate wound healing is achieved. Major Initially adminster 40-50 IU FVIII:C/kg intravenously, followed by 20-25 IU FVIII:C/kg every 8 hours to maintain the FVIII:C plasma level at 80-100% of normal for 7 days. Continue the same dose once or twice daily for another 7 days to maintain the FVIII:C level at 30-50% of normal.
Control and prevention of bleeding von Willebrand Disease (VWD)	Administer 40-80 IU VWF:RCo intravenously (corresponding to 17-33 IU FVIII in Humate-P) per kg body weight every 8 to 12 hours. Adjust the dosage based on the extent and location of bleeding. Administer repeat doses as long as needed based on monitoring of appropriate clinical and laboratory measures
Perioperative management von Willebrand Disease (VWD)	**Loading Doses*(to be administered 1 to 2 hours before surgery)*** Major *VWF:RCo Target Peak Plasma Level: 100 IU/dL* *FVIII:C Target Peak Plasma Level: 80-100 IU/dL* *Calculation of Loading Dose:* ((Target peak plasma VWF:RCo level – baseline plasma VWF:RCo level) –Body wt (kg)) /IVR (in vivo recovery)

Indication	Dose
	If the IVR is not available, assume an IVR of 2.0 IU/dL per IU/kg and calculate the loading dose as follows: (100 – baseline plasma VWF:RCo) x Body Weight (kg)/2.0 Minor *VWF:RCo Target Peak Plasma Level: 50-60 IU/dL* *FVIII:C Target Peak Plasma Level: 40-50 IU/dL* *Calculation of Loading Dose:*((Target peak plasma VWF:RCo level – baseline plasma VWF:RCo level) –Body weight (kg)) /IVR (in vivo recovery) Emergency *VWF:RCo Target Peak Plasma Level: 100 IU/dL* *FVIII:C Target Peak Plasma Level: 80-100 IU/dL* Administer a dose of 50-60 IU VWF:RCo/kg body weight. **Maintenance Doses** The initial maintenance dose of Humate-P for the prevention of excessive bleeding during and after surgery should be half of the loading dose, irrespective of additional dosing required to meet FVIII:C targets. Subsequent maintenance doses should be based on the patient's VWF:RCo and FVIII levels.

Wilate

Indication	Dose
Control of bleeding episodes von Willebrand Disease (VWD)	Calculation of the required dose of VWF:RCo is based on the empirical finding that 1 IU VWF:RCo per kg body weight raises the plasma VWF activity by approximately 2% of normal activity or 2 IU/dL, using the following formula: – *Required IU = body weight (kg) x desired VWF:RCo rise (%) (IU/dL) x 0.5 (IU/kg per IU/dL)* – *Expected VWF:RCo rise (% of normal) = 2 x administered IU / body weight (kg)* Adjust the dosage and frequency of administration to the clinical effectiveness in the individual patient. The ratio between VWF:RCo and FVIII activities in Wilate is approximately 1:1. The dosage should be adjusted according to the extent and location of the bleeding. Minor Loading Dose: Administer 20-40 IU/kg intravenously Maintenance Dose: Adminster 20-30 IU/kg intravenously every 12-24 hours, as needed for up to 3 days VWF:RCo and FVIII activity trough levels > 30%. Major Loading Dose: Administer 40-60 IU/kg intravenously Maintenance Dose: Administer 20-40 IU/kg intravenously every 12-24 hours as needed for up to 5-7 days VWF:RCo and FVIII activity trough levels > 50%.
Perioperative management of bleeding von Willebrand Disease (vWD)	Calculation of the required dose of VWF:RCo is based on the empirical finding that 1 IU VWF:RCo per kg body weight raises the plasma VWF activity by approximately 2% of normal activity or 2 IU/dL, using the following formula: – *Required IU = body weight (kg) x desired VWF:RCo rise (%) (IU/dL) x 0.5 (IU/kg per IU/dL)*

<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td></td><td>
Expected VWF:RCo rise (% of normal) = 2 x administered IU / body weight (kg)
Adjust the dosage and frequency of administration to the clinical effectiveness in the individual patient.
<u>Minor</u>
<u>Loading Dose</u>: Administer 30-60 IU/kg intravenously
<u>Maintenance dose:</u> Administer 15-30 IU/kg intravenously or half of the loading dose every every 12-24 hours until wound healing achieved, up to 3 days. VWF:RCo trough levels > 30% and peak levels 50%.
<u>Major</u>
<u>Loading dose:</u> Adminster 40-60 IU/kg intravenously
<u>Maintenance dose:</u> Administer 20-40 IU/kg intravenously or half the loading dose every 12-24 hours((at least 2 doses within the first 24 hours after the start of surgery) until wound healing achieved, up to 6 days or more. VWF:RCo trough levels > 50% and peak levels 100%.
</td></tr>
<tr><td>Routine Prophylaxis von Willebrand Disease (VWD)</td><td>
Calculation of the required dose of VWF:RCo is based on the empirical finding that 1 IU VWF:RCo per kg body weight raises the plasma VWF activity by approximately 2% of normal activity or 2 IU/dL, using the following formula:

Required IU = body weight (kg) x desired VWF:RCo rise (%) (IU/dL) x 0.5 (IU/kg per IU/dL)
Expected VWF:RCo rise (% of normal) = 2 x administered IU / body weight (kg)

Adjust the dosage and frequency of administration to the clinical effectiveness in the individual patient.
<u>Adults and pediatric patients at least 6 years of age:</u> Administer 20-40 IU/kg intravenously 2 or 3 times per week
</td></tr>
<tr><td>Control and prevention of bleeding/ Routine Prophylaxis Congenital Hemophilia A</td><td>
Calculation of the required dose of Factor VIII is based on the empirical finding that 1 IU Factor VIII per kg body weight raises the plasma Factor VIII activity by approximately 2% of normal activity or 2 IU/dL when assessed using the one stage clotting assay. Use the following formula to determine the required dose:

Required IU = body weight (kg) x desired Factor VIII rise (%) (IU/dL) x 0.5 (IU/kg per IU/dL)
Expected Factor VIII rise (% of normal) = 2 x administered IU / body weight (kg)

Dose and duration of therapy depend on the patient's weight, type and severity of hemorrhage, FVIII level, and presence of inhibitors. Titrate dose and frequency to the patient's clinical response, individual needs, severity of deficiency, severity of hemorrhage, desired FVIII level, and presence of inhibitor, and the patient's clinical condition. Patients may vary in their pharmacokinetic (e.g., half-life, in vivo recovery) and clinical responses to Wilate.
<u>Routine Prophylaxis</u>
A guide for dosing as routine prophylaxis to reduce the frequency of bleeding is provided below. Exact dosing should be defined by the patient's clinical status and response.
<table>
<tr><th>Patients</th><th>Recommended Dose (IU/kg)</th><th>Frequency</th></tr>
<tr><td>Adolescents and adults</td><td>20-40 IU/kg</td><td>Every 2-3 days</td></tr>
</table>
<u>Treatment of Hemorrhages</u>
A guide for dosing in the treatment of major and minor hemorrhages is provided below. Exact dosing should be defined by the patient's clinical status and response.
<table>
<tr><th>Hemorrhage Type</th><th>Recommended Dose (IU/kg)</th><th>Frequency</th><th>Frequency</th></tr>
<tr><td>Minor</td><td>30-40</td><td>Repeat every 12-24 hours</td><td>At least 1 day, until bleed stops</td></tr>
<tr><td>Moderate</td><td>30-40</td><td>Repeat every 12-24 hours</td><td>3+ days, until bleed stops</td></tr>
</table>
</td></tr>
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Indication	Dose			
	Major	35-50	Repeat every 12-24 hours	3+ days, until bleed stops
	Life-Threatening	35-50	Repeat every 8-24 hours	Until threat has resolved

VIII. Billing Code/Availability Information

HCPCS & NDC:

Drug	Manufacturer	J-Code	1 Billable Unit Equiv.	Vial Size	NDC
Alphanate	Grifols Biologicals, LLC	J7186	1 IU	250 units	- 68516-4601 - 68516-4611
				500 units	- 68516-4602 - 68516-4612
				1000 units	- 68516-4603 - 68516-4613
				1500 units	- 68516-4604 - 68516-4614
				2000 units	- 68516-4609 - 68516-4615
Humate-P	CSL Behring LLC	J7187	1 IU	600 units	63833-0615
				1200 units	63833-0616
				2400 units	63833-0617
Wilate	Octapharma USA, Inc	J7183	1 IU VWF:RCO	500 units	67467-0182
				1000 units	

IX. References

1. Alphanate [package insert]. Los Angeles, CA; Grifols Biologicals Inc.; June 2023. Accessed November 2023
2. Humate-P [package insert]. Kankakee, IL; CSL Behring LLC; August 2020. Accessed November2023.
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4. 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.
5. 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.
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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 January 2019.
11. First Coast Service Options, Inc. Local Coverage Determination (LCD): Hemophilia Clotting Factors (L33684). Centers for Medicare & Medicaid Services, Inc. Updated on 01/04/2019 with effective date 01/01/2019. Accessed January 2019.
12. Novitas Solutions, Inc. Local Coverage Determination (LCD): Hemophilia Clotting Factors (L35111). Centers for Medicare & Medicaid Services, Inc. Updated on 01/19/2018 with effective date 01/01/2018. Accessed January 2019.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D66	Hereditary factor VIII deficiency
D68.01	Von Willebrand disease, type 1
D68.020	Von Willebrand disease, type 2A
D68.021	Von Willebrand disease, type 2B
D68.022	Von Willebrand disease, type 2M
D68.023	Von Willebrand disease, type 2N
D68.03	Von Willebrand disease, type 3
D68.04	Acquired von Willebrand disease
D68.09	Other von Willebrand disease

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

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

Jurisdiction(s): N
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56482&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP

Jurisdiction(s): J,M	**NCD/LCD Document (s):** A56065
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56065&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): H,L	**NCD/LCD Document (s):** A56433
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56433&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

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, 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

Policy Rationale: Humate, Alphanate, and Wilate were 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 Humate, Alphanate, and Wilate 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.