Neighborhood Health Plan OF RHODE ISLAND™
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Hemophilia Products – Factor IX: Alphanine SD, Alprolix, Bebulin, BeneFIX, Idelvion, Ixinity, Mononine, Profilnine, Rebinyn, and Rixubis

(Intravenous)

Effective date: 01/01/2020

Review date: 10/02/2019, 12/18/19

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*

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

II. Dosing Limits

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

- N/A

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

- Alprolix: 23,000 billable units per 28 day supply
- Alphanine: 36,800 billable units per 28 day supply
- Benefix: 36,800 billable units per 28 day supply
- Bebulin: 36,800 billable units per 28 day supply
- Idelvion: 25,300 billable units per 28 day supply
- Rixubis: 73,600 billable units per 28 day supply
- Ixinity: 36,800 billable units per 28 day supply
- Profilnine: 36,800 billable units per 28 day supply
- Mononine: 36,800 billable units per 28 day supply
- Rebinyn: 23,000 billable units per 28 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. AlphaNine SD, Alprolix, Bebulin, BeneFIX, Profilnine SD, Mononine, Rixubis, IXINITY, Idelvion and Rebinyn

Coverage is provided in the following conditions:

Hemophilia B (congenital factor IX deficiency aka Christmas disease) †

- Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management *(*Authorizations valid for 1 month)*; **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes *(excluding Rebinyn)*; **AND**
    - Patient must have severe hemophilia B (factor IX level of <1%); **OR**
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **AND**
- Therapy NOT used for induction of immune tolerance in patients with Hemophilia B for ONLY the following products:
  - Alprolix
  - Rixubis
  - Ixinity
  - Idelvion
  - Rebinyn

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.

- If the request is for Alprolix, Idelvion, or Rebinyn, a half-life study should be performed to determine the appropriate dose and dosing interval.
  - For Alprolix, 50 IU/kg every 7 days is the preferred dosing regimen. To obtain 100 IU every 10 days, a half-life study must be submitted showing a significant clinical benefit over 50 IU/kg every 7 days.
  - Prior to switching to Alprolix, Idelvion, or Rebinyn, a half-life study should also be performed on current non- EHL factor IX product to ensure that a clinical benefit will be achieved.
- 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);

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.); **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 12 month authorization period

VI. Dosage/Administration

Alprolix

Indication	Dose
Control and prevention of bleeding episodes Hemophilia B	One unit per kilogram body weight increases the circulating Factor IX level by 1% (IU/dL). Estimate the required dose or the expected in vivo peak increase in Factor IX level expressed as IU/dL (or % of normal) using the following: IU/dL (or % of normal) = [Total Dose (IU)/Body Weight (kg)] x Recovery (IU/dL per IU/kg) Minor and Moderate Circulating Factor IX required (% of normal) = 30-60 IU/dL -Repeat every 48 hours as needed Major Circulating Factor IX required (% of normal) = 80-100 IU/dL - Consider repeat dose after 6-10 hours, then every 24 hours for 3 days, then every 48 hours until healing achieved.
Perioperative management Hemophilia B	Minor Circulating Factor IX required (% of normal) = 50-80 IU/dL -Repeat every 24-48 hours as needed, until bleeding stops and healing is achieved. Major

	Circulating Factor IX required (% of normal) = 60-100 IU/dL (initial level) - Consider repeat dose after 6-10 hours, then every 24 hours for 3 days, then every 48 hours until bleeding stops and healing achieved.
Routine prophylaxis Hemophilia B	50 IU/kg once weekly or 100 IU/kg once every 10 days. Adjust dosing regimen based on individual response.

AlphaNine SD

Indication	Dose
Control and prevention of bleeding episodes Hemophilia B	One unit per kilogram body weight increases the circulating Factor IX level by 1% (IU/dL). Number of Factor IX IU required = body wt (kg) x Desired increase in Plasma Factor IX(percent) x 1.0 IU/kg Minor Circulating Factor IX required (20 – 30 % of normal) = 20-30 IU/kg -Repeat every 12 hours as needed for 1-2 days Moderate Circulating Factor IX required (25 - 50% of normal) = 25-50 IU/kg -Repeat every 12 hours as needed for 2-7 days Major Circulating Factor IX required (50% of normal) = 50-100 IU/kg - Consider repeat dose after 12 hours as needed for 3-5 days. Following this treatment period, FIX levels should be maintained at 20% (20 IU FIX/kg/twice daily) until healing has been achieved. Major hemorrhages may require treatment for up to 10 days
Routine prophylaxis Hemophilia B §	25-40 IU/kg two times weekly or 15-30 IU/kg two times weekly. Adjust dosing regimen based on individual response.
Perioperative management Hemophilia B	Prior to surgery, FIX should be brought to 50-100% of normal (50-100 IU/kg repeat every 12 hours). For the next 7 to 10 days, or until healing has been achieved, the patient should be maintained at 50-100%FIX levels (50-100 IU/kg every 12 hours).

BeneFIX

Indication	Dose
Control and prevention of bleeding episodes Hemophilia B and Perioperative	One unit per kilogram body weight increases the circulating Factor IX level by 1% (IU/dL). ADULT: Number of Factor IX IU required = body wt (kg) x Desired increase in Plasma Factor IX(percent) x 1.3 IU/kg; CHILD (<15 years) Number of Factor IX IU required = body wt (kg) x Desired increase in Plasma Factor IX(percent) x 1.4 IU/kg Minor

management of Hemophilia B	Circulating Factor IX required (% of normal) = 20-30 IU/dL -Repeat every 12-24 hours as needed for 1-2 days Moderate Circulating Factor IX required (% of normal) = 25-50 IU/dL -Repeat every 12-24 hours as needed for 2-7 days Major Circulating Factor IX required (% of normal) = 50-100 IU/dL - Consider repeat dose after 12-24 hours as needed for 7- 10 days.
Routine prophylaxis Hemophilia B §	25-40 IU/kg two times weekly or 15-30 IU/kg two times weekly. Adjust dosing regimen based on individual response.

Bebulin

Indication	Dose
Control and prevention of bleeding episodes Hemophilia B	One unit per kilogram body weight increases the circulating Factor IX level by 1% (IU/dL). Number of Factor IX IU required = body wt (kg) x Desired increase in Plasma Factor IX(percent) x 1.2 IU/kg Minor Circulating Factor IX required (% of normal) (20%)= 25-35 IU/dL -Repeat every 24 hours as needed until adequate wound healing Moderate Circulating Factor IX required (% of normal) (40%)= 50-65 IU/dL -Repeat every 24 hours as needed for 2 days or until adequate wound healing Major Circulating Factor IX required (% of normal)(>60%) = 75-90 IU/dL - Consider repeat dose after 24 hours as needed for 2-3 days or until adequate wound healing.
Routine prophylaxis Hemophilia B §	25-40 IU/kg two times weekly or 15-30 IU/kg two times weekly. Adjust dosing regimen based on individual response.
Perioperative management Hemophilia B	Minor Circulating Factor IX required (% of normal) (40-60%)= 50-75 IU/dL given 1 hour prior to surgery, repeat every 12 hours, and continue replacement therapy over 1 to 2 weeks postop until adequate wound healing is achieved. Major Circulating Factor IX required (% of normal) (>60%)= 75-90 IU/dL given 1 hour prior to surgery, repeat every 12 hours, and continue replacement therapy over for up to 2 weeks postop. If treatment is required beyond 2 weeks post-up, then dosing interval can be adjusted to every 24 hours and continued until adequate wound healing is achieved.

Idelvion

Indication	Dose
Control and prevention of bleeding episodes	• One IU of IDELVION per kg body weight is expected to increase the circulating activity of Factor IX as follows: o Adolescents and adults: 1.3 IU/dL per IU/kg o Pediatrics (<12 years): 1 IU/dL per IU/kg • Administer intravenously. Do not exceed infusion rate of 10 mL per minute. • Dosage and duration of treatment with IDELVION depends on the severity of the Factor IX deficiency, the location and extent of bleeding, and the patient's clinical condition, age and recovery of Factor IX. • Determine the initial dose using the following formula: o Required Dose (IU) = Body Weight (kg) x Desired Factor IX rise (% of normal or IU/dL) x (reciprocal of recovery (IU/kg per IU/dL)) • Adjust dose based on the patient's clinical condition and response. Minor/Moderate Desired peak Factor IX Level (% of normal or IU/dL): 30-60, dosed every 48-72 hours for at least 1 day until healing is achieved Major Desired peak Factor IX Level (% of normal or IU/dL): 60-100, dosed every 48-72 hours for 7-14 days until bleeding stops. Maintenance dose is weekly.
Perioperative management Hemophilia B	Minor Desired peak Factor IX Level (% of normal or IU/dL): 50-80, dosed every 48-72 hours for at least 1 day until healing is achieved Major Desired peak Factor IX Level (% of normal or IU/dL): 60-100, dosed every 48-72 hours for 7-14 days until bleeding stops. Repeat dose every 48-72 hours for the first week or until healing is achieved. Maintenance dose is once or twice weekly.
Routine prophylaxis Hemophilia B	Patients ≥12 years of age: 25-40 IU/kg body weight every 7 days. Patients who are well-controlled on this regimen may be switched to a 14-day interval at 50-75 IU/kg body weight. Patients <12 years of age: 40-55 IU/kg body weight every 7 days.

Ixinity

Indication	Dose
Control and prevention of bleeding episodes Congenital Hemophilia B	One IU per kg body weight increases the circulating activity of factor IX by 0.698 IU/dL Initial dose: Required factor IX units (IU) = body weight (kg) x desired factor IX increase (% of normal of IU/dL) x reciprocal of observed recovery (IU/kg per IU/dL) Maintenance dose: Depends upon the type of bleed or surgery, clinical response, and the severity of the underlying factor IX deficiency

	Minor Desired peak Factor IX Level (% of normal or IU/dL): 30-60, dosed every 24 hours on days 1-3 until healing is achieved Moderate Desired peak Factor IX Level (% of normal or IU/dL): 40-60, dosed every 24 hours on days 2-7 until healing is achieved Major or Life threatening Desired peak Factor IX Level (% of normal or IU/dL): 60-100, dosed every 12 – 24 hours on days 2-14 until healing is achieved
Perioperative management Congenital Hemophilia B	Minor Pre-op: Desired peak Factor IX Level (% of normal or IU/dL) 50-80 Post-op: Desired peak Factor IX Level (% of normal or IU/dL) 30-80, dosed every 24 hours on days 1-5, depending on type of procedure Major Pre-op: Desired peak Factor IX Level (% of normal or IU/dL)60-80 Post-op: Desired peak Factor IX Level (% of normal or IU/dL) 40-60, dosed every 8 – 24 hours on days 1-3, or 30-50 dosed every 8 – 24 hours on days 4-6, or 20-40 dosed every 8 -24 hours on days 7-14

Mononine

Indication	Dose
Control and prevention of bleeding episodes and perioperative management Hemophilia B	One unit per kilogram body weight increases the circulating Factor IX level by 1% (IU/dL). Estimate the required dose with the following formula: Number of Factor IX IU required (IU) = Body Weight (in kg) x desired Factor IX increase (% or IU/dL normal) x 1.0 IU/kg [per IU/dL] Minor Spontaneous Hemorrhage Prophylaxis Circulating Factor IX required (% of normal)(15-25%) = up to 20-30IU/kg for one dose. Repeat in 24 hours if necessary. Major Trauma or Surgery Circulating Factor IX required (% of normal)(25-50%) = up to 75 IU/kg Dosed every 18-30 hours depending on $T_{1/2}$ and measured Factor IX levels. Continue for up to 10 days depending upon nature of insult.

Profilnine SD

Indication	Dose
Control and prevention of bleeding episodes Hemophilia B	One unit per kilogram body weight increases the circulating Factor IX level by 1% (IU/dL). Number of Factor IX IU required = body wt (kg) x Desired increase in Plasma Factor IX(percent) x 1.0 IU/kg Mild to Moderate

Indication	Dose
	Single dose of product sufficient to raise plasma factor IX levels to 20 to 30 percent of normal. 20-30 IU/kg every 16-24 hours until hemorrhage stops and healing is achieved. For minor, may repeat for 1-2 days, for moderate, may repeat for 2-7 days. Major Single dose of product sufficient to raise plasma factor IX levels to 30 to 50 percent of normal. Daily infusions are generally required.
Routine prophylaxis Hemophilia B §	25-40 IU/kg two times weekly or 15-30 IU/kg two times weekly. Adjust dosing regimen based on individual response.
Perioperative management Hemophilia B	Surgery associated with bleeding in factor IX deficient patients requires factor IX levels of 30 to 50 percent. 30-50 IU/kg every 16-24 hours for 7-10 days until healing is achieved. For dental extractions, the factor IX level should be raised to 50 percent immediately prior to procedure; additional factor IX complex may be given if bleeding recurs.

Rebinyn

Indication	Dose
On-demand treatment and control of bleeding episodes Congenital Hemophilia B	Minor and Moderate 40 IU/kg of actual body weight. A single dose should be sufficient for minor and moderate bleeds. Additional doses of 40 IU/kg can be given. Major 80 IU/kg of actual body weight. Additional doses of 40 IU/kg can be given.
Perioperative management of bleeding Congenital Hemophilia B	Minor Pre-op: 40 IU/kg of actual body weight (single pre-op dose should be sufficient) Post-op: Additional doses can be given if required Major Pre-op: 80 IU/kg of actual body weight Peri/Post-op: 40 IU/kg of actual body weight. As clinically needed for the perioperative management of bleeding, repeated doses of 40 IU/kg (in 1-3 day intervals) within the first week after major surgery may be administered. Due to the long half-life the frequency of dosing in the post-surgical setting may be extended to once weekly after the first week until bleeding stops and healing is achieved.

Rixubis

Indication	Dose
Control and prevention of	One IU per kilogram body weight increases the circulating activity of Factor IX by 0.7 IU/dL for patients <12 years of age and 0.9 IU/dL for patients ≥ 12 years of age.

Indication	Dose
bleeding episodes Hemophilia B	Initial dose = body wt (kg) x desired factor IX increase (percent of normal or IU/dL) x reciprocal of observed recovery (IU/kg per IU/dL) Minor Circulating Factor IX level required (% or IU/dL) = 20-30 every 12 - 24 hours for at least 1 day, until healing is achieved Moderate Circulating Factor IX level required (% or IU/dL) = 25-50 every 12 - 24 hours for 2 – 7 days, until bleeding stops and healing is achieved Major Circulating Factor IX level required (% or IU/dL) = 50-100 every 12 - 24 hours for 7 – 10 days, until bleeding stops and healing is achieved
Routine prophylaxis Hemophilia B	Dosing for previously treated patients (PTPs): Patients <12 years of age 60 – 80 IU/kg twice weekly Patients ≥ 12 years of age 40 – 60 IU/kg twice weekly Adjust the dose based on the individual patient's age, bleeding pattern, and physical activity.
Perioperative management Hemophilia B	Minor Circulating Factor IX level required (% or IU/dL) = 30-60 every 24 hours for at least 1 day, until healing is achieved Major Circulating Factor IX level required (% or IU/dL) = 80-100 every 8 - 24 hours for 7 – 10 days, until bleeding stops and healing is achieved

§ Utrecht and/or Malmö protocols used as basis for dosing

VII. Billing Code/Availability Information

HCPCS & NDC:

Drug	Manufacturer	J-Code	1 Billable Unit Equiv.	Vial Size	NDC
AlphaNine SD	Grifols Biologicals Inc	J7193	1 IU	500 units	-68516-3600 -68516-3602 -68516-3605
				1000 units	-68516-3600 -68516-3603 -68516-3606
				1500 units	-68516-3600 -68516-3601

					- 68516-3604
Mononine	CSL Behring LLC	J7193	1 IU	1000 units	00053-6233
Alprolix	Biogen Idec, Inc	J7201	1 IU	250 units	64406-0966
				500 units	64406-0911
				1000 units	64406-0922
				2000 units	64406-0933
				3000 units	64406-0944
				4000 units	64406-0977
Bebulin	Baxalta US Inc	J7194	1 IU	Unassigned size	64193-0445
Profilnine SD	Grifols Biologicals Inc	J7194	1 IU	500 units	– 68516-3200 – 68516-3201 – 68516-3204
				1000 units	– 68516-3200 – 68516-3202 – 68516-3205
				1500 units	– 68516-3200 – 68516-3203 – 68516-3206
BeneFIX	Wyeth Biopharma	J7195	1 IU	250 units	58394-0633
				500 units	58394-0634
				1000 units	58394-0635
				2000 units	58394-0636
				3000 units	58394-0637
Ixinity	Cangene Corp	J7195	1 IU	250 units	70504-0287
				500 units	- 70504-0270 - 70504-0282
				1000 units	- 53270-0271 - 53270-0283 - 53270-0285
				1500 units	- 53270-0272 - 53270-0284 - 53270-0286
				2000 units	70504-0288
				3000 units	70504-0289
Rixubis	Baxalta US Inc	J7200	1 IU	250 units	00944-3026
				500 units	00944-3028
				1000 units	00944-3030
				2000 units	00944-3032
				3000 units	00944-3034
Idelvion	Novozymes Biopharma A/S	J7202	1 IU	250 units	69911-0864
				500 units	69911-0865
				1000 units	69911-0866
				2000 units	69911-0867
Rebinyn	Novo Nordisk Inc	J7203	1 IU N/A	500 units	00169-7905
				1000 units	00169-7901
				2000 units	00169-7902

VIII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D67	Hereditary factor IX deficiency

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	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