Hemophilia Products – Factor IX: AlphaNine SD, Alprolix, BeneFIX, Idelvion, Ixinity, Mononine, Profilnine, Rebinyn, and Rixubis
(Intravenous)

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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) [NDC Unit]:

- N/A

B. Max Units (per dose and over time) [HCPCS Unit]:

Alprolix, Rebinyn	23,000 billable units per 28-day supply
Idelvion	25,300 billable units per 28-day supply
AlphaNine SD, Ixinity, Profilnine, Mononine	36,800 billable units per 28-day supply
BeneFIX	46,000 billable units per 28-day supply
Rixubis	73,600 billable units per 28-day supply

III. Initial Approval Criteria[1-11,15]

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.

Coverage is provided in the following conditions:

Universal Criteria [1-5,7-9]

- Therapy NOT used for induction of immune tolerance in patients with Hemophilia B [ONLY the following products]:
  - Alprolix
  - Rixubis
  - Ixinity
  - Idelvion
  - Rebinyn
  - AlphaNine SD
  - Mononine
  - BeneFIX; **AND**

Hemophilia B (congenital factor IX deficiency aka Christmas disease) † Φ [1-9]

- 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

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); Φ Orphan Drug *(NOTE: Only applies to Alphanine SD, Alprolix, BeneFIX, Idelvion, and Mononine)*

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 [1-11,15]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), nephrotic syndrome, 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 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; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

VI. Dosage/Administration[1-9]

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	Adults and adolescents ≥12 years of age 50 IU/kg once weekly or 100 IU/kg once every 10 days. Adjust dosing regimen based on individual response. Children <12 years of age Start with 60 IU/kg once weekly. Adjust dosing regimen based on individual response. More frequent or higher doses may be needed in children <12 years of age, especially in children <6 years of age.

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) = 30-50 IU/kg - Repeat dose every 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 and perioperative management of Hemophilia B	One IU per kilogram body weight increases the circulating Factor IX level by 0.8 ± 0.2 IU/dL in adolescents/adults (≥12 years) and 0.7 ± 0.3 IU/dL in children (< 12 years). Initial dose: Number of Factor IX IU required (IU) = body weight (kg) x desired factor IX increase (% of normal or IU/dL) x reciprocal of observed recovery (IU/kg per IU/dL) • Minor hemorrhage: Circulating Factor IX activity required [% of normal or (IU/dL)]: 20-30, dosed every 12 to 24 hours for 1 to 2 days. • Moderate hemorrhage: Circulating Factor IX activity required [% of normal or (IU/dL)]: 25-50, dosed every 12 to 24 hours for 2 to 7 days until bleeding stops and healing begins. • Major hemorrhage: Circulating Factor IX activity required [% of normal or (IU/dL)]: 50-100, dosed every 12 to 24 hours for 7 to 10 days. *Dosage and duration of treatment with BeneFIX depend 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.*
Routine prophylaxis to reduce the	Patients ≥ 16 years of age: • 100 IU/kg once weekly

frequency of bleeding episodes	• Adjust the dosing regimen (dose or frequency) based on the patient's clinical response.

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 • 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. <u>Minor/Moderate</u> 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 <u>Major</u> Desired peak Factor IX Level (% of normal or IU/dL): 60-100, dosed every 48-72 hours for 7-14 days until healing is achieved. Maintenance dose is weekly.
Perioperative management Hemophilia B	<u>Minor</u> 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 <u>Major</u> Desired peak Factor IX Level (% of normal or IU/dL): 60-100, dosed every 48-72 hours for 7-14 days until healing is achieved. 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	<u>Patients ≥12 years of age</u>: 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. <u>Patients <12 years of age</u>: 40-55 IU/kg body weight every 7 days.

Ixinity

Indication	Dose
Control and prevention of bleeding episodes	One IU per kg body weight increases the circulating activity of factor IX by 0.98 IU/dL. Patients ≥ 12 years of age:

Congenital Hemophilia B	• 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 bleeding episode: 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 bleeding episode: 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 bleeding episode: 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	Patients ≥ 12 years of age: Minor surgery: • 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 surgery: • 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, then 30-50 dosed every 8-24 hours on days 4-6, and then 20-40 dosed every 8 -24 hours on days 7-14
Routine prophylaxis to reduce the frequency of bleeding episodes	Patients ≥ 18 years of age: • 40 to 70 IU/kg twice weekly • Adjust the dose based on the individual patient's bleeding pattern and physical activity.

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 20-30 IU/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

Indication	Dose
Control and prevention of bleeding episodes Hemophilia B	Patients ≥ 18 years of age: 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 to Moderate Single dose of product sufficient to raise plasma Factor IX levels to 20-30% 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 30-50% of normal. 30-50 IU/kg every 16-24 hours for up to 3-10 days. Following this treatment period, maintain Factor IX levels at 20% of normal until healing has been achieved.
Routine prophylaxis Hemophilia B §	Patients ≥ 18 years of age: 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	Patients ≥ 18 years of age: Surgery associated with bleeding in Factor IX deficient patients require Factor IX levels of 30-50% of normal. For dental extractions, the Factor IX level should be raised to 50% of normal immediately prior to procedure. 30-50 IU/kg every 16-24 hours for 7-10 days until healing is achieved. Maintain Factor IX levels at 30-50% of normal until healing has been achieved.

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 bleeding episodes Hemophilia B	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. 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 Code & NDC:

Drug	Manufacturer	HCPCS Code	1 Billable Unit Equiv.	Vial Size	NDC
AlphaNine SD	Grifols Biologicals Inc.	J7193	1 IU	500 units	68516-3601 68516-3607
				1000 units	68516-3602 68516-3608
				1500 units	68516-3603 68516-3609
Mononine	CSL Behring LLC	J7193	1 IU	500 units	00053-6232
				1000 units	00053-6233
Alprolix	Bioverativ Therapeutics Inc.	J7201	1 IU	250 units	71104-0966
				500 units	71104-0911
				1000 units	71104-0922
				2000 units	71104-0933
				3000 units	71104-0944
				4000 units	71104-0977
Profilnine	Grifols Biologicals Inc.	J7194	1 IU	500 units	68516-3201 68516-3207
				1000 units	68516-3202 68516-3208
				1500 units	68516-3203 68516-3209
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	Aptevo BioTherapeutics LLC	J7195	1 IU	250 units	70504-0287
				500 units	70504-0282
				1000 units	70504-0283
				1500 units	70504-0284
				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	CSL Behring LLC	J7202	1 IU	250 units	69911-0864
				500 units	69911-0865
				1000 units	69911-0866
				2000 units	69911-0867
				3500 units	69911-0869
Rebinyn	Novo Nordisk Inc.	J7203	1 IU	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), 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: 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/LCA/LCD):

Jurisdiction(s): N	**NCD/LCA/LCD Document (s):** A56482
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/LCA/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/LCA/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