SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: 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: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Factor IX Deficiency Therapy (Hemophilia B) (MEDICAL)

Drug Requested: select one drug below

Human Plasma-derived Factor IX Replacement Products		
❑ J7193 AlphaNine®	❑ J7194 Profilnine®	
Recombinant Factor IX Replacement Products		
❑ J7195 Ixinity®, BeneFIX®	❑ J7200 Rixubis®	
Extended Half-life Factor IX Replacement Products		
❑ J7201 Alprolix®	❑ J7202 Idelvion®	❑ J7203 Rebinyn®

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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Dosing Limits:

A. Quantity Limit (max daily dose) [NDC Unit]

- N/A

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

- Alprolix: 34,500 billable units per 30-day supply
- Idelvion: 18,400 billable units per 28-day supply
- Rebinyn: 18,400 billable units per 28-day supply
- Ixinity: 64,000 billable units per 28-day supply
- AlphaNine SD: 36,800 billable units per 28-day supply
- Profilnine: 36,800 billable units per 28-day supply
- BeneFIX: 46,000 billable units per 28-day supply
- Rixubis: 55,200 billable units per 28-day supply

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Part I. Initial Authorization

- ❑ Diagnosis of congenital Factor IX deficiency has been confirmed by blood coagulation testing
- ❑ Medication prescribed by a specialist familiar with treating patients with hemophilia (Factor IX deficiency)
- ❑ If member was treated with prior gene therapy for hemophilia B (e.g., Hemgenix® (etranacogene dezaparvovec-drlb), Beqvez™ (fidanacogene elaparvovec-dzkt)) and requires FIX replacement therapy, documentation is submitted to show that FIX activity levels have decreased and/or bleeding has not been controlled
- ❑ Requested medication will be used as treatment in at least **ONE** of the following:
  - ❑ On-demand treatment and control of bleeding episodes **(Authorization will be approved for 6 months)**

    Please Attach On-Demand Treatment Dosing Calculations [Dosage regimen to adhere to most current recommended FDA-label and/or compendia recommendations (see Part IV)]
  - ❑ Perioperative management **(Authorization will be approved for 1 month to accommodate for procedure)**

    Name/Description of Procedure: _____

    Date of Procedure: _____

    Dosage regimen must adhere to most current recommended FDA-label and/or compendia recommendations (see Part IV):

    _____

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- ❑ Routine prophylaxis **(Authorization will be approved for a 12-month period)**
  Dosage regimen must adhere to most current recommended FDA-label and/or compendia recommendations (see Part IV):

- ❑ **FOR ROUTINE PROPHYLAXIS:** Requested medication will be sed as treatment in at least **ONE** of the following:
  - ❑ Severe Factor IX deficiency (a Factor IX level of <1%) **AND** member must meet **ONE** of the following:
    - ❑ Member has a history of life-threatening hemorrhage requiring on-demand use of Factor IX therapy
    - ❑ Member has a history of repeated, serious spontaneous bleeding episodes requiring on-demand use of Factor IX therapy

Part II. If Requesting Extended-Half Life (EHL) Products: J7201 Alprolix, J7202 Idelvion, J7203 Rebinyn

- ❑ Member must have had a trial and failure of a non-extended half-life clotting factor replacement product: BeneFIX, Ixinity, Rixubis, AlphaNine, Profilnine **[NOTE: Submit past medical history, FIX levels, trials of prior therapy, etc. to convey that the member is NOT a candidate for a non-extended half-life product]**
- ❑ Provider must submit a half-life study to determine the appropriate dose and dosing interval of the EHL product when initiated
- ❑ **FOR ROUTINE PROPHYLAXIS, ALL** the following must be met:
  - ❑ Requested medication will **NOT** be used in combination with other FIX products, Hympavzi® (marstacimab-hncq), Alhemo® (concizumab-mtci), and/or Qfitlia® (fitusiran) in those with hemophilia B as prophylactic therapy
  - ❑ If the request exceeds any of the following dosing limits, documentation must be submitted specifying why the member is not a suitable candidate prophylaxis therapy with Hympavzi® (marstacimab-hncq), Alhemo® (concizumab-mtci), or Qfitlia® (fitusiran):
    - ❑ 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
    - ❑ Idelvion: 25-40 IU/kg every 7 days for patients ≥12 years of age; 40-55 IU/kg every 7 days for <12 years of age
    - ❑ Rebinyn: 40 IU/kg body weight once weekly

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Part III. Renewal Clinical Authorization

- ❑ Requested medication will be used as treatment in at least **ONE** of the following:
  - ❑ On-demand treatment and control of bleeding episodes **(Authorization will be approved for 6 months)**

    Please Attach On-Demand Treatment Dosing Calculations [Dosage regimen to adhere to most current recommended FDA-label and/or compendia recommendations (see Part IV)]
  - ❑ Perioperative management **(NO RENEWAL AUTHORIZATIONS – PLEASE COMPLETE PART I)**
  - ❑ Routine prophylaxis **(Authorization will be approved for a 12-month period)**

    Dosage regimen must adhere to most current recommended FDA-label and/or compendia recommendations (see part IV):

    _____

    NOTE: Provider must submit clinical rationale (i.e., past medical records, weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy) for an increase in dose
- ❑ Provider must confirm **ALL** the following:
  - ❑ Member has experienced an absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: anaphylaxis and hypersensitivity reactions (e.g., angioedema, chest tightness, hypotension, urticaria, wheezing, dyspnea, etc.), thromboembolic events (pulmonary embolism, venous thrombosis, and arterial thrombosis), development of neutralizing antibodies (inhibitors), nephrotic syndrome, etc.
  - ❑ Member continues to meet criteria in Part I and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.
  - ❑ Member has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

Part IV. Dosage/Administration

Hemophilia Dosing For BMI

- 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)

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Indication	Dose
Alprolix	
On-demand treatment and control of bleeding episodes Hemophilia B	One unit per kilogram body weight increases the circulating Factor IX level by 1% (IU/dL) in adults and children ≥6 years of age and by 0.6% (IU/dL) in children under 6 years of age. 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	One unit per kilogram body weight increases the circulating Factor IX level by 1% (IU/dL) in adults and children ≥6 years of age and by 0.6% (IU/dL) in children under 6 years of age. 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** 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.

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Indication	Dose
AlphaNine SD	
On-demand treatment and control 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	
On-demand treatment and control of bleeding episodes and Perioperative management 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.

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Indication	Dose
BeneFIX	
Routine prophylaxis Hemophilia B	• 100 IU/kg once weekly Adjust the dosing regimen (dose or frequency) based on the patient's clinical response.
Idelvion	
On-demand treatment and control of bleeding episodes Hemophilia B	• 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. **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 healing is achieved. Maintenance dose is weekly.
Perioperative management Hemophilia B	• 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. **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 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.

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Indication	Dose
Idelvion	
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	
On-demand treatment and control of bleeding episodes Hemophilia B	One IU per kilogram body weight increases the circulating activity of Factor IX by 0.79 IU/dL for patients <12 years of age and 0.98 IU/dL for patients ≥ 12 years of age. • **Initial dose:** Required factor IX units (IU) = body weight (kg) x desired factor IX increase (% of normal or 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 for 1-3 days until healing is achieved • **Moderate bleeding episode:** Desired peak Factor IX Level (% of normal or IU/dL): 40-60, dosed every 24 hours for 2-7 days 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 for 2-14 days until healing is achieved
Perioperative management Hemophilia B	One IU per kilogram body weight increases the circulating activity of Factor IX by 0.79 IU/dL for patients <12 years of age and 0.98 IU/dL for patients ≥ 12 years of age. **Initial dose:** Required factor IX units (IU) = body weight (kg) x desired factor IX increase (% of normal or 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 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 for 1-5 days, 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 for 1-3 days, then 30-50 dosed every 8-24 hours for 4-6 days, and then 20-40 dosed every 8-24 hours for 7-14 days

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Indication	Dose
Ixinity	
Routine prophylaxis Hemophilia B	Patients ≥ 12 years of age: • 40 to 70 IU/kg twice weekly Patients < 12 years of age: • 35 to 75 IU/kg twice weekly **NOTE:** Adjust the dosing regimen (dose or frequency) based on the patient's clinical response. Adjust the dose based on the individual patient's age, bleeding pattern, and physical activity.
Profilnine	
On-demand treatment and control 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	
On-demand treatment and control of bleeding episodes 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.

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Indication	Dose
Rebinyn	
Perioperative management 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.
Routine prophylaxis Hemophilia B	40 IU/kg once weekly. Adjust the dose based on the individual patient's bleeding pattern and physical activity.
Rixubis	
On-demand treatment and control 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.

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Indication	Dose
Rixubis	
Perioperative management 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. **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

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____
  NPI or DEA # of administering location: _____

OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee**: 5/22/2025
REVISED/UPDATED/REFORMATTED: ~~9/24/2025;~~ **10/24/2025**