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Prior Authorization Criteria

Hemophilia and Blood Factor Products

All requests for Hemophilia and Blood Factor Products require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Hemophilia or Blood Factor Products all of the following criteria must be met:

- Must be prescribed by or in consultation with a hematologist
- Documentation of the prescription drug, dose and directions from the prescriber must be submitted with each authorization.
- The requested assay and quantity are within the prescription directions
- For prophylactic dosing, the dispensed assay NDC must be as close to the physician written dose as possible (dose optimization)
- The number of on-hand (prn doses) at the member's home should not exceed two doses barring any extreme extenuating circumstances that prevents timely delivery of appropriate doses, clinical judgment should be used for any exceptions.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- For a longer acting Recombinant Factor product, must provide documentation showing the member has tried and failed or had an intolerance/contraindication to a shorter acting Recombinant Factor product OR physician documents rationale for use of a longer acting recombinant factor product versus a shorter acting recombinant factor product.

Coverage may be provided with a diagnosis of Factor VIII Disorder (Hemophilia A) and the following criteria is met:

- Must be used for one of the following indications:
    - Treatment and control of bleeding episodes
    - Perioperative management of bleeding
    - Prevention and control of bleeding episodes
- For mild disease, the member tried and failed or had an intolerance or contraindication to desmopressin
- When inhibitors are present:
    - The member's Factor level or level of severity is documented
    - For moderate to severe hemophilia, must provide documentation of type of inhibitor (low-responding or high-responding inhibitors)
    - Must have factor inhibitor level ≤ 10 Bethesda units (BU)/mL (*antihemophilic factor is usually not effective in members with Factor VIII inhibitor levels > 10 BU/mL, as it is impossible or impractical to achieve hemostasis with factor VIII concentrates unless procedures to temporarily decreased plasma inhibitor levels are employed prior to administration of antihemophilic factor*)
    - Treatment with an Immune Tolerance Induction (ITI) regimen requires the following:
        - Must have a factor inhibitor level between 5 and 10 BU/mL and be a high responder

        - Documentation of initiation of ITI within five years of the member being diagnosed with inhibitors

Coverage may be provided with a diagnosis of Factor IX Disorder (Hemophilia B/Christmas Disease) and the following criteria is met:

- Must be used for one of the following indications:
    - Treatment and control of bleeding episodes
    - Perioperative management of bleeding
    - Prevention and control of bleeding episodes
- When inhibitors are present:
    - The member's Factor level or level of severity is documented
    - For moderate to severe hemophilia, must provide documentation of type of inhibitor (low-responding or high-responding inhibitors)
    - Treatment with an Immune Tolerance Induction (ITI) regimen requires the following:
        - Must have a factor inhibitor level between 5 and 10 BU/mL and be a high responder
        - Documentation of initiation of ITI within five years of the member being diagnosed with inhibitors

Coverage may be provided with a diagnosis of Factor VII deficiency (extrinsic factor) deficiency for the following:

- Treatment and control of bleeding episodes
- Perioperative management of bleeding
- Prevention and control of bleeding episodes

Coverage may be provided with a diagnosis of Factor X (Stuart-Prower) deficiency for the following:

- Treatment and control of bleeding episodes
- Perioperative management of bleeding
- Prevention and control of bleeding episodes

Coverage may be provided with a diagnosis of Factor XIII (fibrin stabilizing) deficiency for the following:

- Treatment and control of bleeding episodes
- Perioperative management of bleeding
- Prevention and control of bleeding episodes

Coverage may be provided with a diagnosis of acquired hemophilia for the following:

- Treatment of acute bleeding episodes
- Perioperative management of bleeding

Coverage may be provided with a diagnosis of Glanzmann's thrombasthenia refractory to platelet transfusions for the following:

- Treatment of acute bleeding episodes
- Perioperative management of bleeding

Coverage may be provided with a diagnosis of von Willebrand disease for the following:

- Treatment of acute bleeding episodes when the member has tried and failed or had an intolerance or contraindication to desmopressin when clinically appropriate
- Perioperative management of bleeding
- If the diagnosis is significant menorrhagia in women with von Willebrand disease, the following must be provided in addition to a trial and failure of desmopressin:
    - Documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to BOTH of the following:
        - Combined oral contraceptives or levonorgestrel intrauterine device
        - Antifibrinolytics (tranexamic acid or ε-aminocaproic acid)

Initial Duration of Approval: 12 weeks

Reauthorization criteria:

- Must provide the current number of on-hand doses and number of bleeding episodes since the previous authorization
- For prophylactic dosing, coverage will not be granted for additional doses if greater than a 7-day supply is on hand unless on-demand dosing is medically necessary
- If inhibitors are present, Bethesda assay titers are required
- For treatment with ITI, continued therapy is no longer considered medically necessary when both of the following criteria are met:
    - Inhibitor levels become undetectable (negative Bethesda assay)
    - Recovery of Factor VIII levels after infusion are normal (defined as at least 66% of expected level and a half-life of ≥ 7 hours are considered sufficient normal pharmacokinetic responses to characterize a complete tolerance)

Reauthorization Duration of approval: 12 weeks

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

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HEMOPHILIA AND BLOOD FACTOR PRODUCTS PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: pounds or kg

PRESCRIPTION INFORMATION (Copy of Rx/Order from Physician is required)

	Product 1	Product 2	Product 3
Product Name			
Frequency			
NDC			
Day Supply (from Rx)			
Dates Needed	**From:**_____ **To:** _____		

Dispensing Information (Based on Rx)				Dispensing Information (Assay Availability)		
Dose Type	**Units Per Dose**	**Total # of Doses**	**Vial Strength (Per Manufacturer Label)**	**Assay to Dispense**	**# of Vials Requested**	**Total Units Requested**
☐ Prophylaxis Dose						
☐ On Demand (PRN)						
☐ ITI						
☐ Surgical/dental prophylaxis						

MEDICAL INFORMATION

If request is for surgical/dental prophylaxis, document procedure and date:_____

Degree of factor deficiency: ☐ Mild ☐ Moderate ☐ Severe
Inhibitors Present? ☐ Yes ☐ No
Type of inhibitor response: ☐ Low responding ☐ High responding **Bethesda Titer (BU):** _____BU

☐ **Hemophilia A (Factor VIII)**
- **Did the member previously try desmopressin?** ☐ **Yes** ☐ **No**

☐ **Hemophilia B (Factor IX disorder, Christmas Disease)**

☐ **von Willebrand's disease, subtype:** ☐ **1** ☐ **2A** ☐ **2B** ☐ **2M** ☐ **2N** ☐ **3**
- **Did the member previously try desmopressin?** ☐ **Yes** ☐ **No**

Does the member have significant menorrhagia with von Willebrand disease
☐ **Yes** ☐ **No**
- **Did the member previously try desmopressin?** ☐ **Yes** ☐ **No**
- **Did the member previously try combined oral contraceptives or levonorgestrel intrauterine device?** ☐ **Yes** ☐ **No**

Did the member previously try antifibrinolytics? ☐ **Yes** ☐ **No**

☐ **Factor VII disorder**

☐ **Factor XIII disorder-fibrin stabilizing factor deficiency**

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PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

Member Name:	DOB:
Gateway ID:	Member weight: pounds or kg

Number of factor doses currently on-hand at home: _____
Number of bleeds reported since last dispensing of factor product: _____
Date of previous dispense/shipment: _____
Previous month units DISPENSED: _____ units, USED: _____ units, REMAINING: _____ units

Prescribing Physician Signature	Date