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.

**Hemophilia and Blood Factor Products Prior Authorization Criteria:**

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
• 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

**Initial Duration of Approval:** 1 month

**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 if either of the following criteria are met:
  o 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 >6 hours are considered sufficient normal pharmacokinetic responses to characterize a complete tolerance)

Reauthorization Duration of approval: 1 month

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.