Gateway Health
Prior Authorization Criteria

Hemophilia and other Blood Factor Products

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

Hemophilia and other Blood Factor Products Prior Authorization Criteria:

- Coverage is provided for Blood Factor Products when all of the following criteria is met:
  - Documentation of a diagnosis of Hemophilia and type of deficiency OR von Willebrand disease
  - Treatment is prescribed by a hematologist
  - The specialty pharmacy has supplied the prescription drug, dose, and directions from the prescriber for each authorization.
  - For reauthorization requests, the specialty pharmacy has supplied the current number of on-hand doses and number of bleeding episodes since the last authorization
  - The requested dose and frequency should be appropriate based on treatment guidelines and within FDA approved dosing recommendations
  - 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 member or caregiver is administering the medication at home
  - Documentation states the member or caregiver has been trained on appropriate injection technique and is able to self-administer the correct dose
  - 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
  - A shorter acting Recombinant Factor product has been tried with inadequate response prior to using a longer acting Recombinant Factor product OR physician documents rationale for use of a longer acting recombinant factor product versus a shorter acting recombinant factor product
  - If documentation of inhibitors or ITI therapy, the criteria corresponding to each of those situations below should be met

- Coverage is provided for the following FDA approved indications:
  - Treatment of spontaneous and trauma-induced bleeding episodes
  - Prevention of excessive bleeding during and after surgery
  - Prevention and control of bleeding episodes in adults and children with Factor VII, VIII, IX, or XIII deficiency
  - Treatment of acute bleeding episodes and perioperative management of bleeding in patients with Glanzmann’s thrombasthenia when:
    - Refractory to platelet transfusions, with or without antibodies to platelets
  - Treatment of acute bleeding episodes and perioperative management of bleeding in patients with acquired hemophilia
Treatment of moderate to severe bleeding episodes in von Willebrand Disease when:
- The product being requested has a labeled indication for von Willebrand AND
- The patient received a trial of Desmopressin when clinically appropriate OR
- The patient has a contraindication to Desmopressin OR
- The patient will be undergoing surgery when a prophylaxis regimen is requested
- The patient has documentation of Type 3 disease AND evidence of inhibitors when a bypassing agent is requested
- The severity of the bleed is documented (i.e. Minor, Major)
  - Dosing for minor bleed should not exceed 2 doses per day
  - Dosing for major bleed should not exceed 3 doses per day

Treatment of Hemophilia A in the presence of confirmed inhibitors when:
- The member’s Factor VIII level (% activity) or level of severity is documented as an inhibitor
- For mild (>5%) hemophilia, the member experienced therapeutic failure to Stimate (desmopression) or documentation of clinical rationale as to why it cannot be used
- For moderate (>1% to <5%) to severe (<1%) hemophilia, documentation of type of inhibitor (low-responding inhibitors or high-responding inhibitors)
- If Factor VIII inhibitor levels are >5-10 Bethesda units/mL and the member is a high responder, documentation is provided indicating the member is receiving FVIII concentrate as part of an Immune Tolerance Induction (ITI) regimen and not used for prophylaxis
- For reauthorization, Bethesda assay titers are required

Treatment of moderate or severe Hemophilia A or B with inhibitors with a bypassing agent (aPCC, FEIBA or rfVIIa, NovoSeven) when:
- Prevention and control of bleeding episodes while on an ITI regimen is necessary OR
- Perioperative management OR
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes conditional to the initiation of ITI therapy
- For reauthorization, Bethesda assay titers are required

Treatment with Immune Tolerance Induction (ITI) will be approved when:
- Member has a diagnosis of Hemophilia A with confirmed inhibitors AND
- Documentation of an inhibitor titer less than 10 BU/mL AND
- Documentation of initiation of ITI within five years of the member being diagnosed with inhibitors

**AND**

- Continued ITI is no longer considered medically necessary when all of the following criteria are met:
  - Inhibitor levels become undetectable (negative Bethesda assay); **OR**
  - 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)

- For reauthorization, Bethesda assay titers are required

- **Coverage duration:**
  - Benefit approved for 12 weeks. A reauthorization is required every 12 weeks with appropriate laboratory documentation.
  - For prophylactic dosing, coverage will not be granted for additional doses if there is greater than 7 days between requests unless on-demand dosing is medically necessary.

- 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.