Hemophilia Agents Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

POLICY REVIEW CYCLE

Effective Date
9/1/2023

Date of Origin
7/1/2021

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Advate® [Antihemophilic Factor (recombinant)] Lyophilized powder for reconstitution, for intravenous injection	Children and adults with hemophilia A (congenital factor VIII deficiency) for: Control and prevention of bleeding episodes Perioperative management Routine prophylaxis to prevent or reduce the frequency of bleeding episodes Not indicated for von Willebrand disease		1
Adynovate® [Antihemophilic Factor (recombinant) PEGylated] Lyophilized powder for solution for intravenous injection	Children and adults with hemophilia A (congenital factor VIII deficiency) for: On-demand treatment and control of bleeding episodes Perioperative management Routine prophylaxis to reduce the frequency of bleeding episodes Limitation of Use: Not indicated for von Willebrand disease		2
Afstyla® [antihemophilic Factor (recombinant), Single Chain] Lyophilized powder for solution for intravenous injection	Adults and children with hemophilia A (congenital Factor VIII deficiency) for: On-demand treatment and control of bleeding episodes Routine prophylaxis to reduce the frequency of bleeding episodes Perioperative management of bleeding Limitation of Use: Not indicated for von Willebrand disease		3
Alphanate®	The control and prevention of bleeding episodes in adult and pediatric patients with Factor VIII (FVIII) deficiency due to hemophilia A.		4

Agent(s)	FDA Indication(s)	Notes	Ref#
[Antihemophilic factor/von Willebrand factor complex (human)] Lyophilized powder for solution for intravenous injection	Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand Disease (vWD) in whom desmopressin (DDAVP) is either ineffective or contraindicated. Not indicated for patients with severe VWD (Type 3) undergoing major surgery.		
AlphaNine SD® [Coagulation Factor IX (Human)] Powder for reconstitution for intravenous use	The prevention and control of bleeding in patients with Factor IX deficiency due to hemophilia B. AlphaNine SD contains low, non-therapeutic levels of Factors II, VII, and X, and, therefore, is *not* indicated for the treatment of Factor II, VII or X deficiencies. This product is also *not* indicated for the reversal of coumarin anticoagulant-induced hemorrhage, nor in the treatment of hemophilia A patients with inhibitors to Factor VIII.		5
Alprolix® [Coagulation Factor IX (recombinant), Fc Fusion protein] Powder for solution for intravenous use	Adults and children with hemophilia B for: On-demand treatment and control of bleeding episodes Perioperative management of bleeding Routine prophylaxis to reduce the frequency of bleeding episodes Limitation of Use: Alprolix is not indicated for induction of immune tolerance in patients with hemophilia B		6
Altuviiio™ (antihemophilic factor [recombinant],Fc-VWFXTEN fusion protein-ehtl) Lyophilized powder for intravenous use	Use in adults and children with hemophilia A (congenital Factor VIII deficiency) for: • Routine prophylaxis to reduce the frequency of bleeding episodes • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding Limitation of Use: • Altuviiio is not indicated for treatment of von Willebrand disease		59
BeneFIX® [Coagulation Factor IX (Recombinant)] Powder for reconstitution	Adult and children with hemophilia B (congenital factor IX deficiency of Christmas disease) for: On-demand treatment and control of bleeding episodes Peri-operative management of bleeding Routine prophylaxis to reduce the frequency of bleeding episodes Limitation of Use: BeneFIX is not indicated for induction of immune tolerance in patients with hemophilia B		7

Agent(s)	FDA Indication(s)	Notes	Ref#
for intravenous use			
Coagadex® [(coagulation Factor X (human)] lyophilized powder for solution for intravenous injection	• Adults and children with hereditary Factor X deficiency for: ○ Routine prophylaxis to reduce the frequency of bleeding episodes ○ On-demand treatment and control of bleeding episodes ○ Perioperative management of bleeding in patients with mild or moderate hereditary Factor X deficiency Limitation of Use: Perioperative management of bleeding in major surgery in patients with severe hereditary Factor X deficiency has not been studied		8
Corifact® [Factor XIII Concentrate (Human)] Lyophilized powder for solution for intravenous injection	Adult and pediatric patients with congenital FXIII deficiency for: Routine prophylactic treatment Peri-operative management of surgical bleeding		9
Eloctate® [Antihemophilic Factor (recombinant), Fc Fusion Protein] Lyophilized powder for solution for intravenous injection	Adults and children with Hemophilia A (congenital Factor VIII deficiency) for: On-demand treatment and control of bleeding episodes Perioperative management of bleeding Routine prophylaxis to reduce the frequency of bleeding episodes Limitation of Use: Not indicated for von Willebrand disease		10
Esperoct® [antihemophilic factor (recombinant). glycopegylated-exei] Lyophilized powder for solution for intravenous injection	Adults and children with hemophilia A for: On-demand treatment and control of bleeding episodes Perioperative management of bleeding Routine prophylaxis to reduce the frequency of bleeding episodes Esperoct is not indicated for the treatment of von Willebrand disease		11
FEIBA®	Use in hemophilia A and B patients with inhibitors for: Control and prevention of bleeding episodes Perioperative management		12

Agent(s)	FDA Indication(s)	Notes	Ref#
[Anti-inhibitor Coagulant Complex] Lyophilized powder for solution for intravenous injection	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes Not indicated for the treatment of bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to coagulation factor VIII or coagulation factor IX		
Helixate FS® [Antihemophilic Factor (recombinant), Formulated with Sucrose] Lyophilized powder for reconstitution for intravenous injection	On-demand treatment and control of bleeding episodes in adults and children with hemophilia A Perioperative management of bleeding in adults and children with hemophilia A Routine prophylaxis to reduce the frequency of bleeding episodes in children with hemophilia A and to reduce the risk of joint damage in children without pre-existing joint damage Routine prophylaxis to reduce the frequency of bleeding episodes in adults with hemophilia A Not indicated for the treatment of von Willebrand disease		13
Hemofil M® [Antihemophilic Factor (Human), Method M, Monoclonal] Dried preparation for reconstitution for intravenous use	Indicated in hemophilia A (classical hemophilia) for the prevention and control of hemorrhagic episodes. Not indicated for the treatment of von Willebrand disease		14
Humate-P® [Antihemophilic Factor/von Willebrand Factor Complex (Human)]	Treatment and prevention of bleeding in adults with hemophilia A (classical hemophilia). Adult and pediatric patients with von Willebrand disease (VWD) for: Treatment of spontaneous and trauma-induced bleeding episodes Prevention of excessive bleeding during and after surgery. This applies to patients with severe VWD as well as patients with mild to moderate VWD where use of desmopressin is known or inadequate. Not indicated for the prophylaxis of spontaneous bleeding episodes in VWD		15
Idelvion® [Coagulation Factor IX (recombinant)]	Children and adults with Hemophilia B (congenital Factor IX deficiency) for: On-demand treatment and control of bleeding episodes Perioperative management of bleeding Routine prophylaxis to reduce the frequency of bleeding episodes Limitation of Use: Idelvion is not indicated for immune tolerance induction in patients with Hemophilia B		16

Agent(s)	FDA Indication(s)	Notes	Ref#
Lyophilized powder for solution for intravenous use			
Ixinity® [Coagulation Factor IX (recombinant)] Lyophilized powder for solution for intravenous use	Adults and children ≥ 12 years of age with hemophilia B for: • On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes Limitation of Use: • Ixinity is not indicated for induction of immune tolerance in patients with hemophilia B		17
Jivi® [antihemophilic factor (recombinant), PEGylated-aucl] Lyophilized powder for solution for intravenous use	Use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for: On-demand treatment and control of bleeding episodes Perioperative management of bleeding Routine prophylaxis to reduce the frequency of bleeding episodes Limitation of Use: Jivi is not indicated for use in children < 12 years of age due to a greater risk for hypersensitivity reactions Jivi is not indicated for use in previously untreated patients (PUPs) Jivi is not indicated for the treatment of von Willebrand disease		18
Koāte/Koāte®-DVI [Antihemophilic Factor (Human)] Lyophilized powder for solution for intravenous injection	Control or prevention of bleeding episodes or in order to perform emergency and elective surgery on individuals with hemophilia Koāte is indicated for the treatment of von Willebrand disease		19
Kogenate FS® [Antihemophilic Factor (recombinant), Formulated with sucrose] Lyophilized powder for reconstitution with vial adapter for	On-demand treatment and control of bleeding episodes in adults and children with hemophilia A Perioperative management of bleeding in adults and children with hemophilia A Routine prophylaxis to reduce the frequency of bleeding episodes in children with hemophilia A and to reduce the risk of joint damage in children without pre-existing joint damage Routine prophylaxis to reduce the frequency of bleeding episodes in adults with hemophilia A Not indicated for the treatment of von Willebrand disease		20

Agent(s)	FDA Indication(s)	Notes	Ref#
intravenous use			
Kovaltry® [Antihemophilic Factor (Recombinant)] Lyophilized powder for solution for intravenous injection	Indicated for use in adults and children with hemophilia A (congenital Factor VIII deficiency) for: On-demand treatment and control of bleeding episodes Perioperative management of bleeding Routine prophylaxis to reduce the frequency of bleeding episodes Not indicated for the treatment of von Willebrand disease		21
Mononine® [Coagulation Factor IX (Human)] Lyophilized concentrate for reconstitution for intravenous use	The prevention and control of bleeding in Factor IX deficiency, also known as Hemophilia B or Christmas disease. Limitation of Use: Mononine is not indicated in the treatment or prophylaxis of Hemophilia A patients with inhibitors to Factor VIII Mononine contains non-detectable levels of Factors II, VII and X (less than or equal to 0.0025 IU per Factor IX unit using standard coagulation assays) and is, therefore, not indicated for replacement therapy of these clotting factors. Mononine is also not indicated in the treatment or reversal of coumarin-induced anticoagulation or in a hemorrhagic state caused by hepatitis-induced lack of production of liver dependent coagulation factors		22
NovoEight® [Antihemophilic Factor (Recombinant)] Lyophilized powder for solution for intravenous use	Adults and children with hemophilia A for: On-demand control and prevention of bleeding Perioperative management Routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Not indicated for the treatment of von Willebrand disease		23
NovoSeven RT® (coagulation Factor VIIa, recombinant) Lyophilized powder for solution, for intravenous use	• Treatment of bleeding episodes and perioperative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets • Treatment of bleeding episodes and perioperative management in adults with acquired hemophilia		24
Nuwiq®	Adults and children with Hemophilia A for: On-demand treatment and control of bleeding episodes		25

Agent(s)	FDA Indication(s)	Notes	Ref#
[Antihemophilic Factor (Recombinant)] Lyophilized powder for solution for intravenous injection	Perioperative management of bleeding Routine prophylaxis to reduce the frequency of bleeding episodes Not indicated for the treatment of von Willebrand disease		
Obizur® [Antihemophilic Factor (Recombinant), Porcine Sequence] Lyophilized powder for solution for intravenous injection	Treatment of bleeding episodes in adults with acquired hemophilia A Limitation of Use: Safety and efficacy of Obizur has not been established in patients with baseline anti-porcine factor VIII inhibitor titer greater than 20 BU. Not indicated for the treatment of congenital hemophilia A or von Willebrand disease		26
Profilnine® SD (Factor IX complex) Lyophilized concentrate for reconstitution for intravenous use	The prevention and control of bleeding in patients with factor IX deficiency (hemophilia B) Profilnine SD contains non-therapeutic levels of factor VII and is not indicated for use in the treatment of VII deficiency		27
Rebinyn® [Coagulation Factor IX (recombinant), GlycoPEGylated] Powder for solution for intravenous use	Adults and children with hemophilia B (congenital Factor IX deficiency) for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes Limitation of Use: • Rebinyn is not indicated for immune tolerance induction in patients with hemophilia B		28
Recombinate™ [Antihemophilic Factor (Recombinant)]	Indicated in hemophilia A (classical hemophilia) for the prevention and control of hemorrhagic episodes It is also indicated in the perioperative management of patients with hemophilia A (classical hemophilia)		29

Agent(s)	FDA Indication(s)	Notes	Ref#
Lyophilized powder for reconstitution for intravenous injection	It can be of therapeutic value in patients with acquired Factor VIII inhibitors not exceeding 10 Bethesda Units per mL Not indicated for the treatment of von Willebrand disease		
Rixubis® [Coagulation Factor IX (recombinant)] Lyophilized powder for solution for intravenous use	Adults and children with hemophilia B for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes Rixubis is not indicated for induction of immune tolerance in patients with Hemophilia B		30
Sevenfact® [coagulation factor VIIa (recombinant)-jncw] Lyophilized powder for solution, for intravenous use	Treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with Hemophilia A or B with inhibitors Limitation of Use: Sevenfact is not indicated for treatment of congenital factor VII deficiency		31
Tretten® [Coagulation Factor XIII A-Subunit (Recombinant)] Lyophilized powder for solution for intravenous injection	Routine prophylaxis of bleeding in patients with congenital factor XIII A-subunit deficiency. Not for use in patients with congenital factor XIII B-subunit deficiency		32
Vonvendi® [von Willebrand factor (recombinant)] Lyophilized powder for solution for intravenous injection	Use in adults (age 18 and older) diagnosed with von Willebrand disease (VWD) for: On-demand treatment and control of bleeding Perioperative management of bleeding		33

Agent(s)	FDA Indication(s)	Notes	Ref#
Wilate® [von Willebrand Factor/Coagulation Factor VIII Complex (Human)] Powder for solution for intravenous injection	Indicated in children and adults with von Willebrand disease (VWD) for: On-demand treatment and control of bleeding episodes Perioperative management of bleeding Adolescents and adults with hemophilia A for: Routine prophylaxis to reduce the frequency of bleeding episodes On-demand treatment and control of bleeding episodes		34
Xyntha®/Xynthα® Solofuse™ [Antihemophilic factor (recombinant)] Lyophilized powder for solution for intravenous injection	Indicated for use in adults and children with hemophilia A for: On-demand treatment for control and prevention of bleeding episodes Perioperative management Routine prophylaxis to reduce the frequency of bleeding episodes Not indicated in patients with von Willebrand's disease		35

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Hemophilia	Hemophilia A, also called Factor VIII (FVIII) deficiency or classic hemophilia, is a genetic disorder caused by missing or defective Factor VIII (FVIII), a clotting protein. Although it is passed down from parents to children, about 1/3 of cases found have no previous family history.(36) Hemophilia B, also called Factor IX (FIX) deficiency or Christmas disease, is a genetic disorder caused by missing or defective Factor IX, a clotting protein. Although it is also passed down from parents to children, about 1/3 of cases are caused by a spontaneous mutation.(37) The MASAC suggests the number of doses required for provision of home therapy varies greatly and is dependent upon the type of hemophilia (FVIII, FIX), the level of severity (severe, moderate, mild), the presence of an inhibitor, the prescribed regimen (on-demand, prophylaxis, immune tolerance), the number of bleeding episodes experienced regardless of the prescribed regimen, individual pharmacokinetics, the products utilized, and the level of physical activity. For patients on prophylaxis, a minimum of one major dose and two minor doses should be available in addition to the prophylactic doses utilized monthly. For patients with severe or moderate hemophilia treated on-demand, the number of doses required to be available at home may be based upon historical bleeding patterns, with at least one major and two minor doses added to assure a level of safety.(49) A major dose is defined as a correction of clotting factor that achieves a level of 60-100+% clotting factor activity that is utilized to treat a bleeding episode that is expected to require a higher hemostatic level such as when bleeds occur in a target joint, or joint/area with a risk of significant sequelae (e.g., hip, head, GI bleed, etc.). A minor dose is defined as a correction of clotting factor that achieves a level of 30-60% clotting factor activity that is utilized to treat a bleeding episode that is treated

	early, in a non-critical area and treatable with a lower hemostatic level (e.g., early non-major joints, small muscle bleeds, and skin/soft tissue, etc.).(49)
Hemophilia A	Recombinant FVIII (rFVIII) products are treatment of choice for hemophilia A as recommended by MASAC. First generation rFVIII products contain animal and/or human plasma-derived proteins in the cell culture medium and in the final formulation vial (Recombinate). Second generation rFVIII products contain animal or human plasma proteins in the culture medium but not in the final formulation (Helixate, Kogenate). Third/fourth generation rFVIII products do not contain any animal or human plasma-derived proteins in the culture medium or in the final formulation vial.(38) In view of the demonstrated benefits of prophylaxis (regular/scheduled administration of clotting factor concentrate to prevent bleeding) begun at a young age in persons with hemophilia A or B, MASAC recommends that prophylaxis be considered standard of care therapy for individuals with severe hemophilia A (FVIII less than 1%) including those with inhibitors. Prophylactic therapy may also be considered for persons with moderate and mild hemophilia with a severe phenotype. Prophylactic therapy should be instituted early (prior to the onset of frequent bleeding).(60) Approximately 1 in 5 people with hemophilia A will develop an antibody – called an inhibitor – to the clotting factor concentrate(s) used to treat or prevent their bleeding episodes. Developing an inhibitor is one of the most serious and costly medical complications of a bleeding disorder because it becomes more difficult to treat bleeds. Inhibitors most often appear in the first 50 exposure days of clotting factor concentrates.(40,41) The National Hemophilia Foundation classifies inhibitors as low responding and high responding in addition to low titer (less than 5 BU) and high titer (greater than or equal to 5 BU). In low responding inhibitors when the patient receives Factor VIII the inhibitor titer does not rise. These patients can be treated with higher doses of the CFC. If the inhibitor titer increases with CFC it is considered high- responding. For high responding inhibitors, the situation becomes much more complicated as even large doses of infused CFC are often rendered ineffectual by the sheer potency of the antibody response.(42) In the cases of high-responding inhibitors treatment is based on several components including the type of hemophilia and the nature of the bleed. During a life or limb-threatening bleeding episode, physicians can remove antibodies from the body using plasmapheresis. This is only a temporary solution however as within a few days the body will produce large amounts of new antibodies. For the person with a high responding inhibitor there are therapies that can effectively treat bleeds by circumventing the need to replace FVIII. These agents are commonly referred to as bypassing agents (BPAs) and include activated prothrombin complex concentrate (aPCC) and recombinant activated Factor VII concentrates. Hemlibra, a therapy that does not function by FVIII or Factor IX replacement, is a newer therapy that can be used for these patients.(42) If left unchecked, a persistent inhibitor will present a severe burden on patients and families, as the ongoing physical, emotional, and in many cases financial toll continue to intensify. Healthcare providers will often attempt to proactively stamp out an inhibitor through immune tolerance therapy (ITI). ITI is an approach to inhibitor eradication where the body's immune system begins to tolerate a therapy after daily doses of factor are administered over time. The majority of people who undergo ITI therapy will see an improvement within 12 months, but more difficult cases can take two years or longer.(27) There is a general consensus that failure of ITI is the inability to achieve successful tolerance within 2-3 years of initiation of an ITI regimen.(43) ITI can take several months to several years to be effective. The Hemophilia Federation of America recommends that if success has not occurred within 33 months

	of beginning ITT and there is a lack of a 20% decrease in the inhibitor titer over a 6 month period, that it is considered a failure.(44) Emicizumab-kxwh is a recombinant, humanized, bispecific immunoglobulin G4 monoclonal antibody that substitutes for part of the cofactor function of activated factor VIII (FVIII) by bridging activated factor IX and Factor X. Emicizumab-kxwh is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children of all ages, newborn and older, with hemophilia A with and without Factor VIII inhibitors. There is significant reduction in annualized bleeding rates at all doses for all age groups, with or without inhibitors.(45) There is limited data on the concomitant use of emicizumab prophylaxis during ITI. There is a case series of children with hemophilia A and inhibitors who underwent ITI in combination with emicizumab prophylaxis (Atlanta Protocol), and a larger clinical trial of this protocol is underway [MOTIVATE study (NCT04023019)].(45) The MOTIVATE study is a non-interventional, multicenter, observational, international study in male persons with hemophilia A who have developed inhibitors to any replacement coagulation Factor VIII (FVIII product). The purpose of the study is to capture different approaches in the management and to evaluate the efficacy and safety of immune tolerance induction, including the combination of FVIII and emicizumab.(46) Treatments for patients with inhibitors continue to be investigated. Sequential or concomitant therapy with rFVIIa and aPCC might be helpful in difficult-to treat patients for whom monotherapy with either agent is ineffective. Clinical data is limited, and more substantial, well-controlled studies evaluating this approach are needed. Combined use of the two agents should only be carried out in the inpatient setting that has experience of this treatment, along with careful monitoring.(57) Another form of combination therapy involves the administration of FVIII with either rFVIIa or aPCC for prophylaxis. An invitro study using plasma from patients with high-titer inhibitors demonstrated that the addition of FVIII enhanced the hemostatic effect of both bypassing agents. FVIII combined with aPCC had a synergistic effect on thrombin formation, whereas FVIII combined with rFVIIa had an additive effect.(57)
Hemophilia A - Acquired	Under certain conditions, individuals who were not born with hemophilia may develop antibodies or inhibitors that cause destruction of FVIII, resulting in clinical bleeding due to very low levels of this clotting factor. Such inhibitors may be seen in patients with cancer, systemic lupus erythematosus, and other autoimmune disorders. Often no associated condition can be identified.(38) Although about 1/3 of patients do not require therapy to control bleeds, bleeding severity varies and more than 1/3 of patients had multiple bleeding episodes. Subcutaneous bleeding (ecchymoses) is the most common manifestation of acquired hemophilia followed by hematoma, melena, hematuria, and retroperitoneal. Intracranial hemorrhage is rare but can be fatal. In contrast to congenital hemophilia A, joint bleeding is infrequent.(47)
Hemophilia B	The Medical and Scientific Advisory Council (MASAC) and National Hemophilia Foundation (NHF) guidelines on treatment of hemophilia B recommend Recombinant FIX (rFIX) products over plasma-derived products as the treatment of choice.(38) In view of the demonstrated benefits of prophylaxis (regular/scheduled administration of clotting factor concentrate to prevent bleeding) begun at a young age in persons with hemophilia A or B, MASAC recommends that prophylaxis be considered standard of care therapy for individuals with severe hemophilia B (factor IX less than 1%) including those with inhibitors. Prophylactic therapy may also be considered for persons with moderate and mild hemophilia with a severe phenotype. Prophylactic therapy should be instituted early (prior to the onset of frequent bleeding).(48)
Congenital Factor VII Deficiency	Factor VII (FVII), or proconvertin, deficiency was first recognized in 1951. Considered the most common of rare bleeding disorders its incidence is estimated at 1 per 300,000-500,000. It is inherited in an autosomal recessive fashion, and it affects men

	and women equally. FVII is a protein that, when bound to tissue factor, initiates the clotting cascade which leads to the formation of a blood clot.(42) Symptoms are usually linked to the level of FVII in the blood, but not always. For instance, some people with low FVII levels may have mild symptoms. Babies are often diagnosed with FVII deficiency within the first 6 months of life, after sustaining a bleed in the central nervous system, such as an intracranial hemorrhage, or gastrointestinal tract. People with severe FVII deficiency experience joint and muscle bleeds, easy bruising, and bleeds after surgery. Bleeds can also occur in the skin, mouth, nose and genitourinary tract. Women often experience severe menorrhagia.(42) The main treatment for FVII deficiency is recombinant Factor VIIa (rFVIIa). Prothrombin complex concentrates (PCCs) can also be used, but the amount of Factor VII they contain can vary considerably. Fresh frozen plasma (FFP) is also an option.(42) Because of the very short half-life of FVII, prophylaxis in FVII deficiency is considered a difficult endeavor. The clinical efficacy and safety of prophylactic regimens, and indications for their use, were evaluated in FII deficient patient in the Seven Treatment Evaluation Registry (STER). Information was recorded in the STER database from 34 patients with FVII deficiency receiving prophylaxis in 13 hemophilia centers (11 countries).(50) The reasons for initiating prophylaxis and the treatment regimens used varied among the patients analyzed. Overall prophylaxis yielded "excellent" results in 68% of the courses.(50)
Factor XIII (Fibrin Stabilizing Factor) Deficiency	Factor XIII (FXIII), or fibrin stabilizing factor, deficiency was first reported in the literature in 1960. It is the rarest factor deficiency, occurring in 1 per 5 million births. It is inherited in an autosomal recessive fashion, meaning that both parents must carry the gene to pass it on to their children; it affects men and women equally.(54) FXIII protein stabilizes the formation of a blood clot. Without it, a clot will still develop, but will then break down and cause recurrent bleeds. Umbilical cord bleeding is common in factor XIII deficiency, reported in almost 80% of cases. Up to 30% of patients sustain a spontaneous intracranial hemorrhage, a brain bleed, which is the leading cause of mortality. Because patients with FXIII deficiency form a clot, clotting tests come back normal. Instead, diagnosis is made using FXIII assays and a clot solubility test.(54) Corifact is made from the pooled plasma of healthy donors. It can be used for patients lacking FXIII or who have reduced levels of it. People receiving Corifact may develop antibodies against FXIII, making the product ineffective. If higher than recommended doses are given, there is a risk of clot formation. Tretten, is approved for routine prophylaxis in people with congenital FXIII A-subunit deficiency. It is an intravenous infusion product for children and adults; 95% of patients with FXIII deficiency have the A-subunit deficiency.(54)
Glanzmann's Thrombasthenia	People with Glanzmann's thrombasthenia (GT) have platelets that lack a protein (glycoprotein IIb/IIIa) that helps them stick together to form a clot. Laboratory test are needed to diagnose GT. The symptoms of GT include bruising, petechiae, nosebleeds, and heavy menstrual bleeding. GT affects approximately 1 in a million people.(51)
Hereditary Factor X Deficiency	Factor X (FX), or Stuart-Prower factor, deficiency was first identified in the 1950s in the US and England in two patients. The incidence of FX deficiency is estimated at 1 in 500,000 to 1 in a million. Inheritance is autosomal recessive, meaning females and males can equally be affected. The factor X protein plays an important role in activating the enzymes that help to form a clot. It needs vitamin K for synthesis, which is produced by the liver.(52) People with mild FX deficiency experience easy bruising, nose or mouth bleeds, and bleeding after trauma or surgery. Symptoms for patients with severe FX deficiency

	include excessive umbilical cord bleeding, joint bleeds, intramuscular bleeds, and a high risk of intracranial hemorrhage in the first weeks of life.(52) Women with FX deficiency may additionally exhibit menorrhagia, or heavy menstrual bleeding. Pregnant women with FX may experience first trimester miscarriage or post-partum hemorrhage and should receive consultation by a hematologist and obstetrician prior to delivery.(52) Diagnosis is made through family history, prothrombin time (PT) test, partial thromboplastin time (PTT) or activated partial thromboplastin time (APTT) test. Diagnosis can be confirmed by a FX assay.(52) Factor X deficiency produces a variable bleeding tendency; patient with severe Factor X deficiency tend to have the most clinically significant bleeding symptoms observed in rare coagulation disorders. Factor X deficiency has been classified into 3 groups: severe (Factor X level less than 1%), moderate (Factor X level 1 -5%), and mild (Factor X level 6-10%). Factor X levels above 20% are infrequently associated with bleeding, and heterozygotes are usually asymptomatic.(53) Because Factor X is synthesized in the liver, liver disease may result in decreased Factor X levels. Vitamin K deficiency and warfarin use also result in decreased levels of Factor X.(53) For minor bleeding symptoms, topical and antifibrinolytic agents may be adequate. Topical powders for nosebleeds may be helpful in the treatment of epistaxis, and fibrin glue preparations can be used at surgical sites to achieve local hemostasis. Aminocaproic acid can be used as a mouthwash or taken orally for oral bleeding or recurrent epistaxis. Aminocaproic acid is also reported to be effective in the treatment of idiopathic menorrhagia and is used with generally good results in women with bleeding disorders. Tranexamic acid is a better tolerated and more potent antifibrinolytic agent that also can be used.(53) The National Hemophilia Foundation Medical and Scientific Advisory Council (MASAC) recommends that patients who use on-demand therapy or who infrequently infuse have doses of product available at home to allow for safe patient care; this will provide care in an emergency, as local healthcare facilities cannot be relied upon to stock the appropriate replacement products for these patients. Patients treated on prophylaxis require extra doses at home to treat breakthrough bleeding episodes. These doses should not be subtracted from the calculated monthly doses designated for prophylaxis and should be replaced as utilized. Patients and family members are encouraged to track expiration dates of product on a monthly basis, and doses that are about to expire should be utilized first to prevent waste.(49)
Von Willebrand Disease	Von Willebrand disease (VWD) is an inheritable bleeding disorder. People with VWD are either missing or low in the clotting protein von Willebrand factor (VWF) or it doesn't work as it's supposed to. People with VWD are not able to form a platelet plug, or it will take longer to form. VWD is the most common bleeding disorder, affecting up to 1% of the US population or approximately 1 in every 100 people. It occurs equally in men and women. However, women may be more symptomatic due to heavy menstrual bleeding (periods). VWD occurs equally across all races and ethnicities.(55) There are three main types of VWD. A fourth type, acquired VWD, is not hereditary.(55) • Type 1 VWD is found in 60%-80% of patients. People with type 1 VWD have a low levels of VWF in their blood. Levels of VWF in the blood range from 20%-50% of normal. The symptoms are usually mild. There is one subtype called Type 1C where the VFW has increase clearance leading to prolonged bleeding. • Type 2 VWD is found in 15%-30% of patients. People with type 2 VWD have a normal levels of VWF, but the factor doesn't function as it should. Type 2 is broken down into four subtypes: type 2A, type 2B, type 2M and type 2N,

	depending on the specific way the VWF is defective. Symptoms are mild to moderate. • Type 3 VWD is found in 5%-10% of patients. People with type 3 VWD have a very low levels or no VWF in their blood. Some people with this type of VWD may also be low in factor VIII (factor eight). Symptoms are typically severe, and include spontaneous bleeding episodes, often into their joints and muscles. • Acquired VWD. This type of VWD in adults results after a diagnosis of an autoimmune disease, such as lupus, or from heart disease or some types of cancer. It can also occur after taking certain medications. Treatment for VWD depends on the diagnosis and severity. Some bleeds are mild enough not to require treatment at all. The most common treatment for VWD is DDAVP (desmopressin acetate), which stimulates the release of VWF from cells.(55) Persons with type 1, 2A, 2M, and 2N VWD may be treated with the synthetic agent desmopressin if they have been shown by a DDAVP trial to be responsive.(56) More severe forms of VWD are treated with factor replacement therapy, which are either plasma-derived (made from human blood products) or recombinant (synthetic). These clotting factor products are rich in VWF and factor VIII (factor 8). Clotting factor products are injected into a vein in the arm to replace the missing factor in the blood. They may also be used to treat mild VWD in people who do not respond to DDVAP.(55)
Pain	People with bleeding disorders experience both acute and chronic pain associated with bleeding. Bleeding into soft tissues and joints, whether spontaneous or associated with trauma, often causes acute pain. Repeated bleeding events over time can lead to long-term changes in affected tissues, particularly joints. Chronic arthropathy causes disability and reduces quality of life due to chronic pain. (58) Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain in patients with bleeding disorders. Non-steroidal anti-inflammatory drugs (NSAIDs) should typically be avoided in patients with bleeding disorders, particularly higher doses over extended durations, due to risks of potential short-term interference with platelet function and of GI ulcer formation. Selective COX-2 inhibitors (e.g., celecoxib) appear to be associated with decreased risk of anti-platelet effects and ulcer formation when compared to NSAIDs and may be considered. (58)
Safety (1-35)	**Advate** is contraindicated in: Patients who have life-threatening hypersensitivity reactions, including anaphylaxis, to mouse or hamster protein or other constituents of the product (mannitol, trehalose, sodium chloride, histidine, Tris, calcium chloride, polysorbate 80, and/or glutathione) **Adynovate** is contraindicated in: Patients who have had prior anaphylactic reaction to Adynovate, the parent molecule (Advate), mouse or hamster protein, or excipients of Adynovate **Afstyla** is contraindicated in: Patients who have had life-threatening hypersensitivity reactions, including anaphylaxis to Afstyla or its excipients, or hamster proteins **AlphaNine SD** has no known FDA labeled contraindications **Alprolix** is contraindicated in: Individuals who have a known history of hypersensitivity reactions, including anaphylaxis, to the product or its excipients **Altuviiio** is contraindicated in: Patients who have had severe hypersensitivity reactions, including anaphylaxis, to Altuviiio or excipients of Altuviiio

	BeneFIX is contraindicated in: Patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster protein **Coagadex** is contraindicated in: Patients who have had life-threatening hypersensitivity reactions to Coagadex or any of the components. Drug interaction studies have not been performed with Coagadex. Based on the mechanism of action, Coagadex is likely to be counteracted by direct and indirect Factor Xa inhibitors. **Corifact** is contraindicated in: Patients with known anaphylactic or severe systemic reactions to human plasma-derived products **Eloctate** is contraindicated in: Patients who have had life-threatening hypersensitivity reactions, including anaphylaxis, to Eloctate or excipients of Eloctate (sucrose, sodium chloride, L-histidine, calcium chloride and polysorbate 20) **Esperoct** is contraindicated in: Patients who have known hypersensitivity to Esperoct or its components, including hamster protein **FEIBA** is contraindicated in: History of anaphylactic or severe hypersensitivity reactions to FEIBA or any of its components, including factors of the kinin generating system Disseminated intravascular coagulation (DIC) Acute thrombosis or embolism (including myocardial infarction) **FEIBA** contains a black box warning for: Thromboembolic events have been reported during post-marketing surveillance, particularly following the administration of high doses and/or in patients with thrombotic risk factors Monitor patients receiving FEIBA for signs and symptoms of thromboembolic events **Helixate FS** is contraindicated in: Patients who have life-threatening hypersensitivity reactions, including anaphylaxis to mouse or hamster protein or other constituents of the product **Hemofil M** is contraindicated in: Patients with a known hypersensitivity to the active substance, to excipients, or to mouse proteins **Humate-P** is contraindicated in: Anaphylactic or severe systemic reaction to antihemophilic factor or VWF preparations **Idelvion** is contraindicated in: Patients who have had life-threatening hypersensitivity reactions to Idelvion or its components, including hamster proteins **Ixinity** is contraindicated in: Patients with known hypersensitivity to Ixinity or its excipients, including hamster protein **Jivi** is contraindicated in: Patients who have a history of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product

	Koāte is contraindicated in: Patients who have had hypersensitivity reactions, including anaphylaxis, to Koāte or its components **Kogenate FS** is contraindicated in: Patients who have life-threatening hypersensitivity reactions, including anaphylaxis to mouse or hamster protein or other constituents of the product **Kovaltry** is contraindicated in: Patients who have history of hypersensitivity reactions to the active substance, mouse or hamster protein, or other constituents of the product **Mononine** is contraindicated in: Known hypersensitivity to mouse protein **NovoEight** is contraindicated in: Patients who have had life-threatening hypersen¬sitivity reactions, including anaphylaxis, to NovoEight or its components, including hamster proteins **NovoSeven RT** has no known contraindications but does contain a black box warning of: Serious arterial and venous thrombotic events following administration of NovoSeven RT Discuss the risks and explain the sign and symptoms of thrombotic and thromboembolic events to patients who will receive NovoSeven RT Monitor patients for signs or symptoms of activation of the coagulation system and for thrombosis **Nuwiq** is contraindicated in: Patients who have manifested life-threatening hypersensitivity reactions, including anaphylaxis, to the product or its components **Obizur** is contraindicated in: Patients who have had life-threatening hypersensitivity reactions to OBIZUR or its components, including hamster protein **Profilnine** has no known FDA labeled contraindications **Rebinyn** is contraindicated in: Patients who have known hypersensitivity to Rebinyn or its components, including hamster proteins **Recombinate** is contraindicated in: Patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including bovine, mouse or hamster proteins **Rixubis** is contraindicated in: Known hypersensitivity to Rixubis or its excipients including hamster protein Disseminated intravascular coagulation (DIC) Signs of fibrinolysis **Sevenfact** is contraindicated in: Known allergy to rabbits or rabbit proteins. Severe hypersensitivity reaction to Sevenfact or any of its components **Sevenfact** contains a black box warning of: Serious arterial and venous thrombotic events may occur following administration of Sevenfact Discuss the risk and explain the sign and symptoms of thrombotic and thromboembolic

	events to patients who will receive Sevenfact Monitor patients for signs or symptoms of activation of the coagulation system and for thrombosis **Tretten** is contraindicated in: Hypersensitivity to the active substance or to any of the excipients **Vonvendi** is contraindicated in: Patients who have had life-threatening hypersensitivity reactions to Vonvendi or its components (tri-sodium citrate dihydrate, glycine, mannitol, trehalose-dihydrate, polysorbate 80, and hamster or mouse proteins) **Wilate** is contraindicated in: Patients with known hypersensitivity reactions, including anaphylactic or severe systemic reaction, to human plasma-derived products, any ingredient in the formulation, or components of the container **Xyntha** is contraindicated in: Patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster proteins

REFERENCES

Number	Reference
1	Advate prescribing information. Shire. December 2018.
2	Adynovate prescribing information. Shire. May 2018.
3	Afstyla prescribing information. CSL Behring. December 2019.
4	Alphanate prescribing information. Grifols Biologicals Inc. June 2018.
5	AlphaNine SD prescribing information. Grifols. June 2018.
6	Alprolix prescribing information. Bioverativ. October 2020.
7	BeneFIX prescribing information. Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC. November 2022.
8	Coagadex prescribing information. Bio Products Laboratory USA. September 2018.
9	Corifact prescribing information. CSL Behring. December 2019.
10	Eloctate prescribing information. Biogen. December 2020.
11	Esperoct prescribing information. Novo Nordisk. August 2022.
12	FEIBA prescribing information. Baxalta. February 2020.
13	Helixate FS prescribing information. CSL Behring. May 2016.
14	Hemofil M prescribing information. Baxalta US Inc. June 2018.
15	Humate-P prescribing information. CSL Behring. September 2017.
16	Idelvion prescribing information. CSL Behring. July 2020.
17	Ixinity prescribing information. Aptevo BioTherapeutics. November 2022.
18	Jivi prescribing information. Bayer HealthCare LLC. August 2018.
19	Koāte prescribing information. Kedrion Biopharma, Inc. January 2022.
20	Kogenate FS prescribing information. Bayer. May 2016.
21	Kovaltry prescribing information. HealthCare LLC. December 2022.
22	Mononine prescribing information. CSL Behring. December 2019.
23	NovoEight prescribing information. Novo Nordisk. July 2020.
24	NovoSeven RT prescribing information. Novo Nordisk Inc. July 2020.
25	Nuwiq prescribing information. Octapharma. July 2017.
26	Obizur prescribing information. Baxalta. July 2020.

Number	Reference
27	Profilnine prescribing information. Grifols Biologicals Inc. March 2021.
28	Rebinyn prescribing information. Novo Nordisk. August 2022
29	Recombinate prescribing information. Shire. June 2018.
30	Rixubis prescribing information. Baxalta. June 2020.
31	Sevenfact prescribing information. HEMA Biologics, LLC. April 2020.
32	Tretten prescribing information. Novo Nordisk. June 2020.
33	Vonvendi prescribing information. Baxalta. February 2019.
34	Wilate prescribing information. Octapharma. September 2019.
35	Xyntha prescribing information. Wyeth. August 2019.
36	National Hemophilia Foundation. Bleeding Disorders A-Z/Types/Hemophilia A. Accessed at: https://www.hemophilia.org/bleeding-disorders-a-z/types/hemophilia-a
37	National Hemophilia Foundation. Bleeding Disorders A-Z/Types/Hemophilia B. Accessed at:https://www.hemophilia.org/bleeding-disorders-a-z/types/hemophilia-b.
38	Medical and Scientific Advisory Council (MASAC) MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Document #272. April 2022.
39	~~National Hemophilia Foundation. Steps for Living. The Basics of Bleeding Disorders/Treatment Basics. 2016.~~ Reference no longer used
40	National Hemophilia Foundation. One Size Does Not Fit All: Individualized Therapy. Dr Steven Pipe. September 2016. Accessed at https://www.hemophilia.org/educational-programs/education/online-education/one-size-does-not-fit-all-individualized-therapy
41	CDC Centers for Disease Control and Prevention. Inhibitors and Hemophilia. Accessed at: https://www.cdc.gov/ncbddd/hemophilia/inhibitors.html
42	National Hemophilia Foundation Bleeding Disorders A-Z Overview Inhibitors Treatment for Inhibitors. Accessed at: https://www.hemophilia.org/bleeding-disorders-a-z/overview/inhibitors/treatment-for-inhibitors.
43	Srivastave A, Santagostino E, Dougall A, et al. World Federation of Hemophilia Guidelines for the Management of Hemophilia. 3rd edition. August 2020.
44	Dimichele DM, Hoots WK, Pipe SW, et al. International workshop on immune tolerance induction: consensus recommendations. Haemophilia (2007), 13 (Suppl. 1), 1-22.
45	Medical and Scientific Advisory Committee (MASC). MASAC Document 268 - Recommendation on the Use and Management of Emicizumab-kxwh (Hemlibra®) for Hemophilia A with and without Inhibitors. April 2022.
46	Clinicatrials.gov. NCT04023019. Treatment of Hemophilia A Patients With FVIII Inhibitors (MOTIVATE). Accessed at: https://clinicaltrials.gov/ct2/show/NCT04023019?term=NCT04023019&draw=2&rank=1
47	National Hemophilia Foundation. Bleeding Disorders A-Z/Types/Inherited Platelet Disorders. Accessed at: https://www.hemophilia.org/bleeding-disorders-a-z/types/inherited-platelet-disorders.
48	Medical and Scientific Advisory Committee. MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B with and without Inhibitors. MASAC Document #267. April 2022.
49	Medical and Scientific Advisory Committee. MASAC Document 242 - MASAC Recommendation Regarding Doses of Clotting Factor Concentrate in the Home. June 2016.
50	Konkle BA, Ebbesen LS, Erhardtsen E, et al. Randomized, prospective clinical trial of recombinant factor VIIa for secondary prophylaxis in hemophilia patients with inhibitors. J Thromb Haemost 2007; 5: 1904-13.
51	Napolitano M, Glanslly-Blalzot M, Dolce A, et al. Prophylaxis in congenital factor VII deficiency: indications, efficacy and safety. Results from the Seven Treatment Evaluation Registry (STER). Haematologica 2013 Apr; 98(4):538-44.
52	National Hemophilia Foundation. Bleeding Disorders, Types of Bleeding Disorders, Other Factor Deficiencies, Factor X. Accessed at: https://www.hemophilia.org/Bleeding-Disorders/Types-of-Bleeding-Disorders/Other-Factor-Deficiencies/Factor-X.

Number	Reference
53	Brown DL, Kouides PA. Diagnosis and treatment of inherited Factor X deficiency. Hemophilia. 2008;14, 1176-1182.
54	National Hemophilia Foundation. Bleeding Disorders A-Z/Types/Other Factor Deficiencies/Factor XIII. Accessed at: https://www.hemophilia.org/bleeding-disorders-a-z/types/other-factor-deficiencies/factor-xiii.
55	National Hemophilia Foundation. Bleeding Disorders A-Z/Types/Von Willebrand Disease. Accessed at: https://www.hemophilia.org/bleeding-disorders-a-z/types/von-willebrand-disease.
56	Medical and Scientific Advisory Committee. MASAC Document 266 - MASAC Recommendations Regarding the Treatment of von Willebrand Disease. March 2021.
57	Ljung R, Auerswald G, Benson G, et al. Inhibitors in haemophilia A and B: Management of bleeds, inhibitor eradication and strategies for difficult-to-treat patients. Eur J Haematol. 2019;102:111-122.
58	Medical and Scientific Advisory Committee. MASC Document 260 – Management of Chronic Pain in Persons with Bleeding Disorders: Guidance for Practical Application of The Centers for Disease Control's Opioid Prescribing Guidelines. March 2020.
59	Altuviiio Prescribing Information. Bioverativ Therapeutics, Inc. February 2023.
60	Medical and Scientific Advisory Council, MASAC Document 267 - Recommendation Concerning Prophylaxis for Hemophilia A and B with and without inhibitors. April 2022.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Xyntha ; Xyntha solofuse	antihemophil fact rcmb (bdd-rfviii,mor) for inj kit ; antihemophil fact rcmb(bdd-rfviii,mor) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Nuwiq	antihemophil fact rcmb (bdd-rfviii,sim) for inj kit ; antihemophil fact rcmb(bdd-rfviii,sim) for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Jivi	antihemophil fact rcmb(bdd-rfviii peg-aucl) for inj ; antihemophil fact rcmb(bdd-rfviii peg-aucl)for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Novoeight	antihemophilic fact rcmb (bd trunc-rfviii) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Nuwiq	antihemophilic fact rcmb (bdd-rfviii,sim) for inj ; antihemophilic factor rcmb (bdd-rfviii,sim) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Altuviiio	antihemophilic fact rcmb fc-vwf-xten-ehtl for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Afstyla	antihemophilic fact rcmb single chain for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Hemofil m ; Koate ; Koate-dvi	antihemophilic factor (human) for inj	1000 UNIT ; 1700 UNIT ; 250 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Obizur	antihemophilic factor (recomb porc) rpfviii for inj	500 UNIT	M ; N ; O ; Y	N		
Advate ; Kovaltry	Antihemophilic Factor rAHF-PFM For Inj ; antihemophilic factor rahf-pfm for inj ; antihemophilic factor recomb (rahf-pfm) for inj	1000 ; 1000 UNIT ; 1500 ; 1500 UNIT ; 2000 ; 2000 UNIT ; 250 ; 250 UNIT ; 3000 ; 3000 UNIT ; 4000 UNIT ; 500 ; 500 UNIT	M ; N ; O ; Y	N		
Eloctate	antihemophilic factor rcmb (bdd-rfviiifc) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ;	M ; N ; O ; Y	N		

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
		500 UNIT ; 5000 UNIT ; 6000 UNIT ; 750 UNIT				
Recombinate	antihemophilic factor recomb (rfviii) for inj	1241 -1800 UNIT ; 1801 - 2400 UNIT ; 220 -400 UNIT ; 401 -800 UNIT ; 801 - 1240 UNIT	M ; N ; O ; Y	N		
Kogenate fs	antihemophilic factor recomb (rfviii) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Esperoct	antihemophilic factor recomb glycopeg-exei for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Adynovate	antihemophilic factor recomb pegylated for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT ; 750 UNIT	M ; N ; O ; Y	N		
Alphanate ; Humate-p	antihemophilic factor/vwf (human) for inj	1000 UNIT ; 1000-2400 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 250-600 UNIT ; 500 UNIT ; 500-1200 UNIT	M ; N ; O ; Y	N		
Wilate	antihemophilic factor/vwf (human) for inj	1000-1000 UNIT ; 500-500 UNIT	M ; N ; O ; Y	N		
Feiba	antiinhibitor coagulant complex for iv soln	1000 UNIT ; 2500 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3500 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Benefix	coagulation factor ix (recombinant) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Alphanine sd ; Mononine	coagulation factor ix for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Sevenfact	coagulation factor viia (recom)-jncw for inj	1 MG ; 5 MG	M ; N ; O ; Y	N		
Novoseven rt	coagulation factor viia (recomb) for inj	1 MG ; 2 MG ; 5 MG ; 8 MG	M ; N ; O ; Y	N		
Coagadex	coagulation factor x (human) for inj	250 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Tretten	coagulation factor xiii a-subunit for inj	2000 -3125 UNIT	M ; N ; O ; Y	N		
Profilnine	factor ix complex for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Corifact	factor xiii concentrate (human) for inj kit	1000 -1600 UNIT	M ; N ; O ; Y	N		
Vonvendi	von willebrand factor (recombinant) for inj	1300 UNIT ; 650 UNIT	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Target Agent(s) EXCEPT Coagadex, NovoSeven RT, and Sevenfact									
Altuviiio	antihemophilic fact rcmb fc-vwf-xten-ehtl for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Advate ; Kovaltry	Antihemophilic Factor rAHF-PFM For Inj ; antihemophilic factor rahf-pfm for inj ; antihemophilic factor recomb (rahf-pfm) for inj	1000 ; 1000 UNIT ; 1500 ; 1500 UNIT ; 2000 ; 2000 UNIT ; 250 ; 250 UNIT ; 3000 ; 3000 UNIT ; 4000 UNIT ; 500 ; 500 UNIT					Dependent on patient weight and number of doses		
Adynovate	antihemophilic factor recomb pegylated for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500					Dependent on patient weight and number of doses		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
		UNIT ; 750 UNIT							
Afstyla	antihemophilic fact rcmb single chain for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Alphanate ; Humate-p	antihemophilic factor/vwf (human) for inj	1000 UNIT ; 1000-2400 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 250-600 UNIT ; 500 UNIT ; 500-1200 UNIT					Dependent on patient weight and number of doses		
Alphanine sd ; Mononine	coagulation factor ix for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Benefix	coagulation factor ix (recombinant) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Coagadex	coagulation factor x (human) for inj	250 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Corifact	factor xiii concentrate (human) for inj kit	1000 - 1600 UNIT					Dependent on patient weight and		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
							number of doses		
Eloctate	antihemophilic factor rcmb (bdd-rfviiifc) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT ; 5000 UNIT ; 6000 UNIT ; 750 UNIT					Dependent on patient weight and number of doses		
Esperoct	antihemophilic factor recomb glycopeg-exei for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Feiba	antiinhibitor coagulant complex for iv soln	1000 UNIT ; 2500 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Hemofil m ; Koate ; Koate-dvi	antihemophilic factor (human) for inj	1000 UNIT ; 1700 UNIT ; 250 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3500 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Jivi	antihemophil fact rcmb(bdd-rfviii peg-aucl) for inj ;	1000 UNIT ; 2000					Dependent on patient weight and		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	antihemophil fact rcmb(bdd-rfviii peg-aucl)for inj	UNIT ; 3000 UNIT ; 500 UNIT					number of doses		
Kogenate fs	antihemophilic factor recomb (rfviii) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Novoeight	antihemophilic fact rcmb (bd trunc-rfviii) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Novoseven rt	coagulation factor viia (recomb) for inj	1 MG ; 2 MG ; 5 MG ; 8 MG					Dependent on patient weight and number of doses		
Nuwiq	antihemophil fact rcmb (bdd-rfviii,sim) for inj kit ; antihemophil fact rcmb(bdd-rfviii,sim) for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Nuwiq	antihemophilic fact rcmb (bdd-rfviii,sim) for inj ; antihemophilic factor rcmb (bdd-rfviii,sim) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Obizur	antihemophilic factor (recomb porc) rpfviii for inj	500 UNIT					Dependent on patient weight and number of doses		
Profilnine	factor ix complex for inj	1000 UNIT ;					Dependent on patient		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
		1500 UNIT ; 500 UNIT					weight and number of doses		
Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		
Recombinate	antihemophilic factor recomb (rfviii) for inj	1241 - 1800 UNIT ; 1801 - 2400 UNIT ; 220 - 400 UNIT ; 401 - 800 UNIT ; 801 - 1240 UNIT					Dependent on patient weight and number of doses		
Sevenfact	coagulation factor viia (recom)-jncw for inj	1 MG ; 5 MG					Dependent on patient weight and number of doses		
Tretten	coagulation factor xiii a-subunit for inj	2000 - 3125 UNIT					Dependent on patient weight and number of doses		
Vonvendi	von willebrand factor (recombinant) for inj	1300 UNIT ; 650 UNIT					Dependent on patient weight and number of doses		
Wilate	antihemophilic factor/vwf (human) for inj	1000-1000 UNIT ; 500-500 UNIT					Dependent on patient weight and number of doses		
Xyntha ; Xyntha solofuse	antihemophil fact rcmb (bdd-rfviii,mor) for inj kit ; antihemophil fact rcmb(bdd-rfviii,mor) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT					Dependent on patient weight and number of doses		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Advate ; Kovaltry	Antihemophilic Factor rAHF-PFM For Inj ; antihemophilic factor rahf-pfm for inj ; antihemophilic factor recomb (rahf-pfm) for inj	1000 ; 1000 UNIT ; 1500 ; 1500 UNIT ; 2000 ; 2000 UNIT ; 250 ; 250 UNIT ; 3000 ; 3000 UNIT ; 4000 UNIT ; 500 ; 500 UNIT	Medicaid
Adynovate	antihemophilic factor recomb pegylated for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ;	Medicaid

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
		3000 UNIT ; 500 UNIT ; 750 UNIT	
Afstyla	antihemophilic fact rcmb single chain for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Alphanate ; Humate-p	antihemophilic factor/vwf (human) for inj	1000 UNIT ; 1000-2400 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 250-600 UNIT ; 500 UNIT ; 500-1200 UNIT	Medicaid
Alphanine sd ; Mononine	coagulation factor ix for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	Medicaid
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Medicaid
Altuviiio	antihemophilic fact rcmb fc-vwf-xten-ehtl for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Medicaid
Benefix	coagulation factor ix (recombinant) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Coagadex	coagulation factor x (human) for inj	250 UNIT ; 500 UNIT	Medicaid
Corifact	factor xiii concentrate (human) for inj kit	1000 -1600 UNIT	Medicaid
Eloctate	antihemophilic factor rcmb (bdd-rfviiifc) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT ; 5000 UNIT ; 6000 UNIT ; 750 UNIT	Medicaid
Esperoct	antihemophilic factor recomb glycopeg-exei for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Feiba	antiinhibitor coagulant complex for iv soln	1000 UNIT ; 2500 UNIT ; 500 UNIT	Medicaid
Hemofil m ; Koate ; Koate-dvi	antihemophilic factor (human) for inj	1000 UNIT ; 1700 UNIT ; 250 UNIT ; 500 UNIT	Medicaid
Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3500 UNIT ; 500 UNIT	Medicaid
Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Jivi	antihemophil fact rcmb(bdd-rfviii peg-aucl) for inj ; antihemophil fact rcmb(bdd-rfviii peg-aucl)for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Kogenate fs	antihemophilic factor recomb (rfviii) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Novoeight	antihemophilic fact rcmb (bd trunc-rfviii) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Novoseven rt	coagulation factor viia (recomb) for inj	1 MG ; 2 MG ; 5 MG ; 8 MG	Medicaid
Nuwiq	antihemophil fact rcmb (bdd-rfviii,sim) for inj kit ; antihemophil fact rcmb(bdd-rfviii,sim) for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Medicaid
Nuwiq	antihemophilic fact rcmb (bdd-rfviii,sim) for inj ; antihemophilic factor rcmb (bdd-rfviii,sim) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Medicaid
Obizur	antihemophilic factor (recomb porc) rpfviii for inj	500 UNIT	Medicaid
Profilnine	factor ix complex for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	Medicaid
Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Recombinate	antihemophilic factor recomb (rfviii) for inj	1241 -1800 UNIT ; 1801 -2400 UNIT ; 220 -400 UNIT ; 401 -800 UNIT ; 801 -1240 UNIT	Medicaid
Sevenfact	coagulation factor viia (recom)-jncw for inj	1 MG ; 5 MG	Medicaid
Tretten	coagulation factor xiii a-subunit for inj	2000 -3125 UNIT	Medicaid
Vonvendi	von willebrand factor (recombinant) for inj	1300 UNIT ; 650 UNIT	Medicaid
Wilate	antihemophilic factor/vwf (human) for inj	1000-1000 UNIT ; 500-500 UNIT	Medicaid
Xyntha ; Xyntha solofuse	antihemophil fact rcmb (bdd-rfviii,mor) for inj kit ; antihemophil fact rcmb(bdd-rfviii,mor) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Advate ; Kovaltry	Antihemophilic Factor rAHF-PFM For Inj ; antihemophilic factor rahf-pfm for inj ; antihemophilic factor recomb (rahf-pfm) for inj	1000 ; 1000 UNIT ; 1500 ; 1500 UNIT ; 2000 ; 2000 UNIT ; 250 ; 250 UNIT ; 3000 ; 3000 UNIT ; 4000 UNIT ; 500 ; 500 UNIT	Medicaid
Adynovate	antihemophilic factor recomb pegylated for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT ; 750 UNIT	Medicaid
Afstyla	antihemophilic fact rcmb single chain for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Alphanate ; Humate-p	antihemophilic factor/vwf (human) for inj	1000 UNIT ; 1000-2400 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 250-600 UNIT ; 500 UNIT ; 500-1200 UNIT	Medicaid
Alphanine sd ; Mononine	coagulation factor ix for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	Medicaid
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Medicaid
Altuviiio	antihemophilic fact rcmb fc-vwf-xten-ehtl for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Medicaid
Benefix	coagulation factor ix (recombinant) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Coagadex	coagulation factor x (human) for inj	250 UNIT ; 500 UNIT	Medicaid
Corifact	factor xiii concentrate (human) for inj kit	1000 -1600 UNIT	Medicaid
Eloctate	antihemophilic factor rcmb (bdd-rfviiifc) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT ; 5000 UNIT ; 6000 UNIT ; 750 UNIT	Medicaid
Esperoct	antihemophilic factor recomb glycopeg-exei for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Feiba	antiinhibitor coagulant complex for iv soln	1000 UNIT ; 2500 UNIT ; 500 UNIT	Medicaid
Hemofil m ; Koate ; Koate-dvi	antihemophilic factor (human) for inj	1000 UNIT ; 1700 UNIT ; 250 UNIT ; 500 UNIT	Medicaid
Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3500 UNIT ; 500 UNIT	Medicaid

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Jivi	antihemophil fact rcmb(bdd-rfviii peg-aucl) for inj ; antihemophil fact rcmb(bdd-rfviii peg-aucl)for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Kogenate fs	antihemophilic factor recomb (rfviii) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Novoeight	antihemophilic fact rcmb (bd trunc-rfviii) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Novoseven rt	coagulation factor viia (recomb) for inj	1 MG ; 2 MG ; 5 MG ; 8 MG	Medicaid
Nuwiq	antihemophil fact rcmb (bdd-rfviii,sim) for inj kit ; antihemophil fact rcmb(bdd-rfviii,sim) for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Medicaid
Nuwiq	antihemophilic fact rcmb (bdd-rfviii,sim) for inj ; antihemophilic factor rcmb (bdd-rfviii,sim) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Medicaid
Obizur	antihemophilic factor (recomb porc) rpfviii for inj	500 UNIT	Medicaid
Profilnine	factor ix complex for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	Medicaid
Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid
Recombinate	antihemophilic factor recomb (rfviii) for inj	1241 -1800 UNIT ; 1801 -2400 UNIT ; 220 -400 UNIT ; 401 -800 UNIT ; 801 -1240 UNIT	Medicaid
Sevenfact	coagulation factor viia (recom)-jncw for inj	1 MG ; 5 MG	Medicaid
Tretten	coagulation factor xiii a-subunit for inj	2000 -3125 UNIT	Medicaid
Vonvendi	von willebrand factor (recombinant) for inj	1300 UNIT ; 650 UNIT	Medicaid
Wilate	antihemophilic factor/vwf (human) for inj	1000-1000 UNIT ; 500-500 UNIT	Medicaid
Xyntha ; Xyntha solofuse	antihemophil fact rcmb (bdd-rfviii,mor) for inj kit ; antihemophil fact rcmb(bdd-rfviii,mor) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Medicaid

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL** **Initial Evaluation** **See drug specific criteria below for Coagadex, NovoSeven RT, and Sevenfact** **Target Agent(s) EXCEPT Coagadex, NovoSeven RT, and Sevenfact** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient is currently experiencing a bleed AND BOTH of the following: 1. The patient is out of medication **AND**

Module	Clinical Criteria for Approval
	2. The patient needs to receive a ONE TIME emergency supply of medication **OR** D. The patient has an FDA approved diagnosis for the requested agent including intended use (i.e., prophylaxis, ITT/ITI, on-demand, peri-operative) AND ONE of the following: 1. If the patient has a diagnosis of hemophilia A (also known as Factor VIII deficiency or classic hemophilia) BOTH of the following: A. If the requested agent is being used for prophylaxis OR Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI) the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND** B. If the patient has mild hemophilia A (i.e., factor VIII activity level between 5%-40%) ONE of the following: 1. The patient's medication history includes desmopressin (e.g., DDAVP injection, Stimate nasal spray) used for the requested indication AND ONE of the following: A. The patient has had an inadequate response to desmopressin used for the requested indication **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent desmopressin **OR** 2. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 3. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to therapy with desmopressin **OR** 4. The prescriber has provided information supporting why the patient cannot use desmopressin (e.g., shortage in marketplace) **OR** 5. The prescriber has provided documentation that desmopressin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 2. If the patient has a diagnosis of Type 1, Type 2A, Type 2M, or Type 2N von Willebrand Disease (VWD) ONE of the following: A. The patient's medication history includes desmopressin (e.g., DDAVP injection, Stimate nasal spray) used for the requested indication AND ONE of the following: 1. The patient has had an inadequate response to desmopressin used for the requested indication **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent desmopressin **OR** B. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

Module	Clinical Criteria for Approval
	3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** C. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to therapy with desmopressin **OR** D. The prescriber has provided information supporting why the patient cannot use desmopressin (e.g., shortage in marketplace) **OR** E. The prescriber has provided documentation that desmopressin acetate cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient will NOT be using the requested agent in combination with nonsteroidal anti-inflammatory agents (NSAIDs) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided support of using an NSAID for this patient **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Intended use/regimen: prophylaxis, ITT/ITI, on-demand, peri-operative **AND** C. If the patient has a diagnosis of hemophilia A BOTH of the following: 1. Severity of the factor deficiency (i.e., severe is <1% factor activity, moderate is ≥1 to ≤5% factor activity, mild is >5 to 40% factor activity) **AND** 2. Inhibitor status **AND** 7. ONE of the following: A. The patient will NOT be using the requested agent in combination with another agent in the same class included in this program **OR** B. Information has been provided supporting the use of more than one unique agent in the same class (medical record required) **Length of Approval:** One time emergency use: up to 2 weeks Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 6 months ITT/ITI: up to 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Renewal Evaluation** **Target Agent(s) EXCEPT Coagadex, NovoSeven RT, and Sevenfact** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (if current request is for ONE TIME emergency use or the

Module	Clinical Criteria for Approval
	patient ONLY has previous approval(s) for emergency use, must use Initial Evaluation) **AND** 2. If the patient is using the requested agent for Hemophilia A prophylaxis OR ITT/ITT, the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient will NOT be using the requested agent in combination with nonsteroidal anti-inflammatory agents (NSAIDs) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided support of using an NSAID for this patient **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Intended use/regimen: (e.g., prophylaxis, ITT/ITT, on-demand, peri-operative) **AND** C. f the patient has a diagnosis of hemophilia A BOTH of the following: 1. Severity of the factor deficiency (i.e., severe is <1% factor activity, moderate is ≥1 to ≤5% factor activity, mild is >5 to 40% factor activity) **AND** 2. Inhibitor status **AND** 7. ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have >5 on-demand doses on hand **OR** B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand **AND** 8. ONE of the following: A. The patient will NOT be using the requested agent in combination with another agent in the same class included in this program **OR** B. Information has been provided supporting the use of more than one unique agent in the same class (medical record required) **AND** 9. If the patient is using Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI), then ONE of the following: A. The patient has NOT had more than 33 months of ITT/ITI therapy **OR** B. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a ≥ 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical record required) **Length of Approval:** On-demand: up to 3 months Peri-operative dosing: 1 time per request Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Evaluation** **Coagadex** will be approved when ALL of the following are met: 1. ONE of the following:

Module	Clinical Criteria for Approval
	A. Information has been provided that indicates the patient has been treated with the requested agent for the requested use (e.g., prophylaxis, on-demand) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent for the requested use (e.g., prophylaxis, on-demand) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of hereditary Factor X deficiency AND ONE of the following: 1. The patient is currently experiencing a bleed AND BOTH of the following: A. The patient is out of medication **AND** B. The patient needs to receive a ONE TIME emergency supply of medication **OR** 2. The requested agent will be used for prophylaxis treatment AND ONE of the following: A. The patient has severe or moderate Factor X deficiency (Factor X level ≤ 5%) **OR** B. The patient has mild Factor X deficiency (Factor X level 6-10%) AND the prescriber has provided information supporting prophylaxis use of the requested agent (medical records required) **OR** 3. The requested agent will be used as on-demand treatment to control bleeding episodes AND BOTH of the following: A. The prescriber has communicated with the patient (via any means) and has verified that the patient does NOT have more than 5 on-demand doses on hand AND ONE of the following: 1. The patient's medication history includes aminocaproic acid or tranexamic acid used for the requested indication AND ONE of the following: A. The patient has had an inadequate response to aminocaproic acid or tranexamic acid used for the requested indication **OR** B. he prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent aminocaproic acid or tranexamic acid used for the requested indication **OR** 2. The patient has an intolerance or hypersensitivity to aminocaproic acid or tranexamic acid **OR** 3. The patient has an FDA labeled contraindication to BOTH aminocaproic acid AND tranexamic acid **OR** 4. The prescriber has provided information to support the use of the requested agent over BOTH aminocaproic acid AND tranexamic acid **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that BOTH aminocaproic acid AND tranexamic acid cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The requested agent will be used as perioperative management of bleeding AND BOTH of the following:

Module	Clinical Criteria for Approval
	1. The patient has mild (Factor X level 6-10%) or moderate (Factor X level 1-5%) hereditary Factor X deficiency **AND** 2. ONE of the following: A. The patient's medication history includes aminocaproic acid or tranexamic acid used for the requested indication AND ONE of the following: 1. The patient has had an inadequate response to aminocaproic acid or tranexamic acid used for the requested indication **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent aminocaproic acid or tranexamic acid used for the requested indication **OR** B. The patient has an intolerance or hypersensitivity to aminocaproic acid or tranexamic acid **OR** C. The patient has an FDA labeled contraindication to BOTH aminocaproic acid AND tranexamic acid **OR** D. The prescriber has provided information to support the use of the requested agent over BOTH aminocaproic acid AND tranexamic acid **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that BOTH aminocaproic acid AND tranexamic acid cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The prescriber is a specialist (e.g., hematologist) in the area of the patient's diagnosis or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have liver disease **AND** 4. The patient does NOT have vitamin K deficiency **AND** 5. The patient will NOT be using the requested agent in combination with an indirect or direct Factor Xa inhibitor [e.g., apixaban (Eliquis), dalteparin (Fragmin), edoxaban (Savaysa), enoxaparin (Lovenox), fondaparinux (Arixtra), rivaroxaban (Xarelto) or warfarin (Coumadin)] **AND** 6. ONE of the following: A. The patient will NOT be using the requested agent in combination with nonsteroidal anti-inflammatory agents (NSAIDs) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided support of using an NSAID for this patient **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Length of Approval: One time emergency use: 1 time Perioperative management of bleeding: 1 time per request On-demand treatment: 3 months Prophylaxis treatment: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Evaluation** **NovoSeven RT** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of hemophilia A AND BOTH of the following: 1. The patient has inhibitors to Factor VIII **AND** 2. The requested agent is being used for ONE of the following: A. On-demand use for bleeds AND ONE of the following: 1. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have > 5 on-demand doses on hand **OR** 2. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR** B. Prophylaxis AND ALL of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to Immune Tolerance Induction (ITI) [Immune Tolerance Therapy (ITT)] **OR** B. The patient has an inhibitor level ≥ 200 BU (lab records required) **OR** C. Information has been provided indicating why the patient is not a candidate for ITI **AND** 2. The patient will NOT be using the requested agent in combination with Hemlibra **AND** 3. The patient will NOT be using the requested agent in combination with Feiba [activated prothrombin complex (aPCC)] used for prophylaxis (on-demand use of aPCC is acceptable) **OR** C. Peri-operative management of bleeding **OR** D. As a component of Immune tolerance induction (ITI)/Immune tolerance therapy (ITT) AND ONE of the following: 1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR** 2. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a ≥ 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical record required) **OR** B. The patient has a diagnosis of hemophilia B AND BOTH of the following: 1. The patient has inhibitors to Factor IX **AND** 2. The requested agent is being used for ONE of the following: A. On-demand use for bleeds AND ONE of the following: 1. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have > 5 on-demand doses on hand **OR** 2. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR**

Module	Clinical Criteria for Approval
	B. Prophylaxis AND BOTH of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to Immune Tolerance Induction (ITI) [Immune Tolerance Therapy (ITT)] **OR** B. The patient has an inhibitor level ≥ 200 BU (lab records required) **OR** C. Information has been provided indicating why the patient is not a candidate for ITI **AND** 2. The patient will NOT be using the requested agent in combination with Feiba [activated prothrombin complex (aPCC)] used for prophylaxis (on-demand use of aPCC is acceptable) **OR** C. Peri-operative management of bleeding **OR** D. As a component of Immune tolerance induction (ITI)/Immune tolerance therapy (ITT) AND ONE of the following: 1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR** 2. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a ≥ 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical records required) **OR** C. The patient has a diagnosis of congenital Factor VII deficiency AND the requested agent will be used for ONE of the following: 1. On-demand use for bleeds AND ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have > 5 on-demand doses on hand **OR** B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR** 2. Prophylaxis **OR** 3. Perioperative use **OR** D. The patient has a diagnosis of Glanzmann's thrombasthenia AND BOTH of the following: 1. The patient is refractory to platelet transfusions **AND** 2. The requested agent will be used for ONE of the following: A. On-demand use for bleeds AND ONE of the following: 1. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have > 5 on-demand doses on hand **OR** 2. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR** B. Perioperative use **OR** E. The patient has a diagnosis of acquired hemophilia AND the requested agent will be used for ONE of the following: 1. On-demand use for bleeds **AND** ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have > 5 on-demand doses on hand **OR** B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR** 2. Perioperative use **OR** F. The patient has another FDA approved indication for the requested agent and route of administration **OR**

Module	Clinical Criteria for Approval
	G. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with another Factor VIIa agent **AND** 5. ONE of the following: A. The patient will NOT be using the requested agent in combination with nonsteroidal anti-inflammatory agents (NSAIDs) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest 3 months for all other diagnoses NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Evaluation** **Sevenfact** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of hemophilia A AND BOTH of the following: 1. The patient has inhibitors to Factor VIII **AND** 2. The requested agent is being used for on-demand use for bleeds **OR** B. The patient has a diagnosis of hemophilia B AND BOTH of the following: 1. The patient has inhibitors to Factor IX **AND** 2. The requested agent is being used for on-demand use for bleeds **OR** C. The patient has another FDA approved indication for the requested agent and route of administration **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with another Factor VIIa agent **AND** 5. ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient will NOT be using the requested agent in combination with nonsteroidal anti-inflammatory agents (NSAIDs) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR** B. The prescriber has provided information in support of using an NSAID for this patient **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have > 5 on-demand doses on hand **OR** B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand (supportive reasoning required) **Length of Approval:** up to 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Coagadex	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: 1. The requested quantity (dose) is within the FDA labeled dosing **AND** 2. The requested quantity (number of doses) is appropriate based on intended use (e.g., on-demand, perioperative management of bleeding, prophylaxis) **OR** B. The prescriber has provided clinical reasoning for exceeding the defined program quantity limit (dose and/or number of doses) (medical records) **Length of Approval:** One time emergency use: 1 time Perioperative management of bleeding: 1 time per request On-demand treatment: 3 months Prophylaxis treatment: 12 months
NovoSeven RT	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: 1. The requested dose is within the FDA labeled dosing **AND** 2. The requested quantity (number of doses) is appropriate based on intended use (e.g., on-demand, prophylaxis, perioperative) **OR** B. The prescriber has provided clinical reasoning for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required) **Length of Approval:** Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest 3 months for all other diagnoses
Sevenfact	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. ONE of the following:

Module	Clinical Criteria for Approval
	1. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: 1. The requested dose is within the FDA labeled dosing **AND** 2. The requested quantity (number of doses) is appropriate based on intended use (e.g., on-demand) **OR** 2. The prescriber has provided clinical reasoning for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required) **Length of Approval:** up to 3 months
Target Agent(s) EXCEPT Coagadex, NovoSeven RT, and Sevenfact	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. ONE of the following: A. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: 1. The requested quantity (dose) is within the FDA labeled dosing **AND** 2. The requested quantity (number of doses) is appropriate based on intended use (e.g., prophylaxis, on-demand, peri-operative) **OR** B. The prescriber has provided clinical reasoning for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required) **Initial Length of Approval:** One time emergency use: up to 2 weeks Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 6 months ITT/ITI: up to 6 months **Renewal Length of Approval:** On-demand: up to 3 months Peri-operative dosing: 1 time per request Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest