

Last review date: 6/18/2024

Applicable Products:	
Advate (antihemophilic factor, recombinant)	Hemofil M (antihemophilic factor, human)
Adynovate (antihemophilic factor, recombinant, pegylated)	Humate-P (antihemophilic factor, human)
Alphanate (antihemophilic factor/von willebrand factor complex)	Idelvion (Coagulation Factor IX [Recombinant], Albumin Fusion Protein [rIX-FP])
Alprolix (coagulation factor IX [recombinant], fc fusion)	Ixinity (coagulation factor IX (recombinant))
Afstyla (antihemophilic factor, recombinant)	Jivi (antihemophilic factor, recombinant, pegylated)
Altuviiio (antihemophilic factor, recombinant, Fc-VWF-XTEN fusion protein-ehtl)	Koate (antihemophilic factor, human)
Benefix (coagulation factor IX [recombinant])	Kogenate (antihemophilic factor, recombinant)
Beqvez (fidanacogene elaparvovec-dzkt)	Kovaltry (antihemophilic factor, recombinant)
Eloctate (antihemophilic factor, recombinant, Fc fusion protein)	Novoeight (antihemophilic factor, recombinant)
Esperoct (antihemophilic factor, recombinant, glycopegylated)	Nuwiq (antihemophilic factor, recombinant)
Hemlibra (emicizumab-kxwh)	Obizur (antihemophilic factor, recombinant, porcine sequence)
	Rebinyn (coagulation factor IX, recombinant, pegylated)
	Recombinate (antihemophilic factor, recombinant)
	Wilate (antihemophilic factor, human)
	Xyntha (antihemophilic factor, recombinant)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Drug-specific criteria; **AND**
- Must be prescribed by a hematologist; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Humate-P

- Hemophilia A in individuals 18 years and older:
 - Diagnosis of hemophilia A; **AND**
 - Treatment and prevention of bleeding; **OR**
- von Willebrand disease in pediatric and adult individuals
 - Diagnosis of von Willebrand disease:
 - Severe disease; **OR**
 - History of failure, contraindication, or intolerance to treatment with desmopressin in those with mild to moderate disease; **AND**
- One of the following:
 - Treatment of spontaneous and trauma-induced bleeding episodes; **OR**
 - Prevention of excessive bleeding during surgery (i.e., surgical prophylaxis)

Alphanate, Wilate

- Hemophilia A:
 - Routine prophylaxis to reduce the frequency of bleeding episodes; **OR**

- On-demand treatment and control of bleeding episodes; **OR**
- von Willebrand disease:
 - Diagnosis of von Willebrand disease; **AND**
 - One of the following:
 - On-demand treatment and control of bleeding episodes; **OR**
 - Perioperative management of bleeding; **OR**
 - Routine prophylaxis to reduce the frequency of bleeding episodes

Hemofil M, Koate-DVI

- Diagnosis of hemophilia A; **AND**
- For control and prevention of bleeding episodes or to perform emergency and elective surgery in individuals with hemophilia A

Advate, Kogenate FS, Novoeight, Nuwig, Recombinate, Xyntha

- Diagnosis of hemophilia A; **AND**
- One of the following:
 - Control and preventing of bleeding episodes; **OR**
 - Perioperative management; **OR**
 - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

Adynovate, Kovaltry, Afstyla, Jivi, Esperoct, Eloctate, Altuviiiio

- Diagnosis of hemophilia A: **AND**
- Patient is 12 years of age or older (Jivi only); **AND**
- One of the following:
 - On-demand treatment and control of bleeding episodes; **OR**
 - Perioperative management of bleeding; **OR**
 - Routine prophylaxis to reduce the frequency of bleeding episodes

Obizur

- Diagnosis of acquired hemophilia A; **AND**
- For the on-demand treatment and control of bleeding episodes

Hemlibra

- Diagnosis of hemophilia A; **AND**
- One of the following:
 - Routine prophylactic treatment of moderate hemophilia with documented need for prophylaxis treatment or severe status less than 1% of normal factor; **OR**
 - Prophylactic therapy of documented history of one (1) or more episodes of spontaneous bleeding into joints

Ixinity

- Diagnosis of hemophilia B; **AND**
- Patient is 12 years of age or older; **AND**
- One of the following:
 - Control and prevention of bleeding episodes; **OR**
 - Perioperative management

Rebinyn

- Diagnosis of hemophilia B; **AND**

- One of the following:
 - On-demand treatment and control of bleeding episodes; **OR**
 - Perioperative management of bleeding

Benefix, Idelvion, Alprolix

- Diagnosis of hemophilia B; **AND**
- One of the following:
 - On-demand treatment and control of bleeding episodes; **OR**
 - Perioperative management of bleeding; **OR**
 - Routine prophylaxis to reduce the frequency of bleeding episodes

Beqvez

- Patient is 18 years of age or older; **AND**
- Documented diagnosis of moderate-severe or severe hemophilia B (ex. FIX levels less than 2 IU/dL); **AND**
- Prescribed by or in consultation with a hematologist or specialist with experience and expertise in the treatment of hemophilia B; **AND**
- Individual has been on prophylactic FIX replacement therapy for at least six (6) months prior to receiving gene therapy; **AND**
- One of the following:
 - Individual has a current or historical life-threatening hemorrhage; **OR**
 - Individual has repeated, serious spontaneous bleeding episodes; **AND**
- Individual has been tested for anti-AAVRh74var antibodies and is deemed a suitable candidate for treatment

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet the Initial Approval Criteria; **AND**
- Absence of unacceptable toxicity

Length of Authorization:

Beqvez – one time approval; one use per lifetime

All other agents – 1 year

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.