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Policy Number: C15607-A

Hemophilia and Blood Factor Products

PRODUCTS AFFECTED

Plasma Factor VIII concentrates: Hemofil M, Koate DVI

Recombinant Factor VIII concentrates: Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Obizur, Recombinate, Xyntha

Prolonged Half-Life Recombinant Factor VIII concentrates: Adynovate, Afstyla, Eloctate, Esperoct, Jivi

Human Plasma-Derived Factor VIII Concentrates that Contain Von Willebrand Factor: Alphanate, Humate P, Wilate

Factor XIII Concentrate (Recombinant, vWF fusion) agent: Altuviiio

Plasma Factor IX concentrates: Alphanine SD, Mononine, Profilnine SD

Recombinant Factor IX concentrates: Benefix, Ixinity, Rixubis

Prolonged Half-life Recombinant Factor IX concentrates: Alprolix, Idelvion, Rebinyn

Coagulation Factor X (Plasma-derived) agent: Coagadex

Factor XIII Concentrate (Recombinant) agent: Tretten

Factor XIII Concentrate (Plasma-derived) agent: Corifact

Coagulation Factor VIIa (Recombinant) agent: NovoSeven RT, Sevenfact

Anti-inhibitor Coagulant Complex (Plasma-derived) agent: Feiba NF

Von Willebrand factor (Recombinant) agent: Vonvendi

Antihemophilic Agent- Monoclonal Antibody: Hemlibra (emicizumab)

Anti-Tissue Factor Pathway Inhibitor: Alhemo (concizumab), Hympavzi (marstacimab)

Antithrombin lowering therapy: Qfitlia (fitusiran)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as

outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Control and prevention of Hemophilia A hemorrhage, Control and prevention of Hemophilia B hemorrhage, Hemorrhage in von Willebrand disorder, Acquired factor VIII deficiency disease, Congenital factor VII deficiency, Glanzmann's thrombasthenia, Hemophilia with inhibitors to Factor VIII or Factor IX
OBIZUR ONLY: Acquired Hemophilia A

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case- by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS:

1. Documentation of member diagnosis, requested factor product, requested dose and frequency [DOCUMENTATION REQUIRED of member treatment plan which should include the plan for type of bleed and need for prophylaxis if applicable]
   AND
2. Prescriber is requesting a factor product that is in accordance with the products FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines for member’s diagnosis and dosing being prescribed
   AND
3. Prescriber attests to counseling member and/or caregiver that a treatment log be maintained and a copy will be submitted (via prescriber or pharmacy) for renewal purposes (See Appendix)
   *NOTE: If a historical bleed log is unavailable, a new log must be started and submitted for renewal
   AND
4. FOR HEMLIBRA ONLY:
   (i) Documentation member has a diagnosis of hemophilia A and has developed high-titer factor VIII inhibitors (> 5 Bethesda units [BU]) AND Hemlibra (emicizumab) is being prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)
   OR
   (ii) Documentation member has a diagnosis of hemophilia A AND Hemlibra (emicizumab) is being prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis) AND any ONE of the

following: (1) prescriber has determined that the member has had an adequate trial and failed to be sufficiently controlled on prophylaxis with a Factor VIII clotting factor agent, (2) member is under 2 years of age, (3) member has poor venous access, (4) member failed to achieve an adequate trough level while on clinically optimal dose and frequency of a Factor VIII clotting factor agent OR (5) member has documented serious side effect, FDA labeled contraindication, or hypersensitivity to prophylaxis with a Factor VIII clotting factor agent.
NOTE: Per MASAC #290, Recombinant factor VIII products are the recommended treatment of choice for patients with hemophilia A.
AND

5. FOR ALHEMO ONLY:
(i) Documentation member has a diagnosis of hemophilia A or hemophilia B AND Alhemo is being prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis) AND member has factor VIII inhibitors or factor IX inhibitors
OR
(ii) Documentation member has a diagnosis of hemophilia A or hemophilia B AND Alhemo is being prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis) AND any ONE of the following: (1) prescriber has determined that the member has had an adequate trial and failed to be sufficiently controlled on prophylaxis with a Factor VIII or Factor IX clotting factor agent, (2) member has poor venous access, (3) member failed to achieve an adequate trough level while on clinically optimal dose and frequency of a Factor VIII or Factor IX clotting factor agent OR (4) member has documented serious side effect, FDA labeled contraindication, or hypersensitivity to prophylaxis with a Factor VIII or Factor IX clotting factor agent
NOTE: Per MASAC #290, Recombinant factor VIII products are the recommended treatment of choice for patients with hemophilia A. Per MASAC #290, Recombinant factor IX products are the recommended treatment of choice for patients with hemophilia B.
AND
6. FOR HYMPAVZI ONLY: Documentation member has a diagnosis of hemophilia A or hemophilia B AND Hympavzi is being prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis) AND any ONE of the following: (1) prescriber has determined that the member has had an adequate trial and failed to be sufficiently controlled on prophylaxis with a Factor VIII or Factor IX clotting factor agent, (2) member has poor venous access, (3) member failed to achieve an adequate trough level while on clinically optimal dose and frequency of a Factor VIII or Factor IX clotting factor agent OR (4) member has documented serious side effect, FDA labeled contraindication, or hypersensitivity to prophylaxis with a Factor VIII or Factor IX clotting factor agent
NOTE: Per MASAC #290, Recombinant factor VIII products are the recommended treatment of choice for patients with hemophilia A. Per MASAC #290, Recombinant factor IX products are the recommended treatment of choice for patients with hemophilia B.
AND
7. FOR QFITLIA ONLY:
(i) Documentation member has a diagnosis of hemophilia A or hemophilia B AND Qfitlia is being prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis) AND member has factor VIII inhibitors or factor IX inhibitors
OR
(ii) Documentation member has a diagnosis of hemophilia A or hemophilia B AND Qfitlia is being prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis) AND any ONE of the following: (1) prescriber has determined that the member has had an adequate trial and failed to be sufficiently controlled on prophylaxis with a Factor VIII or Factor IX clotting factor agent, (2) member has poor venous access, (3) member failed to achieve an adequate trough level while on clinically optimal dose and frequency of a Factor VIII or Factor IX clotting factor agent OR (4) member has documented serious side effect, FDA labeled contraindication, or hypersensitivity to prophylaxis with a Factor VIII or Factor IX clotting factor agent
NOTE: Per MASAC #290, Recombinant factor VIII products are the recommended treatment of choice for patients with hemophilia A. Per MASAC #290, Recombinant factor IX products are the recommended treatment of choice for patients with hemophilia B.

AND

8. IF THIS IS A NON-FORMULARY/NON-PREFERRED FACTOR PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Documentation of positive clinical response to requested agent
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or unacceptable toxicity from the drug (e.g., symptoms of allergic-anaphylactic reactions [anaphylaxis, dyspnea, rash], thromboembolic events [thromboembolism, pulmonary embolism], and development of neutralizing antibodies [inhibitors])
   AND
3. Prescriber attests to counseling member and/or caregiver that a treatment log be maintained and a copy will be submitted (via prescriber or pharmacy) for renewal purposes (See Appendix)
   AND
4. Any increases in dose must be supported by an acceptable clinical rationale (i.e., weight gain, half- life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.) [DOCUMENTATION REQUIRED]

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of therapy: 12 months
MOLINA REVIEWER NOTE: For Texas Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:

Prescribed by a hematologist or provider at a Hemophilia treatment center. Search Directory (cdc.gov) – Hemophilia Treatment Center (HTC) Directory
MOLINA REVIEWER NOTE: Special consideration should be given if the requesting provider attests a specialist is unavailable in member's vicinity, specialist appointments are not available timely, and/or the requesting provider is actively managing the member's hemophilia and treatment regimen.

AGE RESTRICTIONS:

Alhemo: 12 years of age and older
Hympavzi: 12 years of age and older
Qfitlia: 12 years of age and older
All others: No restrictions

QUANTITY:

No requirements
NOTE: Prescriber or provider should verify the current number of doses (number for prophylaxis therapy, if applicable, and number allotted for PRN bleeds) in member's home. Per MASAC guideline # 242 for those on prophylaxis, a minimum of one major dose and two minor doses should be available in addition to the prophylactic doses utilized MONTHLY.

PLACE OF ADMINISTRATION:

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous, Subcutaneous (Alhemo, Hemlibra, Hympavzi, Qfitlia ONLY)

DRUG CLASS:
Antihemophilic Products

FDA-APPROVED USES:
Refer to product labeling for specific product indications
Control and prevention of Hemophilia A hemorrhage, control, and prevention of Hemophilia B hemorrhage, hemorrhage in von Willebrand disorder, treatment of hemorrhage in congenital fibrinogen deficiency, acquired factor VIII deficiency disease, congenital factor VII deficiency, Glanzmann's thrombasthenia, hemophilia with inhibitors to Factor VIII or Factor IX
OBIZUR ONLY: Routine prophylaxis in Hemophilia A, surgical procedure prophylaxis in Hemophilia A, control of hemorrhage in Hemophilia A

Alhemo (concizumab) is a a tissue factor pathway inhibitor (TFPI) antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A (congenital factor VIII deficiency) with or without FVIII inhibitors or hemophilia B (congenital factor IX deficiency) with or without FIX inhibitors.

Hympavzi (marstacimab) is a tissue factor pathway inhibitor (TFPI) antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with: hemophilia A (congenital factor VIII deficiency) WITHOUT FACTOR VIII INHIBITORS, or hemophilia B (congenital factor IX deficiency) WITHOUT FACTOR IX INHIBITORS.

Qfitlia (fitusiran) is an antithrombin-directed small interfering ribonucleic acid indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Appendix 1:
Treatment Logs:
A treatment log is a record of all your infusions and any bleeds you might have. A treatment log should documenting at least 6 months of bleeds (including prior to starting treatment), and which includes ALL of the following: Date and time of the bleed, location and severity of the bleed, how quickly the bleed was treated, treatment used (e.g., name, expiration date, lot number, number of units administered, etc.), any additional steps taken to manage the bleed (pain medication, ice pack, compression bandages, etc.), level of pain. For infusions not in response to a bleed, record the date and time of the infusion, treatment used (e.g., name, expiration date, lot number, number of units administered, etc.), and reason for the infusion (scheduled prophylaxis, pre-surgery, etc.

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.

(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and
(B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Hemophilia and von Willebrand's disease are the most common congenital bleeding disorders.
The two main types of hemophilia are A and B. Hemophilia A (classic hemophilia) has low levels of clotting factor VIII, or antihemophilic factor (AHF). Hemophilia B (Christmas disease) has low levels of clotting factor IX. AHF is an endogenous glycoprotein necessary for blood clotting and hemostasis. It is a cofactor that is necessary for factor IX to activate factor X in the intrinsic pathway. The main treatment for hemophilia is replacement of clotting factor VIII (for hemophilia A) or clotting factor IX (for hemophilia B). Administration of clotting factors is indicated for hemophilia when a bleeding episode arises (demand treatment) or when bleeding is anticipated or likely (prophylactic treatment).

Hemophilia A and B are classified as mild, moderate, or severe, depending on the amount of clotting factor VIII or IX in the blood.
Mild hemophilia: 5 – 40 percent of normal clotting factor
Moderate hemophilia: 1 – 5 percent of normal clotting factor
Severe hemophilia: Less than 1 percent of normal clotting factor

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Hemophilia and Blood Factor Products are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.
Contraindications to Alhemo (concizumab) include: patients with a history of known serious hypersensitivity to Alhemo or its components or the inactive ingredients.
Contraindications to Hemlibra (emicizumab), Hympavzi (marstacimab), Qfitlia (fitusiran) include: No labeled contraindications.
Contraindications to factor include: hypersensitivity (e.g., anaphylaxis) to antihemophilic factor, hypersensitivity to mouse proteins, hamster protein, bovine protein, rabbit proteins (product specific).
Additional contraindication to Obizur (antihemophilic factor [recombinant], porcine sequence) include: patients with congenital hemophilia A with inhibitors.
Additional contraindications to Rixubis (coagulation factor IX [recombinant]) include: disseminated intravascular coagulation (DIC), signs of fibrinolysis.
Contraindications to Feiba (anti-inhibitor coagulant complex) include: anaphylactic or severe hypersensitivity to anti-inhibitor coagulant complex, disseminated intravascular coagulation (DIC), acute thrombosis or embolism (including myocardial infarction).
Contraindications to Vonvendi (von Willebrand factor [recombinant]) include: hypersensitivity reactions to von Willebrand factor, hypersensitivity to hamster or mouse proteins.

OTHER SPECIAL CONSIDERATIONS:

Feiba (anti-inhibitor coagulant complex) has a Black Box Warning for embolic and thrombotic events.
Hemlibra (emicizumab-kxwh) has a Black Box Warning for thrombotic microangiopathy and thromboembolism.
Qfitlia (fitusiran) has a Black Box Warning for thrombotic events and acute and recurrent gallbladder disease.
NovoSeven (coagulation Factor VIIa, recombinant) has a Black Box Warning for thrombosis.
Sevenfact (coagulation factor VIIa [recombinant]-jncw) has a Black Box Warning for thrombosis.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J7170	Hemlibra Injection, emicizumab-kxwh, 0.5 mg
J7172	Injection, marstacimab-hncq, 0.5 mg
J7175	Coagadex Injection, factor x, (human), 1 i.u
J7179	Vonvendi Injection, von willebrand factor (recombinant), 1 i.u. vwf:rco
J7180	Corifact Injection, factor xiii (antihemophilic factor, human), 1 i.u.
J7181	Tretten Injection, factor xiii a-subunit, (recombinant), per iu
J7182	Novoeight Injection, factor viii, (antihemophilic factor, recombinant), per iu
J7183	Wilate Injection, von willebrand factor complex (human), , 1i.u. vwf:rco
J7185	Xyntha Injection, factor viii (antihemophilic factor, recombinant), per i.u.
J7186	Alphanate/vwf Inj, antihemophilic factor viii/vWF complex (human), per factor viii IU
J7187	Humate-p Injection, von willebrand factor complex , per iu vwf:rco
J7188	Obizur Injection, factor viii (antihemophilic factor, recombinant), per i.u.
J7189	Novoseven Rt Factor viia (antihemophilic factor, recombinant), per1 microgram
J7190	Koate-dvi Factor viii (antihemophilic factor, human) per i.u.
J7192	Recombinate Factor viii (antihemophilic factor, recombinant) per i.u., NOS
J7192	Helixate FS Factor viii (antihemophilic factor, recombinant) per i.u., NOS
J7192	Kogenate Factor viii (antihemophilic factor, recombinant) pe ri.u., NOS
J7192	Advate Factor viii (antihemophilic factor, recombinant) per i.u., NOS
J7193	Alphanine Sd - Factor ix (antihemophilic factor, purified, non-recombinant) per i.u.
J7193	Mononine Factor ix (antihemophilic factor, purified, non-recombinant) per i.u.
J7194	Profilnine Sd Factor ix, complex, per i.u.
J7195	Ixinity Injection, factor ix (antihemophilic factor, recombinant) per iu, NOC

J7195	BeneFIX Injection, factor ix (antihemophilic factor, recombinant) per iu, not otherwise specified
J7198	Feiba NF Anti-inhibitor, per i.u.
J7200	Rixubis Injection, factor ix, (antihemophilic factor, recombinant), per iu
J7201	Alprolix Injection, factor ix, fc fusion protein, (recombinant), 1 i.u.
J7202	Idelvion Injection, factor ix, albumin fusion protein, (recombinant), ,1 i.u.
J7203	Rebinyn Inj factor ix, (antihemophilic factor, recom), glycopegylated,1 iu
J7204	Esperoct Injection, factor viii, antihemophilic factor (recombinant), glycopegylated-exei, per iu
J7205	Eloctate Injection, factor viii fc fusion protein (recombinant), per iu
J7207	Adynovate Injection, factor viii, (antihemophilic factor, recombinant), pegylated, 1 i.u.
J7208	Jivi Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, 1 i.u.
J7209	Nuwiq Injection, factor viii, (antihemophilic factor, recombinant),1 i.u.
J7210	Afstyla Injection, factor viii, (antihemophilic factor, recombinant),1 i.u.
J7211	Kovaltry Injection, factor viii, (antihemophilic factor, recombinant),1 i.u.
J7212	Sevenfact Factor viia (antihemophilic factor, recombinant)-jncw, 1 microgram
J7213	Ixinity Injection, coagulation factor ix (recombinant), 1 i.u.
J7214	Altuviiio Injection, factor viii/von willebrand factor complex, recombinant, per factor viii i.u.

AVAILABLE DOSAGE FORMS:

Advate SOLR 1000UNIT, 1500UNIT, 2000UNIT, 250UNIT, 3000UNIT, 4000UNIT, 500UNIT,
Adynovate SOLR 1000UNIT, 1500UNIT, 2000UNIT, 250UNIT, 3000UNIT, 500UNIT, 750UNIT
Afstyla KIT 1000UNIT, 1500UNIT, 2000UNIT, 2500UNIT, 250UNIT, 3000UNIT, 500UNIT
Alhemo SOPN 60MG/1.5ML, 150MG/1.5ML, 300MG/3ML
Alphanate SOLR 1000UNIT, 1500UNIT, 2000UNIT, 250UNIT, 500UNIT
AlphaNine SD SOLR 1000UNIT, 1500UNIT, 500UNIT
Alprolix SOLR 1000UNIT, 2000UNIT, 250UNIT, 3000UNIT, 4000UNIT, 500UNIT
Altuviiio SOLR 1000UNIT, 2000UNIT, 250UNIT, 3000UNIT, 4000UNIT, 500UNIT
BeneFIX KIT 1000UNIT, 2000UNIT, 250UNIT, 3000UNIT, 500UNIT
Coagadex SOLR 250UNIT, 500UNIT
Corifact KIT 1000-1600UNIT
Eloctate SOLR 1000UNIT, 1500UNIT, 2000UNIT, 250UNIT, 3000UNIT, 4000UNIT, 5000UNIT, 500UNIT, 6000UNIT, 750UNIT
Esperoct SOLR 1000UNIT, 1500UNIT, 2000UNIT, 3000UNIT, 500UNIT
Feiba SOLR 1000UNIT, 2500UNIT, 500UNIT
Hemlibra SOLN 105MG/0.7ML, 150MG/ML, 30MG/ML, 60MG/0.4ML
Hemofil M SOLR 1000UNIT, 1700UNIT, 250UNIT, 500UNIT
Humate-P SOLR 1000-2400UNIT, 250-600UNIT, 500-1200UNIT
Hympavzi SOAJ 150MG/ML
Idelvion SOLR 1000UNIT, 2000UNIT, 250UNIT, 3500UNIT, 500UNIT
Ixinity SOLR 1000UNIT, 1500UNIT, 2000UNIT, 250UNIT, 3000UNIT, 500UNIT
Jivi SOLR 1000UNIT, 2000UNIT, 3000UNIT, 500UNIT
Koate SOLR 1000UNIT, 250UNIT, 500UNIT
Koate-DVI SOLR 1000UNIT, 250UNIT, 500UNIT

Drug and Biologic Coverage Criteria

Kogenate FS KIT 1000UNIT, 2000UNIT, 250UNIT, 3000UNIT, 500UNIT
Kovaltry SOLR 1000UNIT, 2000UNIT, 250UNIT, 3000UNIT, 500UNIT
Mononine SOLR 1000UNIT
Novoeight SOLR 1000UNIT, 1500UNIT, 2000UNIT, 250UNIT, 3000UNIT, 500UNIT
NovoSeven RT SOLR 1MG, 2MG, 5MG, 8MG
Nuwiq KIT 1000UNIT, 1500UNIT, 2000UNIT, 2500UNIT, 250UNIT, 3000UNIT, 4000UNIT, 500UNIT
Nuwiq SOLR 1000UNIT, 1500UNIT, 2000UNIT, 2500UNIT, 250UNIT, 3000UNIT, 4000UNIT, 500UNIT
Obizur SOLR 500UNIT
Profilnine SOLR 1000UNIT, 1500UNIT, 500UNIT
Rebinyn SOLR 1000UNIT, 2000UNIT, 3000UNIT, 500UNIT
Recombinate SOLR 1241-1800UNIT, 1801-2400UNIT, 220-400UNIT, 401-800UNIT, 801-1240UNIT
Rixubis SOLR 1000UNIT, 2000UNIT, 250UNIT, 3000UNIT, 500UNIT
Sevenfact SOLR 1MG, 5MG
Tretten SOLR 2000-3125UNIT
Vonvendi SOLR 1300UNIT, 650UNIT
Wilate KIT 1000-1000UNIT, 500-500UNIT
Xyntha KIT 1000UNIT, 2000UNIT, 250UNIT, 500UNIT
Xyntha Solofuse KIT 1000UNIT, 2000UNIT, 250UNIT, 3000UNIT, 500UNIT

REFERENCES

1. Advate (antihemophilic factor [recombinant]) [prescribing information]. Westlake Village, CA: Baxalta US Inc; March 2023.
2. Adynovate (Antihemophilic Factor, Recombinant, PEGylated) [prescribing information]. Westlake Village, CA: Baxalta US Inc.; August 2023.
3. Afstyla (antihemophilic factor [recombinant]) [prescribing information]. Kankakee, IL: CSL Behring LLC; June 2023.
4. Alhemo (concizumab-mtci) injection, for subcutaneous use [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc.; July 2025.
5. Alphanate (antihemophilic factor/von Willebrand factor complex [human]) [prescribing information]. Los Angeles, CA: Grifols Biologicals LLC; November 2022.
6. AlphaNine coagulation factor ix (human) [prescribing information]. Los Angeles, CA: Grifols Biologicals LLC; November 2022.
7. Alprolix (coagulation factor IX [recombinant]) [prescribing information]. Cambridge, MA: Biogen Idec; May 2023.
8. Altuviiio (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl) lyophilized powder for solution, for intravenous use [prescribing information]. Waltham, MA: Bioverativ Therapeutics, Inc.; March 2025.
9. BeneFix (coagulation factor IX [recombinant]) [prescribing information]. Philadelphia, PA: Wyeth Pharmaceuticals; November 2022.
10. Coagadex (Coagulation Factor X (Human)) lyophilized powder for solution for intravenous use [prescribing information]. Durham, NC: BPL USA, Inc.; May 2024.
11. Corifact, Factor XIII Concentrate (Human) [prescribing information]. Kankakee, IL: CSL Behring LLC; September 2020.
12. Eloctate [Antihemophilic factor (recombinant), Fc fusion protein] [prescribing information]. Cambridge, MA: Biogen Idec Inc.; May 2023.
13. Esperoct [antihemophilic factor (recombinant) glycopegylated-exei] [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc.; February 2024.
14. Feiba (anti-inhibitor coagulant complex) lyophilized powder for solution, for intravenous use [prescribing information]. Lexington, MA: Takeda Pharmaceuticals USA, Inc; December 2024
15. Hemlibra (emicizumab-kxwh) injection, for subcutaneous use [prescribing information]. South San Francisco, CA: Genentech Inc; January 2024.
16. Hemofil M Antihemophilic Factor (Human), Method M, Monoclonal Purified [prescribing information]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.

17. Humate-P [Antihemophilic Factor/von Willebrand Factor Complex (Human)] [prescribing information]. Kankakee, IL: CSL Behring LLC; June 2020.
18. Hympavzi (marstacimab-hncq) injection, for subcutaneous use [prescribing information]. New York, NY: Pfizer Labs; October 2024.
19. Idelvion [Coagulation Factor IX (Recombinant), Albumin Fusion Protein] [prescribing information]. Kankakee, IL: CSL Behring LLC; June 2023.
20. Ixinity [coagulation factor IX (recombinant)] [prescribing information]. Chicago, IL: Medexus Pharma, Inc.; March 2024.
21. Jivi [antihemophilic factor (recombinant), PEGylated-aucl] lyophilized powder for solution, for intravenous use [prescribing information]. Whippany, NJ: Bayer HealthCare LLC; May 2025.
22. Koate, Antihemophilic Factor (Human) [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2022.
23. Kogenate FS (Antihemophilic Factor [Recombinant], Formulated with Sucrose) [prescribing information]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
24. Kogenate FS with BIO-SET [prescribing information]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
25. Kogenate FS with Vial Adapter [prescribing information]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
26. Kovaltry [Antihemophilic Factor (Recombinant)] [prescribing information]. Whippany, NJ: Bayer Healthcare LLC; December 2022.
27. Novoeight (antihemophilic factor, recombinant) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc., July 2020.
28. NovoSeven RT (factor VIIa) [prescribing information]. Plainsboro, NJ: Novo Nordisk; July 2020.
29. Nuwiq, Antihemophilic Factor (Recombinant)[blood coagulation factor VIII (Factor VIII)] Lyophilized Powder for Solution for Intravenous Injection [prescribing information]. Paramus, NJ: Octapharma USA, Inc.; December 2024.
30. Obizur [Antihemophilic Factor (Recombinant), Porcine Sequence] [recombinant (r) analogue of porcine factor VIII (pFVIII)] Lyophilized Powder for Solution for Intravenous Injection [prescribing information]. Lexington, MA: Takeda Pharmaceuticals USA, Inc; December 2024.
31. Profilnine Factor IX Complex [prescribing information]. Los Angeles, CA: Grifols Biologicals LLC; June 2023.
32. Qfitlia (fitusiran) injection, for subcutaneous use [prescribing information]. Cambridge, MA: Genzyme Corporation; March 2025.
33. Rebinyn (Coagulation Factor IX (Recombinant), GlycoPEGylated) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc.; August 2022.
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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information FDA-Approved Uses	Q4 2025
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Age Restrictions FDA-Approved Uses Appendix Other Special Considerations Coding/Billing Information Available Dosage Forms References	Q3 2025

REVISION- Notable revisions: Coding/Billing Information Template Update Products Affected Required Medical Information Age Restrictions FDA-Approved Uses Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q1 2025
REVISION- Notable revisions: Products Affected Required Medical Information Duration of Approval Other Special Considerations Coding/Billing Information Available Dosage Forms References	Q3 2024
REVISION- Notable revisions: Products Affected Diagnosis Required Medical Information Continuation of Therapy Place of Administration Contraindications/Exclusions/Discontinuation Other Special Considerations Coding/Billing Information Available Dosage Forms References	Q3 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Available Dosage Forms References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file