WellMed Doctors helping patients for more than 25 years	**Effective Date:** 01/21/2026	**Revision Date(s):** 12/10/19, 12/9/21, 02/18/22, 07/31/24, 05/31/25, 07/25/25, 08/08/25, 10/01/25, 01/21/2026
Department: PHARMACY	**MMC Review/ Approval Date(s):** 03/15/22, 08/01/24, 01/21/2026	**Page(s): 17**
Policy Number: 040.004 **Title: Coverage Determination Policy for Antihemophilic Agents**		

Regions: ☒ **Texas** ☐ **Florida** ☒ **New Mexico**

Impacted Areas:

☒ Network Management/Provider Services	☒ Utilization Management
☐ Member services	☐ Case management
☐ Quality Management	☐ Disease management
☐ Credentialing	☒ Claims
☐ IT	☐ Human resources
☐ Administration	☐ Finance
☐ Compliance/delegation	☒ Pharmacy
	☐ ALL

Approved by: Megan Ortiz, MD FACOG Senior Medical Director	Megan Lenhart Ortiz, MD, FACOG Digitally signed by Megan Lenhart Ortiz, MD, FACOG Date: 2026.01.23 09:03:54 -06'00'	01/21/2026 **Date:**
Reviewed by: Sherien Zaid, Pharm.D Director, Clinical Pharmacy	Sherien M. Zaid, Pharm.D Digitally signed by Sherien M. Zaid, Pharm.D Date: 2026.01.23 11:54:40 -06'00'	01/21/2026 **Date:**

Available LCD/NCD/LCA:

- National Coverage Determination for Anti-Inhibitor Coagulant Complex (AICC) (110.3)

Disclaimer:

WellMed applies criteria outlined in this policy to complement National Coverage Determination (NCD 110.3) and other CMS guidance related to Antihemophilic agents. The use of this criteria ensures consistent and evidence-based decisions regarding medical necessity and appropriate use of these agents. The criteria aims to reduce inappropriate denials by providing standardized review parameters for when treatment is medically appropriate. By applying the criteria outlined in this policy, WellMed aims to prevent the use of antihemophilic agents when not medically indicated, which can mitigate risks such as unnecessary exposure to these agents, which could result in potential adverse effects such as thromboembolic events, inhibitor development and downstream complications. The benefits of antihemophilic agents include their ability to effectively manage bleeding episodes and provide prophylaxis in patients with hemophilia, especially those with inhibitors. Potential clinical harms of applying the criteria within this policy may include denying access to therapy when otherwise indicated, potentially leading to treatment delays. However, the clinical benefits of using these criteria to supplement general coverage provisions

are expected to outweigh any potential harms, as they promote consistent, evidence-based decision-making and reduce variability in coverage determinations.

Title: Coverage Determination Policy for Antihemophilic Agents

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Coverage Policy Number: 040.004

Line of Business: Medicare Part B

Policy Type: Prior Authorization

Coverage Determination:

Initial/New Requests

Self-administered blood-clotting factors for hemophilia patients and items related to the administration of such factors are covered under Part B when ALL the following criteria exist:

1. The patient is diagnosed with any of the following:
    a. Factor VIII deficiency (classic hemophilia, hemophilia A).
    b. Factor IX deficiency (hemophilia B, Christmas disease, plasma thromboplastin component).
    c. Congenital factor XI deficiency (Hemophilia C).
    d. Von Willebrand's disease.
    e. Acquired hemophilia (acquired Factor VIII autoantibodies most frequently) and other coagulation factor deficiencies, intrinsic circulating anticoagulants, antibodies or inhibitors.
    f. Congenital deficiencies of other clotting factors (such as congenital afibrinogenemia and others).
2. The Factor is used to control bleeding associated with hemophilia.
3. The patient is competent to use such factors without medical or other supervision.
4. A profile of the patient's use and a prescription for supplies should be submitted with a beneficiary new to the Contractor or a newly enrolled beneficiary.

Feiba Anti-Inhibitor Coagulation Complex (AICC) (J7198)

AICC has been shown to be safe and effective and is covered when **ALL** of the following criteria are met:

1. Patient has diagnosis of hemophilia A or B
2. Patient has inhibitors to Factor VIII OR IX
3. Has had major bleeding episodes
4. Has failed to respond to other less-expensive therapies

NovoSeven (J7189)

Factor VIIa (anti-hemophilic factor, recombinant) is covered when ALL of the following criteria are met:

1. Patient has one or more of the following indications:
    a. Treatment of bleeding episodes or perioperative management in hemophilia A or B with inhibitors
    b. Congenital Factor VII deficiency
    c. Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets
    d. Treatment in bleeding episodes and perioperative management in adults with acquired hemophilia.
2. Initially administered under the supervision of a physician experienced in the treatment of bleeding disorders

3. Effectiveness monitored by hemostasis evaluations to provide a basis for modification of the treatment schedule.

PLEASE NOTE: NovoSeven is **NOT** covered for prophylaxis treatment other than for perioperative invasive procedures or surgery.

Hemlibra (J7170)

Emicizumab-kxwh [Hemlibra] is covered when the following criteria are met:

1. Diagnosis of severe hemophilia A
2. Documentation of endogenous factor VIII level less than 1% of normal factor VIII (< 0.01 IU/mL);

OR

1. Diagnosis of hemophilia A regardless of severity
2. Submission of medical records (e.g., chart notes, laboratory values) documenting a failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of prophylactic factor VIII replacement products

OR

1. Diagnosis of hemophilia A
2. Patient has developed high-titer factor VIII inhibitors (≥ 5 Bethesda units [BU])
3. Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Tissue factor pathway inhibitor (TFPI) antagonist:

Alhemo (J7173)

Concizumab-mtci (Alhemo) is covered when the following criteria are met:

1. Diagnosis of hemophilia A or hemophilia B
2. Patient developed high-titer factor VIII inhibitors (for hemophilia A) or factor IX inhibitors (for hemophilia B (≥ 5 Bethesda units [BU])
3. Prescribed by or in consultation with a hemophilia specialist
4. Prescribed for the prevention of bleeding episodes (i.e. routine prophylaxis)

Please NOTE: Alhemo should not be used with bypassing agents (e.g., NovoSeven RT or FEIBA) for routine prophylaxis. Use of bypassing agents should be reserved for the treatment of breakthrough bleeding

Hympavzi (J7172)

Marstacimab-hncq (Hympavzi) is covered when the following criteria are met:

1. Diagnosis of hemophilia A or B without factor VIII or IX inhibitors
2. Documentation of endogenous factor VIII or IX less than 1% of normal factor VIII or IX (less than 0.01 IU/mL)

OR

3. Patient has one or more target joint (i.e. any joint with $\geq$ 3 spontaneous bleeds within 6 months)
4. Patient has failed to meet treatment goals with prophylactic clotting factor VIII (hemophilia A) or IX (hemophilia B) replacement therapy (e.g. continuation of spontaneous bleeds, inability to achieve appropriate trough levels)
5. Prophylactic use of factor VIII or IX replacement therapy is prohibited; on-demand use for breakthrough bleeding is allowed
6. Prescribed for the prevention of bleeding episodes (i.e. routine prophylaxis)

Renewal/Continuation of Therapy Requests

RENEWAL requests for continued use of the above products will be approved if ALL of the following are met:

1. The patient has documentation of positive clinical response
2. The requested dosing regimen remains within the recommended dosing parameters
3. The patient still meets all of the indication-specific criteria above

Alhemo:

1. Patient must have documentation of concizumab-mtci plasma concentration consistently above 200ng/mL

OR

2. If the concizumab-mtci plasma concentration remained below 200 ng/mL at two consecutive measurements, alternative therapies were considered.

NOTE: If the concizumab-mtci plasma concentration remained below 200ng/ml at two consecutive measurements, the benefits of continued Alhemo treatments should be evaluated versus the potential risk of bleeding events, and alternative therapies if available should be considered

FDA Approved Dose and Indication:

DRUG	INDICATION/DOSE
Feiba Anti-Inhibitor Coagulation Complex (AICC) (J7198)	**Hereditary factors IX & VIII deficiency disease with inhibitors** Hemorrhage prophylaxis- • 85 units/kg IV every other day Hemorrhage: • Joint: 50 to 100 units/kg IV every 12 hours until reduction in pain and in acute disability • Mucous: 50 to 100 units/kg IV every 6 hours for at least 1 day or until bleeding resolves • Soft tissue: 100 units/kg IV every 12 hours until bleeding resolves • Severe: 100 units/kg IV every 6 to 12 hours until bleeding resolves Surgical procedure: • Preoperative dose: 50 to 100 units/kg IV immediately before surgery • Postoperative dose: 50 to 100 units/kg IV every 6 to 12 hours until bleeding resolves and healing is achieved
NovoSeven (J7189)	**Acquired hemophilia:** • Hemorrhage: 70 to 90 mcg/kg slow IV bolus every 2 to 3 hours until hemostasis Perioperative prophylaxis: 70 to 90 mcg/kg slow IV bolus prior to surgery, repeat every 2 to 3 hours during surgery and until hemostasis

	Factor VII deficiency • Hemorrhage: 15 to 30 mcg/kg IV bolus, then every 4 to 6 hours until hemostasis achieved • Perioperative prophylaxis: 15 to 30 mcg/kg IV bolus prior to surgery, then repeat every 4 to 6 hours until hemostasis achieved **Glanzmann's thrombasthenia** • Hemorrhage: 90 mcg/kg IV bolus every 2 to 6 hours. Higher doses of 100 to 140 mcg/kg can be used • Perioperative prophylaxis: 90 mcg/kg IV bolus prior to surgery, repeat every 2 to 6 hours. Higher doses of 100 to 140 mcg/kg can be used **Hemophilia A or B**: • Hemorrhage: 90 mcg/kg IV bolus; repeat every 2 hours until hemostasis. At home treatment- 90 mcg/kg IV bolus followed by 15 to 16 mcg/kg/hr for 12 hours with a target trough blood factor VII level of 10 units/mL, OR 160 to 180 mcg/kg bolus followed by 30 mcg/kg/hr for 6 hours with a target trough blood factor VII level of 20 units/mL (off-label dosage) • Perioperative Prophylaxis: Initial: 90 mcg/kg IV bolus immediately prior to intervention and repeat every 2 hours for duration of surgery. Minor post-surgery 90 mcg/kg IV bolus every 2 hours for first 48 hours, then every 2 to 6 hours until healing has occurred. Major post-surgery 90 mcg/kg IV bolus every 2 hours for 5 days then every 4 hours or by continuous infusion at 50 mcg/kg/hr until healing has occurred; additional bolus doses can be given
Hemlibra (J7170)	**Hemophilia A** • Hemorrhage prophylaxis: Initial 3 mg/kg subQ once weekly for 4 weeks. • Maintenance 1.5 mg/kg subQ once weekly OR 3 mg/kg every 2 weeks OR 6 mg/kg every 4 weeks; base dose selection on provider preference with consideration for regimens that may increase patient adherence.
Novoeight (J7182)	**Hemophilia A** • Minor hemorrhage: increase in plasma level of antihemophilic factor of 20-40%*; infuse every 12-24 hours for 1-3 days until bleeding resolved • Moderate hemorrhage: increase in plasma level of antihemophilic factor of 30-60%*; infuse every 12-24 hours for 3 or more days until pain and disability resolved • Major hemorrhage: increase in plasma level of antihemophilic factor of 60-100%*; infuse every 8-24 hours until bleeding has resolved • Routine prophylaxis: 20-50 units/kg 3 times a week OR 20-40 units/kg every other day * Dosage calculation: Body weight (kg) X 0.5 international units/kg X factor VIII activity increase desired (%) = dose required (international units
Wilate (J7183)	**Hemophilia A - Hemorrhage:** • Minor: 30-40 units/kg every 12-24 hours for at least 1 day * • Moderate: 30-40 units/kg every 12-24 hours for at least 3-4 days * • Major: 35-50 units/kg every 12-24 hours for at least 3 to 4 days * • Life threatening: 35-50 units/kg every 8-24 hours until threat has resolved; * • Prophylaxis: 20-40 units/kg every 2-3 days * titrate dose and frequency based on clinical response and clinical condition, severity of deficiency, severity of hemorrhage, desired factor VIII level, and presence of inhibitor

	von Willebrand disorder: See Micromedex for dosing
Xyntha (J7185)	**Hemophilia A** Hemorrhage: • Minor: 10-20 units/kg every 12-24 hours • Moderate: 15-30 units/kg every 12-24 hours • Major: 30-50 units/kg every 8-24 hours Prophylaxis: • 30 international units/kg IV 3 times weekly Surgical prophylaxis: • Minor: 15-30 units/kg every 12-24 hours • Major: 30-50 units/kg every 8-24 hours
Humate P (J7186)	**Hemophilia A – Hemorrhage:** • Minor: 15 units/kg for one dose, then if needed 7.5 units/kg once or twice daily for 1 to 2 days • Moderate: 25 units/kg loading dose, then 15 units/kg every 8-12 hours for 1 to 2 days then once or twice daily • Life-threatening: 40-50 units/kg loading dose, then 20-25 units/kg every 8 hours for 7 days then once or twice daily for 7 days Von Willebrand disorder: See Micromedex for dosing
Rixubis (J7200)	**Hemophilia B** • Hemorrhage: Number of factor IX international units required = body weight (kg) multiplied by desired factor IX increase (% or international units/dL) multiplied by 1.1 dL/kg* Hemorrhage prophylaxis: • Previously treated patients: 40 to 60 international units/kg IV twice a week; adjust as necessary for individual age, bleeding pattern, and physical activity. Perioperative care: • Minor surgery: 30 to 60 international units/dL or 30% to 60% of normal factor IX level* required IV every 24 hours for 1 or more days until healing is achieved • Major surgery: 80 to 100 international units/dL or 80 to 100% of normal factor IX level* required IV every 8 to 24 hours for 7 to 10 days until bleeding stops and healing is achieved
Alprolix (J7201)	**Hemophilia B** Hemorrhage: • Minor to moderate (30% to 60% of normal Factor IX level required): IV bolus infusion; repeat every 48 hours with further evidence of bleeding • Major (80% to 100% of normal Factor IX level required): IV bolus infusion; consider repeat dose after 6 to 10 hours then every 24 hours for the first 3 days; after day 3 may decrease dose and increase interval to every 48 hours or longer until bleeding ceases and healing occurs Surgical prophylaxis and treatment: • Minor (50% to 80% of normal factor IX level required): Single IV bolus infusion, repeat as needed after 24 to 48 hours until bleeding ceases and healing occurs • Major (60% to 100% of normal factor IX initial level required): IV bolus infusion; consider repeat dose after 6 to 10 hours then every 24 hours for first 3 days; after **day** 3 may decrease dose and increase interval to every 48 hours or longer until bleeding ceases and healing occurs

	Prophylaxis: • 50 international units/kg IV bolus infusion once weekly OR 100 international units/kg once IV bolus infusion every 10 days
Esperoct (J7204)	**Hemophilia A** Hemorrhage: • Minor-Moderate: 40 units/kg; for moderate, may repeat an additional dose after 24 hours • Major: 50 units/kg; may repeat doses every 24 hours Perioperative: • 50 units/kg, may repeat after 24 hours Prophylaxis : • 50 units/kg every 4 days, adjust based on bleeding episodes
Idelvion (J7202)	**Hemophilia B** Hemorrhage prophylaxis: • Initial 25 to 40 international units/kg IV infusion every 7 days; may switch to 50 to 75 international units/kg IV every 14 days Hemorrhage: • Minor to moderate: (30% to 60% of circulating Factor IX level required) IV infusion for at least 1 day, until bleeding stops and healing is achieved. May be repeated every 48 to 72 hours, a single dose should be sufficient for most bleeds • Major: (60% to 100% of circulating Factor IX level required) IV infusion every 48 to 72 hours for 7 to 14 days and until bleeding stops and healing is achieved Perioperative: • Minor: (50% to 80% of circulating factor IX level required) IV infusion for at least 1 day or until healing is achieved. May repeat every 48 to 72 hours • Major: (60% to 100% of circulating factor IX initial level required) IV infusion every 48 to 72 hours for the first week or until healing is achieved; continue 7 to 14 days, or until healing complete. Administer maintenance dose 1 to 2 times/week
Nuwiq (J7209)	**Hemophilia A** Hemorrhage: • Minor: Increase in plasma level of antihemophilic factor of 20% to 40% of normal, repeat IV dose every 12 to 24 hours for at least 1 day • Moderate to Major: Increase in plasma level of antihemophilic factor of 30% to 60% of normal, repeat IV dose every 12 to 24 hours for 3 to 4 days • Life-threatening: Increase in plasma level of antihemophilic factor of 60% to 100% of normal, every 8 to 24 hours until hemostasis is achieved Hemorrhage prophylaxis: • 30 to 40 international units/kg IV every other day Surgical procedure: • Minor: Increase in plasma level of antihemophilic factor of 30% to 60% of normal; repeat IV infusions every 24 hours for at least 1 day • Major: Increase in plasma level of antihemophilic factor of 80% to 100% of normal; repeat IV infusions every 8 to 24 hours
Factor IX Complex Human (J7194)	**Hemophilia B** Hemorrhage:

	• Mild to moderate: raise plasma factor IX level to 20% to 30% in a single administration • Severe: raise plasma factor IX level to 30% to 50% administered daily Surgery: raise plasma factor IX level to 30% to 50%
Adynovate- Factor VIII pegylated recombinant (J7207)	**Hemophilia A** Perioperative: • Minor: 30 to 50 international units/kg • Major**:** 40 to 60 international units/kg Prophylaxis: • 40 to 50 international units/kg twice a week Hemorrhage**:** • Minor: 10 to 20 international units/kg IV every 12 to 24 hours • Moderate: 15 to 30 international units/kg IV every 12 to 24 hours • Major: 30 to 50 international units/kg IV every 8 to 24 hours
Eloctate (J7205)	**Hemophilia A** Hemorrhage: • Minor-moderate: 20-30 units/kg IV every 24 to 48 hours until bleeding resolved • Major: 40 to 50 international units/kg IV every 12 to 24 hours for 7 to 10 days or until bleeding resolved Perioperative: • Minor: 25 to 40 units/kg IV every 24 hours for at least 1 day • Major: 40 to 60 international units/kg IV preoperatively, followed by 40 to 50 international units/kg IV after 8 to 24 hours and then every 24 hours Hemorrhage prophylaxis: • Initial 50 units/kg every 4 days. Maintenance 25-65 units/kg every 3-5 days
Thrombate III (J7197)	**Antithrombin III deficiency, Hereditary - Thromboembolic disorder** Peripartum/perioperative Prophylaxis: • Loading dose, (120% - baseline % x body weight (kg))/1.4% units to target AT level 120% of normal. • Maintenance dosage, loading dose x 0.6 units (target AT level 80% to 120% of normal) every 24 hours Treatment and prophylaxis: • Loading dose, (120% - baseline % x body weight (kg))/1.4% units to target AT level 120% of normal. • Maintenance dosage, loading dose x 0.6 units (target AT level 80% to 120% of normal) every 24 hours
Factor IX recombinant nos (J7195)	**BeneFIX- Hemophilia B** • Mild hemorrhage: 20% to 30% of normal factor IX level or 20 to 30 international units/dL factor IX activity required IV every 12 to 24 hours • Moderate hemorrhage: 25% to 50% of normal factor IX level or 25 to 50 international units/dL activity required IV every 12 to 24 hours for 2 to 7 days • Major hemorrhage: 50% to 100% of normal factor IX level or 50 to 100 international units/dL activity required IV every 12 to 24 hours for 7 to 10 days • Long-term prophylaxis: 100 international units/kg IV once weekly **Ixinity- Hemophilia B**

	• Minor hemorrhage: 30% to 60% of normal factor IX level or 30 to 60 international units/dL factor IX activity required IV every 24 hours • Moderate hemorrhage: 40% to 60% of normal factor IX level or 40 to 60 international units/dL factor IX activity required IV every 24 hours • Major or life-threatening hemorrhage: 60% to 100% of normal factor IX level or 60 to 100 international units/dL factor IX activity required IV every 12 to 24 hours • Hemorrhage prophylaxis: Previously treated patients: 40 to 70 international units/kg IV twice weekly • Minor Surgery Pre-op: 50 to 80 international units/dL or 50% to 80% of normal factor IX level required • Major surgery Pre-op: 60 to 80 international units/dL or 60% to 80% of normal factor IX level required
Profilnine (J7194)	**Hemophilia B** • Mild to moderate hemorrhage: raise plasma factor IX level to 20% to 30% in a single administration. • Severe hemorrhage: raise plasma factor IX level to 30% to 50% administered daily. • Surgery: raise plasma factor IX level to 30% to 50% administered for at least 1 week following surgery. • Dental extractions: raise plasma factor IX level to 50% administered just prior to procedure and give additional doses as needed
Factor IX non-recombinant (J7193)	**Hemophilia B** **Alphanine SD** • Mild hemorrhage: 20 to 30 international units/kg IV twice daily. • Moderate hemorrhage: 25 to 50 international units/kg IV twice a day. • Major hemorrhage: 30 to 50 international units/kilogram IV twice a day for at least 3 to 5 days. Followed by 20 international units/kg IV twice a day. • Surgery: 50 to 100 international units/kg IV twice daily for 7 to 10 days. **Mononine** • Mild hemorrhage: 20 to 30 international units/kg IV once and repeated in 24 hours if needed. • Major trauma or surgery: up to 75 international units/kg IV every 18 to 30 hours.
Factor VIII recombinant nos (J7192)	**Hemophilia A** **Kovaltry** • Minor hemorrhage: Increase in plasma level of antihemophilic factor of 20% to 40% of normal, repeat IV dose every 12 to 24 hours. • Moderate hemorrhage: Increase in plasma level of antihemophilic factor of 30% to 60% of normal, repeat IV dose every 12 to 24. • Major hemorrhage: Increase in plasma level of antihemophilic factor of 60% to 100% of normal, every 8 to 24 hours. • Hemorrhage prophylaxis: 20 to 40 international units/kg IV 2 or 3 times per week. • Minor surgery: Increase in plasma level of antihemophilic factor of 30% to 60% of normal; repeat IV infusions every 24 hours. • Major surgery: Increase in plasma level of antihemophilic factor of 80% to 100% of normal; repeat IV infusions every 8 to 24 hours. **Recombinate**

	• Minor hemorrhage, increase in plasma level of antihemophilic factor of 20% to 40% of normal: Begin IV infusions every 12 to 24 hours. • Moderate hemorrhage: Increase in plasma level of antihemophilic factor of 30% to 60% of normal, repeat IV infusion every 12 to 24 hours. • Major hemorrhage: Increase in plasma level of antihemophilic factor of 60% to 100% of normal, repeat IV infusions every 8 to 24 hours. • Minor surgery: Single IV bolus infusion to achieve increase in plasma level of antihemophilic factor of 60% to 80% of normal. • Major surgery: Increase in plasma level of antihemophilic factor of 80% to 100% of normal (pre-and-post operative); repeat IV infusions every 8 to 24 hours.
Koate Factor VIII human (J7190)	**Hemophilia A** **Hemorrhage:** • Mild: single dose of 10 units/kg • Moderate: 15-25 units/kg. Repeat with 10-15 units/kg every 8-12 hours if evidence of further bleeding. • Severe: initially 40 to 50 units/kg; maintenance dose 20 to 25 units/kg every 8 to 12 hours. **Surgery:** • Major procedures: preoperatively 50 units/kg. Repeat infusions every 6 to 12 hours initially as needed and for a total of 10 to 14 days.
Alphanate Antihemophilic VIII/VWF complex (J7186)	**Hemophilia A** **Hemorrhage:** • Minor: 15 units/kg twice daily (1 to 2 days) • Moderate: 25 units/kg twice daily (2 to 7 days) • Major: 40 to 50 units/kg twice daily for at least 3 to 5 days then 25 units/kg twice daily **Von Willebrand disorder - Surgery** • Loading dose, 60 international units VWF:RCo/kg IV • Minor: maintenance dose, 40 to 60 international units VWF:RCo/kg IV every 8 to 12 hours • Major: maintenance dose, 40 to 60 international units VWF:RCo/kg IV every 8 to 12 hours
Alhemo (J7173)	**Hemophilia A – Prophylaxis** • Loading dose: 1mg/kg day 1, followed by 0.2mg/kg once daily until individualization of maintenance dose 4 weeks after initiation of treatment • Maintenance: individualize based on plasma concentrations, goal above 200ng/mL; see Micromedex for recommendations on adjusting dosage **Hemophilia B – Prophylaxis** • Loading dose: 1mg/kg day 1, followed by 0.2mg/kg once daily until individualization of maintenance dose 4 weeks after initiation of treatment • Maintenance: individualize based on plasma concentrations, goal above 200ng/mL; see Micromedex for recommendations on adjusting dosage
Hympavzi (J7172)	**Hemophilia A – Prophylaxis** • Loading dose: 300mg • Maintenance: 150mg weekly, consider 300mg dose in patients 50kg or greater when bleeding control is inadequate

	Hemophilia B – Prophylaxis • Loading dose: 300mg • Maintenance: 150mg weekly, consider 300mg dose in patients 50kg or greater when bleeding control is inadequate

General Background:

Hemophilia is a hereditary blood disease characterized by greatly prolonged coagulation time. The blood fails to clot and abnormal bleeding occurs. It is a sex-linked hereditary trait transmitted by normal heterozygous females who carry the recessive gene. It occurs almost exclusively in males. For purposes of Medicare coverage, hemophilia encompasses Factor VIII deficiency (classic hemophilia, hemophilia A), Factor IX deficiency (hemophilia B, Christmas disease, plasma thromboplastin component), and von Willebrand's disease. Approximately 80% of those with hemophilia have type A, and both are associated with recurrent, spontaneous, and traumatic hemarthrosis.

The frequency and severity of hemorrhagic events induced by hemophilia are related to the amount of coagulation factor in the blood. Those with mild hemophilia (defined as having from 5% to 40% of normal coagulation factor activity) experience complications only after having undergone surgery or experiencing a major physical trauma. Those with moderate hemophilia (from 1% to 5% of coagulation factor activity) experience some spontaneous hemorrhage but normally exhibit bleeding provoked by trauma. Those with severe hemophilia (less than 1% of coagulation factor activity) exhibit spontaneous hemarthrosis and bleeding. Treatment for these patients is dependent on the severity of the disease and may include the administration of blood clotting factors such as Factor VIII, Factor IX, Factor VIIa and, Anti-inhibitors to control the bleeding.

Medicare provides coverage of these factor products through Part A and B coverage. In Part B, Medicare provides coverage in two manners, one of an 'incident to' event where the provider has a cost of the factor and administers, whereby the claim will demonstrate the factor product code and administration codes. Medicare also provides coverage for self-administered blood-clotting factors for hemophilia patients who are competent to use such factors to control bleeding without medical supervision. Medicare covers blood clotting factors for the following conditions:

- Factor VIII deficiency (classic hemophilia, hemophilia A)
- Factor IX deficiency (hemophilia B, Christmas disease, plasma thromboplastin component)
- Congenital factor XI deficiency (Hemophilia C)
- Von Willebrand's disease
- Acquired hemophilia (acquired Factor VIII autoantibodies most frequently) and other coagulation factor deficiencies, intrinsic circulating anticoagulants, antibodies or inhibitors.
- Congenital deficiencies of other clotting factors (such as congenital afibrinogenemia and others).

Anti-Inhibitor Coagulation Complex (AICC) (Feiba, VH Immuno, Autoplex or Hemophilia clotting factor) is a drug used to treat hemophilia in patients with Factor VIII inhibitor antibodies. AICC has been shown to be safe and effective and is covered when furnished to patients with hemophilia A or B and inhibitor antibodies to Factor VIII who have major bleeding episodes and who fail to respond to other less-expensive therapies.

Factor VIIa (anti-hemophilic factor, recombinant) (NovoSeven) is indicated for the treatment of bleeding episodes or perioperative management in hemophilia A or B with inhibitors, congenital Factor VII deficiency and Glanzmann's thromboasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets. NovoSeven is also labeled for treatment in bleeding episodes and perioperative management in adults with acquired hemophilia. NovoSeven is not labeled for prophylaxis treatment other than for perioperative invasive procedures or surgery. NovoSeven, as noted in the Prescribing Information for the product, should be administered to patients initially under the supervision of a physician experienced in the treatment of bleeding disorders. Effectiveness of NovoSeven should be monitored by hemostasis evaluations to provide a basis for modification of the treatment schedule.
Emicizumab-kxwh (Hemlibra®) is approved by the FDA as the originator biological product for routine prophylaxis to prevent or reduce the frequency of bleeding events in adult and pediatric patients (newborn and older) with congenital factor VIII deficiency (hemophilia A) with or without factor VIII inhibitors .

Hympavzi (marstacimab-hncq) injection 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.

Alhemo (concizumab-mtci) injection 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) with factor VIII inhibitors, or hemophilia B (congenital factor IX deficiency) with factor IX inhibitors.

Clinical Evidence:

Antihemophilic factor is usually indicated for hemophilia when a bleeding episode arises (demand treatment) or when bleeding is anticipated or likely (prophylactic treatment). Primary prophylactic therapy may be indicated for patients with severe hemophilia A or B who have less than 1 percent of normal factor (less than 0.01 IU/mL (National Hemophilia Foundation, 2001). Primary prophylactic therapy should be instituted early, prior to the onset of frequent bleeding, with the aim of keeping the trough factor or Factor VIII or Factor IX level above 1 percent between doses (National Hemophilia Foundation, 2001). In some cases, continuous prophylactic therapy may be indicated in persons with hemophilia A or hemophilia B that is not severe (i.e., hemophiliacs with more than 1 percent of normal factor levels) who have repeated episodes of spontaneous bleeding. Inhibitors are antibodies that neutralize Factor VIII and can render replacement therapy ineffective. They are found more commonly in patients with moderate to severe hemophilia (up to 30 percent of those with severe disease) who have received significant amounts of replacement therapy. Immune tolerance strategies in those with identified inhibitors also have been successful. Assuming no anamnestic response, low-titer inhibitors occasionally can be overcome with high doses of Factor VIII. Recombinant human coagulation Factor VIIa (rFVIIa) is indicated for the treatment of patients with bleeding episodes and for the prevention of bleeding in surgical interventions or invasive procedures in patients with hemophilia A or B with inhibitors to Factor VIII or Factor IX. High-titer inhibitors have been treated with variable success using porcine Factor VIII, Factor IX complex concentrates, recombinant Factor VIII, and exchange plasma pheresis. Anti-Inhibitor Coagulant Complex (AICC) is a drug used to treat hemophilia in patients with Factor VIII inhibitor antibodies. AICC has been shown to be safe and effective and is covered by Medicare when furnished to patients with hemophilia A and inhibitor antibodies to Factor VIII who have major bleeding episodes and who fail to respond to other less expensive therapies.

Immune tolerance induction is designed to overcome the effects of antihemophilic factor or Factor IX inhibitors in certain hemophiliac patients, thus restoring effectiveness of antihemophilic factor or Factor IX therapy to resolve active bleeding in these patients. It consists of administration of very high doses of anti-hemophilic factor or Factor IX over an extended period of time.

HCPCS Code:

Description	HCPCS Code
Emicizumab-Kxwh 0.5mg	J7170
Factor XIII anti-hem factor, 1 IU	J7180
Factor VIII recombinant Novoeight, per IU	J7182
Wilate injection, von Willebrand factor complex (human) 1 IU vWF:RCo	J7183
Xyntha injection, factor VIII (antihemophilic factor, recombinant) per IU	J7185
Antihemophilic VIII/VWF complex (human), per factor VIII IU	J7186
Humate-P	J7187
NovoSeven RT, Factor VIIa (antihemophilic factor, recombinant), 1 mcg	J7189
Factor VIII (antihemophilic factor, human), per IU	J7190
Factor VIII recombinant nos, per IU	J7192
Factor IX non-recombinant nos, per IU	J7193
Factor IX Complex, per IU	J7194
Factor IX Recombinant nos, per IU	J7195
Antithrombin III, per IU	J7197
Anti-Inhibitor, per IU	J7198
Factor IX (antihemophilic factor, Recombinant) Rixubis, per IU	J7200
Factor IX, FC fusion protein Recombinant, Alprolix per IU	J7201
Factor IX Idelvion	J7202
Recombinant Esperoct per iu	J7204

Factor VIII FC Fusion Recombinant	J7205
Factor VIII Pegylated Recombinant	J7207
Factor VIII Nuwiq Recombinant	J7209
Alhemo	J7173
Hympavzi	J7172

Acronyms:

NCD = National Coverage Determination; LCD = Local Coverage Determination; CMS = Centers for Medicare and Medicaid Services; FDA = Food and Drug Administration; AICC = Anti-Inhibitor Coagulation Complex

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Policy History/Revision Information:

Date Revised	Type of Changes (Significant or Minor)	List Significant Changes and/or Status of policy
1/18/19	Significant	New coverage criteria adopted from NCD and LCD. - S. Younts, PharmD, MPH, BCPS
12/10/19	Significant	Added New Mexico and Indiana to the regions section and NCD/LCD/LCA information under attachments with hyperlinks. Added coverage for Hemophilia C. Added renewal section. Added information on Hemlibra to the background information section. Added coverage criteria for Hemlibra. Updated references. – Eric McDermott, PharmD
12/9/21	Significant	Updated to new formatting. Tabularized the code list. Included FDA approved doses and indications. Added references. Hyperlinks inserted for table on content. Nana Brobbey, PharmD
02/18/22	Minor	Policy title updated from Hemophilia factors to Antihemophilic agents, Added links for LCD/LCA, updated criteria information for Feiba from Micromedex, updated some dosing from Micromedex, updated references. - Cordelia Osidele, PharmD
07/31/2024	Minor	Annual revision, LCD L35111 information removed as it is retired, Billing policy A56433 information removed – Pathik Tripathi, PharmD
05/31/25	Minor	Formatting and updates to specific medication dosing. Added new medications, Hympvazi and Alhemo, with coverage criteria and their references – S.Zaid, Pharm.D.
07/25/25	Minor	Updated disclaimer section. S.Zaid, PharmD
08/08/25	Minor	Verbiage was updated to “OR” for bullet #2 under criteria for Feiba Anti-Inhibitor Coagulation Complex . S.Zaid, PharmD
10/01/25	Minor	HCPCS code for Alhemo was updated. S.Zaid, PharmD