Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Select Clotting Agents for Bleeding Disorders	MP-RX-FP-82-23	☒ **MMM MA** ☒ **MMM MultiHealth**	11/30/2023	03/24/2026
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Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

Service Description

This document addresses the use of *Anti-Inhibitor Coagulant Complex [Feiba NF], Coagulation Factor X, Human plasma-derived [Coagadex], Factor IIa Recombinant [Novoseven RT, SevenFact], Factor XIII [Corifact, Tretten], Fibrinogen Concentrate [RiaSTAP, Fibryga], Anti-tissue factor pathway inhibitor (anti-TFPI) [Hympavzi, Alhemo], and Antithrombin-directed double-stranded small interfering ribonucleic acid (siRNA) [Qfitlia],* approved by the Food and Drug Administration (FDA) for the treatment of various hereditary blood disorders.

Background Information

This document addresses select clotting factor replacement treatments for various hereditary blood disorders. Fibrin products, fibrin sealants and blood products provided by blood banks are not included in this document. Non-bypassing factor products for hemophilia A and hemophilia B, as well as Hemlibra and agents for von Willebrand disease are addressed in other documents.

Factor replacement treatments can be created from blood products (human plasma-derived) and others that are manufactured (recombinant). Replacement therapy may be given on a routine, preventive basis which is also called prophylactic therapy. The infusion of factor replacements given to stop a bleeding episode is called on-demand or episodic therapy.

Products in this document include:

A. Anti-inhibitor Coagulant Complex
    A. FEIBA
B. Coagulation Factor X, Human plasma-derived
    A. Coagadex
C. Factor VIIa Recombinant
    A. Novoseven RT
    B. SevenFact

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D. Factor XIII
   A. Factor XIII Human plasma-derived ---Corifact
   B. Factor XIII A subunit Recombinant ---Tretten
E. Fibrinogen Concentrate
   A. Human plasma-derived---RiaSTAP
   B. Human fibrinogen ---Fibryga
F. Anti-tissue factor pathway inhibitor (anti-TFPI)
   A. Hympavzi (marstacimab-hncq)
   B. Alhemo (concizumab-mtci)
G. Antithrombin-directed double-stranded small interfering ribonucleic acid (siRNA)
   A. Qfitlia (fitusiran)

Factor X (FX), also called Stuart-Prower factor, can affect females and males equally. The factor X protein is involved in enzyme activation to help produce blood clots.

Factor XIII (FXIII), also called fibrin stabilizing factor, is considered the rarest factor deficiency, and can affect both genders equally. FXIII is responsible for stabilization of blood clots so that the clot doesn't break down and cause recurrent bleeds. FXIII circulates in plasma as FXIII A-subunits and FXIII B-subunits held together by strong bonds. FXIII A is the active unit in the coagulation cascade, while FXIII B acts as only the carrier molecule for subunit A. FXIII B itself does not provide any activity to correct B-subunit deficiencies.

Fibrinogen deficiencies are caused by a deficiency in factor I and includes three forms – afibrinogenemia (absent fibrinogen), hypofibrinogenemia (low levels of fibrinogen), and dysfibrinogenemia (abnormally functioning fibrinogen). Fibrinogen is normally produced in the liver and circulates in the body to help form clots and prevent bleeding. Factor I deficiencies can affect men and women equally.

Inhibitor development is the most common and a severe complication of factor replacement treatment, developing in approximately 15- 20% of people with hemophilia (CDC, 2014). Inhibitors are antibodies to replacement factors which reduce response to factor replacement therapy and may result in need for higher doses of factor products. In addition, the use of other agents, such as bypassing agents, does not replace the missing factor "but go around or (bypass) the factors that are blocked by the inhibitor to help the body form a normal clot" (CDC, 2014) to control bleeding episodes. The FDA-approved bypassing agents are FEIBA, NovoSeven RT, and SevenFact.

FEIBA, NovoSeven RT, and SevenFact all have black box warnings for thromboembolic events, particularly after high doses and/or in patients with thrombotic risk factors. Monitoring for signs and symptoms of thromboembolic events is recommended.

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Qfitlia has a black box warning for thrombotic events and acute and recurrent gallbladder disease. It is recommended to interrupt Qfitlia in patients with a thrombotic event and manage. For individuals with history of symptomatic gallbladder disease, it is recommended that alternative treatments be considered.

Approved Indications

A. Anti-inhibitor Coagulant Complex (FEIBA)
   - Control and prevention of bleeding episodes.
   - Perioperative management.
   - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

B. Coagulation Factor X, Human plasma-derived (Coagadex)
   - 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, moderate and severe hereditary Factor X deficiency

C. Factor VIIa Recombinant (Novoseven RT, SevenFact)
   - Treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors (SevenFact)
   - 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 (Novoseven RT)
   - Treatment of bleeding episodes and perioperative management in adults with acquired hemophilia (Novoseven RT)

D. Factor XIII (Factor XIII Human plasma-derived ---Corifact, Factor XIII A subunit Recombinant ---Tretten)
   - Routine prophylactic treatment and peri-operative management of surgical bleeding in patients with congenital Factor XIII deficiency (Corifact)
   - Routine prophylaxis of bleeding in patients with congenital factor XIII A-subunit deficiency (Tretten)

E. Fibrinogen Concentrate (Human plasma-derived---RiaSTAP, Human fibrinogen ---Fibryga)
   - Treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia
   - Fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency (Fibryga)

F. Anti-tissue factor pathway inhibitor (anti-TFPI) (Hympavzi, Alhemo)
   - 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) or hemophilia B (congenital factor IX deficiency) without factor IX inhibitors. (Hympavzi)

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- 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) or Hemophilia B (congenital factor IX deficiency) with or without FVIII inhibitors. (Alhemo)

G. Antithrombin-directed double-stranded small interfering ribonucleic acid (siRNA) (Qfitlia)
- 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.

Other Uses

A. N/A

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Anti-inhibitor Coagulant Complex (FEIBA)

HCPCS	Description
J7198	Anti-inhibitor; per IU [FEIBA]

ICD-10	Description
D66	Hereditary factor VIII deficiency [hemophilia A]
D67	Hereditary factor IX deficiency [hemophilia B]
Z29.8	Encounter for other specified prophylactic measure
Z79.899	Other long term (current) drug therapy [prophylactic]

Factor VIIa Recombinant (NovoSeven RT)

HCPCS	Description
J7189	Factor VIIa (Anti-hemophilic factor, recombinant), per 1 microgram [NovoSeven RT]

ICD-10	Description

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D66	Hereditary factor VIII deficiency [hemophilia A]
D67	Hereditary factor IX deficiency [hemophilia B]
D68.2	Hereditary deficiency of other clotting factors
D68.311	Acquired hemophilia
D68.318	Hemorrhagic disorder due to intrinsic circulating anticoagulants
D68.4	Acquired coagulation factor deficiency
D69.1	Qualitative platelet defects [when specified as Glanzmann's thrombasthenia]
Z79.899	Other long term (current) drug therapy
Z29.8	Encounter for other specified prophylactic measure

SevenFact (Factor VIIa Recombinant)

HCPCS	Description
J7212	Factor VIIa (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram

ICD-10	Description
D66	Hereditary factor VIII deficiency
D67	Hereditary factor IX deficiency
D68.2	Hereditary deficiency of other clotting factors
D68.311	Acquired hemophilia

Factor X (Coagadex)

HCPCS	Description
J7175	Injection, factor X, (human), 1 I.U. [Coagadex]

ICD-10	Description
D68.2	Hereditary deficiency of other clotting factors
D68.8	Other coagulation defects
D68.9	Coagulation defect, unspecified

Factor XIII (Corifact, Tretten)

HCPCS	Description
J7180	Injection, factor XIII (Anti-hemophilic factor, human), 1 I.U. [Corifact]
J7181	Injection, factor XIII A-subunit, (recombinant), per IU [Tretten]

ICD-10	Description

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D68.2	Hereditary deficiency of other clotting factors
Z29.8	Encounter for other specified prophylactic measure
Z79.899	Other long term (current) drug therapy [prophylactic]

Human fibrinogen (Fibryga)

HCPCS	Description
J7177	Injection, human fibrinogen concentrate, 1 mg [Fibryga]

ICD-10	Description
XW133YB	Transfusion of Nonautologous (Human) Fibrinogen Concentrate, Shelf-stable into Peripheral Vein, Percutaneous Approach, New Technology Group 11 [when specified as administration of Fibryga (human fibrinogen concentrate)]
XW143YB	Transfusion of Nonautologous (Human) Fibrinogen Concentrate, Shelf-stable into Central Vein, Percutaneous Approach, New Technology Group 11 [when specified as administration of Fibryga (human fibrinogen concentrate)]
D68.2	Hereditary deficiency of other clotting factors

Fibrinogen Concentrate, Human plasma-derived (RiaSTAP)

HCPCS	Description
J7178	Injection, human fibrinogen concentrate, 1 mg [RiaSTAP]

ICD-10	Description
D68.2	Hereditary deficiency of other clotting factors

Monoclonal Antibodies (Alhemo, Hympavzi); Qfitlia

HCPCS	Description
J7172	Injection, marstacimab-hncq, 0.5 mg [Hympavzi]
J7173	Injection, concizumab-mtci, 0.5 mg [Alhemo]
J7174	Injection, fitusiran, 0.04 mg [Qfitlia]

ICD-10	Description
D66	Hereditary factor VIII deficiency [hemophilia A]

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D67	Hereditary factor IX deficiency [hemophilia B]
Z79.899	Other long term (current) drug therapy [prophylactic]
Z29.89	Encounter for other specified prophylactic measures

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Clinical Criteria

Human-plasma derived Coagulation Factor X (Coagadex®)

A. Criteria for Initial Approval

Initial requests for Coagadex (Human-plasma derived Coagulation Factor X) may be approved if the following criteria are met:

i. Individual has a diagnosis of severe or moderate hereditary Factor X deficiency (defined as less than 5 IU/dL or 5% endogenous Factor X) (NHf, Srivastava 2020); **AND**
ii. Individual is using for one of the following:
   A. Treatment of acute bleeding episodes; **OR**
   B. Peri-procedural management for surgical, invasive or interventional radiology procedures; **OR**
   C. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes;

OR

iii. Individual has a diagnosis of mild hereditary Factor X deficiency (defined as greater than or equal to 5 IU/dL or 5% endogenous Factor X) (NHF, Srivastava 2020); **AND**
iv. Individual is using for one of the following:
   A. Treatment of acute bleeding episodes; **OR**
   B. Peri-procedural management for surgical, invasive or interventional radiology procedures; **OR**

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C. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes when there is documentation of one of the following:
   1. One or more episodes of spontaneous bleeding into joint; **OR**
   2. One or more episodes severe, life-threatening, of spontaneous bleeding as determined by the prescriber; **OR**
   3. Severe phenotype hemophilia determined by the individual's risk factors that increase the risk of a clinically significant bleed, including but not limited to, participation in activities likely to cause injury/trauma, procoagulant and anticoagulant protein levels, comorbid conditions affecting functional ability and physical coordination, or history of a clinically significant bleed.

B. Criteria for Continuation of Therapy

Continuation requests for Coagadex (Human-plasma derived Coagulation Factor X) may be approved if the following criteria are met:

i. Individual has a diagnosis of hereditary Factor X deficiency; **AND**
ii. Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes).

C. Conditions not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Coagadex (Human-plasma derived Coagulation Factor X) may not be approved for the following:

i. Individual with severe hereditary Factor X deficiency is using for perioperative management of bleeding in major surgery; **OR**
ii. When the above criteria are not met and for all other indications.

D. Approval Duration

i. Initial Approval Duration: Up to 12 months
ii. Reauthorization Approval Duration: Up to 12 months

Anti-inhibitor Coagulant Complex (Feiba®)

A. Criteria for Initial Approval

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Initial requests for FEIBA (Anti-inhibitor Coagulant Complex) may be approved if the following criteria are met:

i. Individual has a diagnosis of hemophilia A or B with inhibitors to Factor VIII or Factor IX; **AND**
ii. Individual is using for one of the following:
   A. Treatment of bleeding episodes; **OR**
   B. Peri-procedural operative management for surgical, invasive, or interventional radiology procedures; **OR**
   C. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

B. Criteria for Continuation Therapy

Continuation requests for FEIBA (Anti-inhibitor Coagulant Complex) may be approved if the following criteria are met:

i. Individual has a diagnosis of hemophilia A or B with inhibitors to Factor VIII or Factor IX; **AND**
ii. Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes).

C. Conditions Not Covered

FEIBA (Anti-inhibitor Coagulant Complex) may not be approved for the following:

i. Individual is using to treat bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to coagulation Factor VIII or coagulation Factor IX; **OR**
ii. When the above criteria are not met and for all other indications.

D. Authorization Duration

i. Initial Approval Duration: Up to 12 months
ii. Reauthorization Approval Duration: Up to 12 months

Factor VIIa Recombinant (NovoSeven RT®)

A. Criteria For Initial Approval

Initial requests for NovoSeven RT (Factor VIIa recombinant) may be approved if the following criteria are met:

i. Individual has one of the following diagnoses:

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A. Hemophilia A or B with inhibitors to Factor VIII or Factor IX; **OR**
B. Acquired hemophilia; **OR**
C. Congenital Factor VII deficiency; **AND**

ii. Individual is using for one of the following:
A. Individual is using for treatment of bleeding episodes; **OR**
B. Individual is using in the prevention of bleeding in surgical interventions or invasive procedures;

OR

iii. Individual has a diagnosis of Glanzmann's thrombasthenia; **AND**
iv. Individual is using for the treatment of bleeding episodes and peri-operative management related to diagnosis; **AND**
v. Individual has documented refractoriness to platelet transfusions with or without antibodies to platelets.

B. Criteria For Continuation of Therapy

Continuation requests for NovoSeven RT (Factor VIIa recombinant) may be approved if the following criteria are met:

i. Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes).
ii. Individual has one of the following diagnoses:
A. Hemophilia A or B with inhibitors to Factor VIII or Factor IX; **OR**
B. Acquired hemophilia; **OR**
C. Congenital Factor VII deficiency; **OR**
D. Individual has a diagnosis of Glanzmann's thrombasthenia

C. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. NovoSeven RT (Factor VIIa recombinant) may not be approved when the above criteria are not met and for all other indications.

D. Authorization Duration

i. Initial Approval Duration: Up to 12 months
ii. Reauthorization Approval Duration: Up to 12 months

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Human plasma-derived Fibrinogen concentrate (RiaSTAP®) or Human fibrinogen (Fibryga®)

A. Criteria For Initial Approval

Initial requests for RiaSTAP (Human plasma-derived Fibrinogen concentrate) or Fibryga (Human fibrinogen) may be approved if the following criteria are met:

i. Individual has a diagnosis of congenital fibrinogen deficiency (afibrinogenemia or hypofibrinogenemia); **AND**
ii. Individual is using for the treatment of acute bleeding episodes.

B. Criteria For Continuation of Therapy

Continuation requests for RiaSTAP (Human plasma-derived Fibrinogen concentrate) or Fibryga (Human fibrinogen) may be approved if the following criteria are met:

i. Individual has a diagnosis of acquired or congenital fibrinogen deficiency (afibrinogenemia or hypofibrinogenemia); **AND**
ii. Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes).

C. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

RiaSTAP (Human plasma-derived Fibrinogen concentrate) or Fibryga (Human fibrinogen) may not be approved for the following:

i. Individual has a diagnosis of dysfibrinogenemia; **OR**
ii. When the above criteria are not met and for all other indications.

D. Authorization Duration

i. Initial Approval Duration: Up to 12 months
ii. Reauthorization Approval Duration: Up to 12 months

Factor VIIa Recombinant (SevenFact®)

A. Criteria For Initial Approval

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Initial requests for SevenFact (Factor VIIa Recombinant) may be approved if the following criteria are met:

i. Individual is 12 years of age or older; **AND**
ii. Individual has a diagnosis of hemophilia A or B with inhibitors to Factor VIII or Factor IX; **AND**
iii. Individual is using for the treatment and control of bleeding episodes.

B. Criteria For Continuation of Therapy

Continuation requests for SevenFact (Factor VIIa Recombinant) may be approved if the following criteria are met:

i. Individual has a diagnosis of hemophilia A or B with inhibitors to Factor VIII or Factor IX; **AND**
ii. Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes).

C. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

SevenFact (Factor VIIa Recombinant) may not be approved for the following:

i. Individual is using for the treatment of congenital factor VII deficiency; **OR**
ii. Individual is using to treat bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to coagulation Factor VIII or coagulation Factor IX; **OR**
iii. When the above criteria are not met and for all other indications.

D. Authorization Duration

i. Initial Approval Duration: Up to 12 months
ii. Reauthorization Approval Duration: Up to 12 months

Factor XIII (Tretten® or Corifact®)

A. Criteria For Initial Approval

Initial requests for Corifact (Human Plasma-derived, Factor XIII) may be approved if the following criteria are met:

i. Individual has a diagnosis of Factor XIII deficiency; **AND**

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ii. Individual is using for routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes; **OR**
iii. Individual is using for peri-procedural management for surgical, invasive or interventional radiology procedures.

Initial requests for Tretten (Recombinant Factor XIII A-Subunit) may be approved if the following criteria are met:

i. Individual has a diagnosis of congenital Factor XIII A-Subunit deficiency; **AND**
ii. Individual is using as routine prophylaxis for bleeding.

B. Criteria For Continuation of Therapy

Continuation requests for Corifact (Human Plasma-derived, Factor XIII) or Tretten (Recombinant Factor XIII A-Subunit) may be approved if the following criteria are met:

i. Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes); **AND**
ii. Individual has a diagnosis of Factor XIII deficiency and is requesting continuation of Corifact; **OR**
iii. Individual has a diagnosis of congenital Factor XIII A-Subunit deficiency and is requesting continuation of Tretten.

C. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Corifact (Human Plasma-derived, Factor XIII) may not be approved for the following:
   A. When the above criteria are not met and for all other indications.
ii. Tretten (Recombinant Factor XIII A-Subunit) may not be approved for the following:
   A. Individual with congenital Factor XIII B-subunit deficiency; **OR**
   B. When the above criteria are not met and for all other indications.

D. Authorization Duration

i. Initial Approval Duration: Up to 12 months
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Hympavzi (marstacimab-hncq)

A. Criteria For Initial Approval

Initial requests for Hympavzi (marstacimab-hncq) may be approved if the following criteria are met:

i. Individual is 12 years of age or older; **AND**
ii. Individual has a diagnosis of moderate to severe hemophilia A (defined as 5 International Units per deciliter [1IU/dL to 5IU/dL] or less endogenous Factor VIII) without inhibitors (Rezende 2024); **AND**
iii. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;

OR

iv. Individual is 12 years of age or older; **AND**
v. Individual has a diagnosis of moderate to severe hemophilia B (defined as 5 International Units per deciliter [5IU/dL or less endogenous Factor IX) without inhibitors (Rezende 2024); **AND**
vi. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;

OR

vii. Individual is 12 years of age or older; **AND**
viii. Individual has a diagnosis of mild hemophilia A or B (defined as endogenous Factor VIII or Factor IX less than 40 IU/dL [less than 40%], but greater than 5 IU/dL) without inhibitors (NHF, Srivastava 2020)**; AND**
ix. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
x. Individual has one of the following:
   A. One or more episodes of spontaneous bleeding into joint; **OR**
   B. One or more episodes of severe, life-threatening, or spontaneous bleeding as determined by the prescriber; **OR**
   C. Severe phenotype hemophilia determined by the individual's risk factors that increase the risk of a clinically significant bleed, including but not limited to, participation in activities likely to cause injury/trauma, procoagulant and anticoagulant protein levels, comorbid conditions affecting functional ability and physical coordination, or history of a clinically significant bleed.

B. Criteria For Continuation of Therapy

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Continuation requests for Hympavzi (marstacimab-hncq) may be approved if the following criteria are met:

i. Individual has a diagnosis of hemophilia A or hemophilia B without factor VIII (for hemophilia A) or factor IX (for hemophilia B) inhibitors; **AND**
ii. Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes).

C. Conditions Not Covered

Hympavzi (marstacimab-hncq) may not be approved when the above criteria are not met and for all other indications.

D. Authorization Duration

i. Initial Approval Duration: Up to 12 months
ii. Reauthorization Approval Duration: Up to 12 months

Alhemo (concizumab-mtci)

A. Criteria For Initial Approval

Initial requests for Alhemo (concizumab-mtci) may be approved if the following criteria are met:

i. Individual is 12 years of age or older; **AND**
ii. Individual has a diagnosis of moderate to severe hemophilia A (defined as 5 International Units per deciliter [1IU/dL to 5IU/dL] or less endogenous Factor VIII) with or without factor VIII inhibitors (Rezende 2024); **AND**
iii. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;

OR

iv. Individual is 12 years of age or older; **AND**
v. Individual has a diagnosis of moderate to severe hemophilia B (defined as 5 International Units per deciliter [5IU/dL or less endogenous Factor IX) with or without factor VIII inhibitors (Rezende 2024); **AND**
vi. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;

OR

vii. Individual is 12 years of age or older; **AND**

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viii. Individual has a diagnosis of mild hemophilia A or B (defined as endogenous Factor VIII or Factor IX less than 40 IU/dL [less than 40%], but greater than 5 IU/dL) with or without factor VIII (for hemophilia A) or factor IX (for hemophilia B) inhibitors (NHF, Srivastava 2020)**; AND**

ix. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**

x. Individual has one of the following:

A. One or more episodes of spontaneous bleeding into joint; **OR**

B. One or more episodes of severe, life-threatening, or spontaneous bleeding as determined by the prescriber; **OR**

C. Severe phenotype hemophilia determined by the individual's risk factors that increase the risk of a clinically significant bleed, including but not limited to, participation in activities likely to cause injury/trauma, procoagulant and anticoagulant protein levels, comorbid conditions affecting functional ability and physical coordination, or history of a clinically significant bleed.

B. Criteria For Continuation of Therapy

Continuation requests for Alhemo (concizumab-mtci)may be approved if the following criteria are met:

i. Individual has a diagnosis of hemophilia A or hemophilia B with or without factor VIII (for hemophilia A) or factor IX (for hemophilia B) inhibitors; **AND**

ii. Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes).

C. Conditions Not Covered

Alhemo (concizumab-mtci) may not be approved when the above criteria are not met and for all other indications.

D. Authorization Duration

i. Initial Approval Duration: Up to 12 months

ii. Reauthorization Approval Duration: Up to 12 months

Qfitlia (fitusiran)

A. Criteria For Initial Approval

Initial requests for Qfitlia (fitusiran) may be approved if the following criteria are met:

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i. Individual is 12 years of age or older; **AND**
ii. Individual has a diagnosis of moderate to severe hemophilia A (defined as 5 International Units per deciliter [5IU/dL] or less endogenous Factor VIII) with or without factor VIII inhibitors (Rezende 2024, Young, Srivastava); **AND**
iii. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;

OR

iv. Individual is 12 years of age or older; **AND**
v. Individual has a diagnosis of moderate to severe hemophilia B (defined as 5 International Units per deciliter [5IU/dL or less endogenous Factor IX) with or without factor IX inhibitors (Rezende 2024, Young, Srivastava); **AND**
vi. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;

OR

vii. Individual is 12 years of age or older; **AND**
viii. Individual has a diagnosis of mild hemophilia A or B (defined as endogenous Factor VIII or Factor IX less than 40 IU/dL [less than 40%] but greater than 5 IU/dL) with or without factor VIII (for hemophilia A) or factor IX (for hemophilia B) inhibitors (NHF,Young, Srivastava); **AND**
ix. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; A**ND**
x. Individual has one of the following:
   A. One or more episodes of spontaneous bleeding into joint; **OR**
   B. One or more episodes of severe, life-threatening, or spontaneous bleeding as determined by the prescriber; **OR**
   C. Severe phenotype hemophilia determined by the individual's risk factors that increase the risk of a clinically significant bleed, including but not limited to, participation in activities likely to cause injury/trauma, procoagulant and anticoagulant protein levels, comorbid conditions affecting functional ability and physical coordination, or history of a clinically significant bleed.

B. Criteria For Continuation of Therapy

Continuation requests for Qfitlia (fitusiran) may be approved if the following criteria are met:

i. Individual has a diagnosis of hemophilia A or hemophilia B with or without factor VIII (for hemophilia A) or factor IX (for hemophilia B) inhibitors; **AND**
ii. Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes).

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C. Conditions Not Covered

Requests for Qfitlia (fitusiran) may not be approved when the above criteria are not met and for all other indications:

i. Individual has established hepatic impairment (Child-Pugh A, B, or C); **OR**
ii. When the above criteria are not met and for all other indications.

D. Authorization Duration

i. Initial Approval Duration: Up to 12 months
ii. Reauthorization Approval Duration: Up to 12 months

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug Name, Dosage Form & Strength	Recommended Dosing Schedule
FEIBA® Anti-inhibitor Coagulant Complex	• 50–100 units/kg IV bolus at ≤2 U/kg/min; may repeat every 6–12 hr as needed. • Routine prophylaxis: 50–75 units/kg IV every other day or 3–4× weekly. • Surgical use: dose to achieve hemostasis pre-/post-op. *Do not exceed 200 units/kg/day.*

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Coagadex® Coagulation Factor X, Human	• 25–50 IU/kg IV over 5–15 min. • Prophylaxis: 25 IU/kg every 3–7 days. • Adjust based on FX activity levels and bleeding phenotype.
Novoseven® RT Factor VIIa Recombinant	• 90 mcg/kg IV every 2–3 hr (common dose for hemophilia with inhibitors). • Congenital FVII deficiency: 15–30 mcg/kg IV every 4–6 hr. • Acquired hemophilia or Glanzmann's: 70–90 mcg/kg IV every 2–6 hr.
SevenFact® Factor VIIa Recombinant	• 75–225 mcg/kg IV every 3 hr until bleeding is controlled. • Typical starting dose: 75 mcg/kg; can escalate per response. • Dosing may be individualized.
Corifact® Factor XIII, Human	• 35 IU/kg IV every 4–6 weeks. • Surgical use: 35 IU/kg IV prior to procedure; repeat if needed. • Target trough FXIII ≥5%.
Tretten® Factor XIII A-subunit Recombinant	• 35 IU/kg IV once every 4 weeks. • Adjust based on FXIII levels (target ≥5%).
Fibryga® Fibrinogen Concentrate, Human	• Initial: 50 mg/kg IV for acute bleeding. • Repeat as needed to maintain fibrinogen ≥150 mg/dL. • Acquired deficiency: 30–70 mg/kg guided by lab values.
RiaSTAP® Fibrinogen Concentrate, Human	• 70 mg/kg IV initially. • Adjust and repeat as needed to maintain fibrinogen ≥150 mg/dL.
Hympavzi® Anti-TFPI (marstacimab-hncq)	• 300 mg subcutaneously once weekly.
Alhemo® Anti-TFPI (concizumab-mtci)	• 0.15 mg/kg subcutaneously once daily. • Dose adjustments based on response or thrombin generation.

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Qfitlia® (Antithrombin-directed double-stranded siRNA)	• Starting dose: 50 mg subcutaneously once every 2 months • Maintain AT activity between 15-35% by adjusting the dose and/or frequency of administration • Measure AT activity using an FDA-cleared test at Weeks 4 (Month 1), 12 (Month 3), 20 (Month 5) and 24 (Month 6) following the starting dose and after any dose modification. • ○ If any AT activity is <15%, a dose reduction is required. The lower dose should be initiated ○ If any AT activity is >35% after 6 months, or if the patient has not achieved satisfactory bleed control, dose escalation should be considered. AT measurements should be restarted after a dose escalation.
Exceptions	
• Weight-based dosing: Use actual body weight unless otherwise specified. • Monitor factor levels where applicable (e.g., Factor XIII, fibrinogen, Factor X) to guide dosing.	

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated Alhemo to include new indication for use in hemophilia A or B with or without inhibitors. Removed C9399, J3590; added HCPCS codes J7172, J7173, J7174. Edited ICD-10 descriptions (D68.9, Z79.899, Z28.89). Grouped Alhemo, Hympavzi, and Qfitlia together. Added Qfitlia clinical criteria and recommended dosing. Clarified diagnoses and inhibitor types for continuation criteria for Coagadex, Feiba, SevenFact, Corifact, Tretten, Hympavzi, and Alhemo. Added authorization durations for Tretten, Corifact, Hympavzi, and Alhemo. Included new Limits/Restrictions section with recommended dosing for all agents. Updated references and fixed formatting.	3/17/2026	03/24/2026
Annual Review	Add Alhemo and Hympavzi criteria. Added HCPCS NOC C9399, J3590, and all diagnosis pend for Alhemo. Added HCPCS C9304 effective 4/1/25. Added ICD-10-CM D66, D67, Z29.8 and Z79.899 for Hympavzi.	6/9/2025	6/19/2025
Annual Review	Add: approved indications per drug; regulatory statement. Update wording and formatting; applicable codes location; medical necessity guidelines formatting and added approval duration. Update Coagadex for new FDA indication. Coding Reviewed: No changes.	3/14/2025	4/2/2025
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023