Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Select Clotting Agents for Bleeding Disorders: 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]	MP-RX-FP-82-23	☒ MMM MA ☒ MMM Multihealth

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]* , clotting factor replacement treatments 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:

- Anti-inhibitor Coagulant Complex
  - FEIBA
- Coagulation Factor X, Human plasma-derived
  - Coagadex
- Factor VIIa Recombinant
  - Novoseven RT
  - SevenFact
- Factor XIII
  - Factor XIII Human plasma-derived ---Corifact
  - Factor XIII A subunit Recombinant ---Tretten

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- Fibrinogen Concentrate
  - Human plasma-derived---RiaSTAP
  - Human fibrinogen ---Fibryga

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.

Approved Indications

A. Anti-inhibitor Coagulant Complex (FEIBA)

   a. Control and prevention of bleeding episodes.
   b. Perioperative management.
   c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

B. Coagulation Factor X, Human plasma-derived (Coagadex)

   a. Routine prophylaxis to reduce the frequency of bleeding episodes
   b. On-demand treatment and control of bleeding episodes
   c. Perioperative management of bleeding in patients with mild, moderate and severe hereditary Factor X deficiency

C. Factor VIIa Recombinant (Novoseven RT, SevenFact)

   a. 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)
   b. 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)
   c. 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)

   a. Routine prophylactic treatment and peri-operative management of surgical bleeding in patients with congenital Factor XIII deficiency (Corifact)
   b. Routine prophylaxis of bleeding in patients with congenital factor XIII A-subunit deficiency (Tretten)

E. Fibrinogen Concentrate (Human plasma-derived---RiaSTAP, Human fibrinogen ---Fibryga)

   a. Treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia
   b. fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency (Fibryga)

Other Uses

i. 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]
D68.311	Acquired hemophilia
D68.318	Other hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies, or inhibitors
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
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

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	Acquired hemophilia

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

Fibrinogen Concentrate, Human plasma-derived (RiaSTAP); Human fibrinogen (Fibryna)

HCPCS	Description
J7177	Injection, human fibrinogen concentrate, 1 mg [Fibryga]
J7178	Injection, human fibrinogen concentrate, 1 mg [RiaSTAP]

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

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
D68.0	Von Willebrand's disease
D68.2	Hereditary deficiency of other clotting factors
D68.311	Acquired hemophilia
D69.1	Qualitative platelet defects

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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

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**

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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 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):

i. Coagadex (Human-plasma derived Coagulation Factor X) may not be approved for the following:
   A. Individual with severe hereditary Factor X deficiency is using for perioperative management of bleeding in major surgery;

   OR

   B. 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

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:

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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 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:

A. Hemophilia A or B with inhibitors to Factor VIII or Factor IX;

OR

B. Acquired hemophilia;

OR

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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).

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 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):

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

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

D. Authorization Duration

iii. Initial Approval Duration: Up to 12 months
iv. Reauthorization Approval Duration: Up to 12 months

Factor VIIa Recombinant (SevenFact®)

A. Criteria For Initial Approval

Initial requests for SevenFact (Factor VIIa Recombinant) 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 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 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):

i. SevenFact (Factor VIIa Recombinant) may not be approved for the following:
   A. Individual is using for the treatment of congenital factor VII deficiency;
   OR
   B. 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
   C. 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**
ii. Individual is using for routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes;

OR

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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).

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.

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Reference Information

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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 06/12/2024	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 6/12/2023	Elevance Health's Medical Policy adoption.	N/A	11/30/2023