# Medical Policy:

## Clotting Disorder Therapy

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---|---|---|
| MG.MM.PH.25 | March 12, 2025 | |



The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Applicable Products

| | |
|---|---|
| Criteria I | AlphaNine SD, Alprolix, BeneFIX, Idelvion, Profilnine SD, Rixubis, IXINITY, and Rebinyn |
| Criteria II | Alphanate, Humate-P |
| Criteria III | Advate, Adynovate, Altuviiio, Eloctate, Hemofil M, Koate-DVI, Kogenate FS,Novoeight, Recombinate, Xyntha, NUWIQ, Afstyla, Kovaltry, Jivi, Esperoct |
| Criteria IV | Feiba NF |
| Criteria V | Novoseven RT |
| Criteria VI | Obizur |
| Criteria VII | Tretten |
| Criteria VIII | Corifact |
| Criteria IX | Wilate |

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|---|---|
| Criteria X | Hemlibra |
| Criteria XI | Vonvendi |
| Criteria XII | Coagadex |
| Criteria XIII | Sevenfact |

## Definitions

| | |
|---|---|
| **Hemophilia A**<br>AKA factor VIII (FVIII) deficiency or classic hemophilia | Genetic disorder caused by missing or defective factor VIII, a clotting protein. |
| **Hemophilia B**<br>AKA factor IX (FIX) deficiency or Christmas disease | Genetic disorder caused by missing or defective factor IX, a clotting protein. |
| **Congenital factor VII deficiency**<br>AKA Hageman Factor | FXII deficiency is inherited in an autosomal recessive fashion, meaning both parents must carry the gene to pass it on to their children |
| **Glanzmann Thrombasthenia** | Genetic disorder in which the platelets have qualitative or quantitative deficiencies of the fibrinogen receptor αIIbβ3 |
| **Von Willebrand disease (VWD)** | Genetic disorder caused by missing or defective von Willebrand factor (VWF), a clotting protein. VWF binds factor VIII, a key clotting protein, and platelets in blood vessel walls, which help form a platelet plug during the clotting process. |

The medications listed in this policy are not covered by the pharmacy benefit. Human Antihemophilic Factor products are covered by the medical benefit and must be obtained by Accredo, our preferred medical specialty provider. Exceptions to Accredo fulfillment may be considered with urgent circumstances on an individual basis.

Specialty trained clinicians at Accredo's Therapeutic Resource Center for bleeding disorders will provide personalized care, and support services to minimize drug-related adverse episodes, and/ or gaps in care. Accredo will perform assay management, coordinate delivery based on site of care, provide financial assistance coordination, and emphasize patient empowerment strategies to improve adherence.

Accredo can be reached by phone at 866.712.5007 or fax 800.330.07566

## Length of Authorization

Initial period of six months

## Dosing Limits [Medical Benefit]

Refer to drug-specific labeling for appropriate dosing and administration

## Guideline

Hemophilia medications are considered medically necessary when the following product-specific criteria are met:

### I. Initial Criteria

### Criteria I — AlphaNine SD, Alprolix, BeneFIX, Idelvion, Profilnine SD, Rixubis, IXINITY, Rebinyn

**1. Hemophilia B**

A. Congenital factor IX deficiency confirmed by blood coagulation testing; **AND**

B. Used to treat at least ONE:

i. Control and prevention of acute bleeding episodes (hemorrhage) **OR**
ii. Routine prophylaxis to prevent or reduce frequency of bleeding episodes (applicable to Alprolix, BeneFIX, Idelvion, IXINITY, Rebinyn, and Rixubis only) **OR**
iii. Perioperative management; **AND**

C. Not used for induction of immune tolerance in members with Hemophilia (applicable to Alprolix, Rixubis, Idelvion, IXINITY, Rebinyn, AlphaNine SD, Mononine and Benefix only)

**Criteria II — Alphanate, Humate-P**

**1. Hemophilia A**

A. Congenital factor VIII deficiency confirmed by blood coagulation testing; **AND**
B. Used to treat at least ONE:
i. Control and prevention of acute bleeding episodes (hemorrhage) **OR**
ii. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes **OR**
iii. Perioperative management

**2. Von Willebrand disease (VWD)**

A. Von Willebrand disease confirmed by blood coagulation and von Willebrand factor testing; **AND**
B. Used as surgical bleeding prophylaxis in members with VWD in whom desmopressin is either ineffective or contraindicated; **OR** to control episodes of acute bleeding (Humate-P only); **AND**
C. Alphanate is not indicated for members with severe (type 3) VWD undergoing major surgery; **AND**
D. HUMATE-P is not indicated for the prophylaxis of spontaneous bleeding episodes in VWD

**Criteria III — Advate, Adynovate, Altuviiio, Eloctate, Hemofil M, Koate-DVI, Kogenate FS, Novoeight, Recombinate, Xyntha, NUWIQ, Afstyla, Kovaltry, Jivi, Esperoct**

**1. Hemophilia A**

A. Congenital factor VIII deficiency confirmed by blood coagulation testing; **AND**
B. Used to treat at least ONE:
i. Control and prevention of acute bleeding episodes (hemorrhage) **OR**
ii. Routine prophylaxis to prevent or reduce frequency of episodic bleeding **OR**
iii. Perioperative management

**Criteria IV — Feiba NF**

****For Medicare members: Feiba- please refer to our separate LCD/NCD Medicare criteria**

**1. Hemophilia A**

A. Congenital factor VIII deficiency confirmed by blood coagulation testing; **AND**
B. Confirmation that member has Factor VIII inhibitors; **AND**
C. Used to treat at least ONE:
i. Control and prevention of acute episodic bleeding (hemorrhage) **OR**
ii. Routine prophylaxis to prevent or reduce the frequency of episodic bleeding **OR**
iii. Perioperative management

**2. Hemophilia B**

A. Congenital factor IX deficiency confirmed by blood coagulation testing; **AND**
B. Confirmation that member has Factor IX inhibitors; **AND**
C. Used to treat at least ONE:
i. Control and prevention of acute episodic bleeding (hemorrhage) **OR**
ii. Routine prophylaxis to prevent or reduce the frequency of episodic bleeding **OR**
iii. Perioperative management

**Criteria V — Novoseven RT**

**1. Hemophilia A**

A. Congenital factor VIII deficiency confirmed by blood coagulation testing; **AND**
B. Confirmation that member has acquired Factor VIII inhibitors; **AND**
C. Used to treat at least ONE:
   i. Control and prevention of acute episodic bleeding (hemorrhage); **OR**
   ii. Perioperative management

**2. Acquired Hemophilia**

A. Diagnosis confirmed by blood coagulation testing; **AND**
B. Used to treat at least ONE:
   i. Control and prevention of acute episodic bleeding (hemorrhage); **OR**
   ii. Perioperative management

**3. Hemophilia B**

A. Factor IX deficiency confirmed by blood coagulation testing; **AND**
B. Confirmation that member has acquired Factor IX inhibitors; **AND**
C. Used to treat at least ONE:
   i. Control and prevention of acute episodic bleeding (hemorrhage); **OR**
   ii. Perioperative management

**4. Congenital Factor VII Deficiency**

A. Factor VII deficiency confirmed by blood coagulation testing; **AND**
B. Used to treat at least ONE:
   i. Control and prevention of acute episodic bleeding (hemorrhage); **OR**
   ii. Perioperative management

**5. Glanzmann's Thrombasthenia**

A. Glanzmann's Thrombasthenia has been confirmed by blood coagulation testing; **AND**
B. Used to treat at least ONE:
   i. Control and prevention of acute episodic bleeding (hemorrhage); **OR**
   ii. Perioperative management; **AND**
C. The use of platelet transfusions is known or suspected to be ineffective or contraindicated

### Criteria VI — Obizur

**1. Acquired Hemophilia A**

A. Factor VIII deficiency confirmed by blood coagulation testing; **AND**
B. Used to treat episodic bleeding; **AND**
C. Not used for congenital Hemophilia A or von Willebrand disease

### Criteria VII — Tretten

**1. Congenital Factor XIII A-subunit deficiency**

A. Factor XIII A-subunit deficiency confirmed by blood coagulation testing; **AND**
B. Used for routine prophylaxis of bleeding

### Criteria VIII — Corifact

**1. Congenital Factor XIII deficiency**

A. Factor XIII deficiency confirmed by blood coagulation testing; **AND**
B. Used to treat at least ONE:
   i. Used for routine prophylactic treatment; **OR**
   ii. Used for perioperative management of surgical bleeding

### Criteria IX — Wilate

**1. Von Willebrand disease (VWD)**

A. VWD confirmed by blood coagulation and von Willebrand factor testing; **AND**

B. Used to treat one of the following:
    i. On-demand treatment and control of bleeding episodes **OR**
    ii. Perioperative management of bleeding

**2. Hemophilia A**

A. Factor VIII deficiency confirmed by blood coagulation testing; **AND**
B. Used to treat one of the following:
    i. Routine prophylaxis to reduce the frequency of bleeding episodes
    ii. On-demand treatment and control of bleeding episodes

**Criteria X — Hemlibra**

**1. Congenital Factor VIII deficiency**

A. Factor VIII deficiency confirmed by blood coagulation testing; **AND**
B. Used for routine prophylactic treatment to prevent or reduce the frequency of episodic bleeding.

**Criteria XI — Vonvendi**

**1. Von Willebrand disease (VWD)**

A. VWD confirmed by blood coagulation and von Willebrand factor testing; **AND**
B. Used to treat at least ONE:
    i. Used for on-demand treatment and control of bleeding episodes; **OR**
    ii. Used for perioperative management of bleeding

**Criteria XII — Coagadex**

**1. Hereditary Factor X deficiency**

A. Diagnosis of congenital factor X deficiency has been confirmed by blood coagulation testing; **AND**
B. Used to treat at least ONE:
    i. Used for on-demand treatment and control of bleeding episodes; **OR**
    ii. Used for perioperative management of surgical bleeding in patients with mild deficiency **OR**
    iii. Routine prophylaxis to reduce the frequency of bleeding episodes

**Criteria XIII — Sevenfact (coagulation factor VIIa [recombinant]-jncw)**

**1. Hemophilia A (Factor VIII Deficiency)/ Hemophilia B (Factor IX Deficiency)**

A. Patient is ≥ 12 years of age; **AND**
B. Diagnosis of congenital factor VIII or IXC deficiency confirmed by blood coagulation testing; **AND**
C. Patient has a diagnosis of Hemophilia A or B with inhibitors; **AND**
D. Sevenfact will be used for treatment and control of bleeding episodes; **AND**
E. Sevenfact will not be used for the treatment of congenital factor VII deficiency.

### II. Renewal Criteria

1. Absence of unacceptable drug-toxicity (e.g.: symptoms of allergic-anaphylactic reactions [i.e., anaphylaxis, dyspnea, rash], thromboembolic events [thromboembolism, pulmonary embolism] and development of neutralizing antibodies [inhibitors])

### Limitations/Exclusions

Hemophilia medications are considered **investigational and not medically necessary** for any indications other than those listed above.

## Applicable Procedure Codes

| Code | Description |
|---|---|
| J7170 | Injection, emicizumab-kxwh, 0.5 mg |
| J7175 | Injection, factor x, (human), 1 i.u. (Coagadex) |
| J7179 | Injection, von willebrand factor (recombinant), (vonvendi), 1 i.u. vwf:rco |
| J7180 | Injection, factor XIII (antihemophilic factor, human), 1 IU |
| J7181 | Injection, factor XIII A-subunit, (recombinant), per IU |
| J7182 | Injection, factor VIII, (antihemophilic factor, recombinant), (NovoEight), per IU |
| J7183 | Injection, von Willebrand factor complex (human), Wilate, 1 IU vWF:RCo |
| J7185 | Injection, factor VIII (antihemophilic factor, recombinant) (XYNTHA), per IU |
| J7186 | Injection, antihemophilic factor VIII/von Willebrand factor complex (human), per factor VIII i.u. |
| J7187 | Injection, von Willebrand factor complex (Humate-P), per IU VWF:RCO |
| J7188 | Injection, factor VIII (antihemophilic factor, recombinant), per IU |
| J7189 | Factor VIIa (antihemophilic factor, recombinant), per 1 mcg |
| J7190 | Factor VIII (antihemophilic factor, human) per IU |
| J7192 | Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified |
| J7193 | Factor IX (antihemophilic factor, purified, nonrecombinant) per IU |
| J7194 | Factor IX complex, per IU |
| J7195 | Injection, factor IX (antihemophilic factor, recombinant) per IU, not otherwise specified |
| J7198 | Antiinhibitor, per IU |
| J7199 | Hemophilia clotting factor, not otherwise classified |
| J7200 | Injection, factor IX, (antihemophilic factor, recombinant), Rixubis, per IU |
| J7201 | Injection, factor ix, fc fusion protein, (recombinant), Alprolix, 1 i.u. |
| J7202 | Injection, factor ix, albumin fusion protein, (recombinant), Idelvion, 1 i.u. |
| J7203 | Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u. |
| J7204 | Injection, factor viii, antihemophilic factor (recombinant), glycopegylated-exei, per iu (Esperoct) Effective date: 07/01/2020 |
| J7205 | Injection, factor VIII Fc fusion protein (recombinant), per IU |
| J7207 | Injection, factor viii, (antihemophilic factor, recombinant), pegylated, 1 i.u. |
| J7208 | Injection, factor viii (antihemophilic factor, recombinant) pegylated-aucl, Jivi, 1 i.u. |
| J7212 | Intravenous Powder for Solution, Factor viia, (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram |
| J7213 | Injection, coagulation factor ix (recombinant), ixinity, 1 i.u. |
| J7214 | Injection, factor viii/von willebrand factor complex, recombinant (altuviiio), per factor viii i.u. |
| J7209 | Injection, factor viii, (antihemophilic factor, recombinant), (Nuwiq), 1 i.u. |
| J7210 | Injection, factor viii, (antihemophilic factor, recombinant), (Afstyla), 1 i.u |
| J7211 | Injection, factor viii, (antihemophilic factor, recombinant), (Kovaltry), 1 i.u |
| J3590 | Unclassified biologics |
| 96365 | Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour |
| 96366 | Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure) |
| 96367 | Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure) |
| 96368 | Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure) |
| 96369 | Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s) |
| 96370 | Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure) |
| 96371 | Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure) |
| 96372 | Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular |
| 96373 | Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intra-arterial |
| 96374 | Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug |

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| 96375 | Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure) |
| 96376 | Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure) |
| 96377 | Application of on-body injector (includes cannula insertion) for timed subcutaneous injection |
| 96379 | Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion |
| 99601 | Home infusion/specialty drug administration, per visit (up to 2 hours); |
| 99602 | Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (List separately in addition to code for primary procedure) |

## ICD-10 Diagnoses

| Code | Description |
|---|---|
| D66 | Hereditary factor VIII deficiency |
| D67 | Hereditary factor IX deficiency |
| D68.0 | Von Willebrand's disease |
| D68.1 | Hereditary factor XI deficiency |
| D68.2 | Hereditary deficiency of other clotting factors |
| D68.311 | Acquired hemophilia |
| D68.9 | Coagulation defect, unspecified |
| D69.1 | Qualitative platelet defects |
| R58 | Hemorrhage, not elsewhere classified |

## Revision History

| Company(ies) | DATE | REVISION |
|---|---|---|
| EmblemHealth & ConnectiCare | 3/12/2025 | Update: For Sevenfact addition of Diagnosis of congenital factor VIII or IXC deficiency confirmed by blood coagulation testing. Addition of Mononine- "Not used for induction of immune tolerance in members with Hemophilia (applicable to Alprolix, Rixubis, Idelvion, IXINITY, Rebinyn, AlphaNine SD, Mononine and Benefix only)" |
| EmblemHealth & ConnectiCare | 4/8/2024 | Added Statement: **For Medicare members: Feiba- please refer to our separate LCD/NCD Medicare criteria |
| EmblemHealth & ConnectiCare | 3/21/2024 | Annual Review: Initial Criteria: Criteria I: Hemophilia B<br>Added "Rixubis" to the Statement: "Routine prophylaxis to prevent or reduce frequency of bleeding episodes (applicable to Alprolix, BeneFIX, Idelvion, IXINITY, Rebinyn, and Rixubis only) OR"<br>Added "AlphaNine SD and Benefix" to the statement: "Not used for induction of immune tolerance in members with Hemophilia (applicable to Alprolix, Rixubis, Idelvion, IXINITY, Rebinyn, AlphaNine SD and Benefix only) " |
| EmblemHealth & ConnectiCare | 09/10/2023 | Added J code - J7214 Injection, factor viii/von willebrand factor complex, recombinant (altuviiio), per factor viii i.u. |
| EmblemHealth & ConnectiCare | 04/21/2023 | Added new drug – Altuviiio to criteria III |
| EmblemHealth & ConnectiCare | 3/2/2023 | Added newly approved indication of Rebinyn to criteria:<br>ii. Routine prophylaxis to prevent or reduce frequency of bleeding episodes (applicable to Alprolix, BeneFIX, Idelvion, IXINITY and Rebinyn only) |
| EmblemHealth & ConnectiCare | 4/07/2022 | Transferred policy to new template |

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| EmblemHealth & ConnectiCare | 02/17/2022 | -Clarified Wilate criteria by removing "used for perioperative management of bleeding"<br>-Clarified Vonvendi criteria by adding "Used for on-demand treatment and control of bleeding episodes. OR Used for perioperative management of bleeding" and removing "Members with severe VWD; OR Members with mild or moderate VWD in whom the use of desmopressin is known or suspected to be ineffective or contraindicated; AND Is NOT being used for routine prophylactic treatment of spontaneous bleeding episodes OR perioperative management of surgical bleeding; AND Is NOT being used for Hemophilia A<br>-Added- Routine prophylaxis to reduce the frequency of bleeding episodes to Coagadex criteria<br>-Added -Perioperative Treatment to Feiba NF Criteria- under Hemophilia A<br>-Removed DSC agents: Helixate FS, Monoclate-P, Bebulin, Mononine |
| EmblemHealth & ConnectiCare | 2/20/2021 | Addition of Sevenfact and its indications per FDA label. Added J7212. Removed following statement from Renewal Criteria: Member continues to meet clinical criteria above |
| EmblemHealth & ConnectiCare | 12/28/2020 | Updated Hemlibra criteria; removed the following: "Confirmation that member has Factor VIII inhibitors", in accordance with FDA labeling |
| EmblemHealth & ConnectiCare | 06/11/2020 | Added J-Code (J7204): Injection, factor viii, antihemophilic factor (recombinant), glycopegylated-exei, per iu (Esperoct) Effective date: 07/01/2020 |
| EmblemHealth & ConnectiCare | 6/03/2020 | Added drug Esperoct to Criteria III in this Medical Policy |
| EmblemHealth & ConnectiCare | 10/01/2019 | Added J code J7208, for Jivi (antihemophilic factor (recombinant) pegylated-aucl Removed Related Medical Guideline for off-label use |
| EmblemHealth & ConnectiCare | 7/10/2019 | Specified Adynovate, Coagadex, Idelvion, and Vonvendi criteria |
| EmblemHealth & ConnectiCare | 1/24/2019 | addition of Jivi |
| EmblemHealth & ConnectiCare | 7/25/2018 | addition of Afstyla, Kovaltry, Rebinyn, and Hemlibra |
| EmblemHealth & ConnectiCare | 10/13/2017 | title changed from Hemophilia Infusion Therapy to Clotting Disorders Therapy. Communicated that dosing should be commensurate with drug-specific labeling and that the initial authorization period is six months. |
| EmblemHealth & ConnectiCare | 6/16/2017 | added control of acute bleeding episodes as a covered indication for Humate-P |
| EmblemHealth & ConnectiCare | 12/3/2018 | Added J7170, J7203 and removed Q9995, C9468 from Applicable Procedure Codes |

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