Medical Policy:

Clotting Disorder Therapy

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.25	June 13, 2025	

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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

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

Definitions

Hemophilia A AKA factor VIII (FVIII) deficiency or classic hemophilia	Genetic disorder caused by missing or defective factor VIII, a clotting protein.
Hemophilia B AKA factor IX (FIX) deficiency or Christmas disease	Genetic disorder caused by missing or defective factor IX, a clotting protein.
Congenital factor VII deficiency 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:

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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

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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**

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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 IX 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

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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 IX 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 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" 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: 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" -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 -Added- Routine prophylaxis to reduce the frequency of bleeding episodes to Coagadex criteria -Added -Perioperative Treatment to Feiba NF Criteria- under Hemophilia A -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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