

Medical Policy

Healthcare Services Department

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| Policy Name Select Clotting Agents for Bleeding Disorders | Policy Number MP-RX-FP-82-23 | Scope <input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth |
| Service Category <div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <input type="checkbox"/> Anesthesia <input type="checkbox"/> Surgery <input type="checkbox"/> Radiology Procedures <input type="checkbox"/> Pathology and Laboratory Procedures </div> <div style="width: 48%;"> <input type="checkbox"/> Medicine Services and Procedures <input type="checkbox"/> Evaluation and Management Services <input type="checkbox"/> DME/Prosthetics or Supplies <input checked="" type="checkbox"/> Part B DRUG </div> </div> | | |
| Service Description <p>This document addresses the use of <i>Anti-Inhibitor Coagulant Complex [Feiba NF]</i>, <i>Coagulation Factor X, Human plasma-derived [Coagadex]</i>, <i>Factor IIa Recombinant [Novoseven RT, SevenFact]</i>, <i>Factor XIII [Corifact, Tretten]</i>, <i>Fibrinogen Concentrate [RiaSTAP, Fibryga]</i>, clotting factor replacement treatments approved by the Food and Drug Administration (FDA) for the treatment of various hereditary blood disorders.</p> <p>Background Information</p> <p>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.</p> <p>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.</p> <p>Products in this document include:</p> <ul style="list-style-type: none"> • Anti-inhibitor Coagulant Complex <ul style="list-style-type: none"> ○ FEIBA • Coagulation Factor X, Human plasma-derived <ul style="list-style-type: none"> ○ Coagadex • Factor VIIa Recombinant <ul style="list-style-type: none"> ○ Novoseven RT ○ SevenFact • Factor XIII <ul style="list-style-type: none"> ○ Factor XIII Human plasma-derived ---Corifact ○ Factor XIII A subunit Recombinant ---Tretten • Fibrinogen Concentrate <ul style="list-style-type: none"> ○ Human plasma-derived---RiaSTAP ○ Human fibrinogen ---Fibryga • Anti-tissue factor pathway inhibitor (anti-TFPI) | | |

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| <ul style="list-style-type: none"> ○ Hymoviz (marstacimab-hncq) ○ Alhemo (concizumab-mtci) <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Approved Indications</p> <ul style="list-style-type: none"> • Anti-inhibitor Coagulant Complex (FEIBA) <ul style="list-style-type: none"> • Control and prevention of bleeding episodes. • Perioperative management. • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes. • Coagulation Factor X, Human plasma-derived (Coagadex) <ul style="list-style-type: none"> ○ 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 | | |

- 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)
- 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)
- 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)
- Anti-tissue factor pathway inhibitor (anti-TFPI) (Hypmavzi, Alhemo)
 - Hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors
 - hemophilia B (congenital factor IX deficiency) without factor IX inhibitors

Other Uses

- 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)

| HCPSC | Description |
|-------|--------------------------------|
| J7198 | Anti-inhibitor; per IU [FEIBA] |

| ICD-10 | Description |
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| 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 | | |
| 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 | | |
| 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 | | |
| | | | |
| 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) | | | |

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| 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 | | | |
| D68.2 | Hereditary deficiency of other clotting factors | | | |
| D68.311 | Acquired hemophilia | | | |
| Hympavzi (marstacimab-hncg) | | | | |
| HCPCS | Description | | | |
| C9304 | Injection, marstacimab-hncq, 0.5 mg [Hympavzi] | | | |
| ICD-10 | Description | | | |
| D66 | Hereditary factor VIII deficiency [hemophilia A] | | | |
| D67 | Hereditary factor IX deficiency [hemophilia B] | | | |
| Z79.899 | Other long term (current) drug therapy | | | |
| Z29.89 | Other long term (current) drug therapy [prophylactic] | | | |
| Alhemo (concizumab-mtci) | | | | |
| HCPCS | Description | | | |
| C9399 | Unclassified drugs or biologicals [when specified as Alhemo (concizumab-mtci)] | | | |
| J3590 | Unclassified biologics [when specified as Alhemo (concizumab-mtci)] | | | |
| ICD-10 | Description | | | |
| | All diagnosis pend [Alhemo] | | | |
| 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. | | | | |

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| <p><i>Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.</i></p> <p>Clinical Criteria</p> <p>Human-plasma derived Coagulation Factor X (Coagadex®)</p> <ul style="list-style-type: none"> Criteria for Initial Approval <p>Initial requests for Coagadex (Human-plasma derived Coagulation Factor X) may be approved if the following criteria are met:</p> <ul style="list-style-type: none"> 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 Individual is using for one of the following: Treatment of acute bleeding episodes; OR Peri-procedural management for surgical, invasive or interventional radiology procedures; OR Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; OR 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 Individual is using for one of the following: Treatment of acute bleeding episodes; OR Peri-procedural management for surgical, invasive or interventional radiology procedures; OR Routine prophylaxis to prevent or reduce the frequency of bleeding episodes when there is documentation of one of the following: One or more episodes of spontaneous bleeding into joint; OR One or more episodes severe, life-threatening, of spontaneous bleeding as determined by the prescriber; OR 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. Criteria for Continuation of Therapy | | |

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| <p>Continuation requests for Coagadex (Human-plasma derived Coagulation Factor X) may be approved if the following criteria are met:</p> <ul style="list-style-type: none"> Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes). Conditions not Covered <p>Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):</p> <ul style="list-style-type: none"> Coagadex (Human-plasma derived Coagulation Factor X) may not be approved for the following: Individual with severe hereditary Factor X deficiency is using for perioperative management of bleeding in major surgery; <p>OR</p> <ul style="list-style-type: none"> When the above criteria are not met and for all other indications. Approval Duration <ul style="list-style-type: none"> Initial Approval Duration: Up to 12 months Reauthorization Approval Duration: Up to 12 months <p>Anti-inhibitor Coagulant Complex (Feiba®)</p> <ul style="list-style-type: none"> Criteria for Initial Approval <p>Initial requests for FEIBA (Anti-inhibitor Coagulant Complex) may be approved if the following criteria are met:</p> <ul style="list-style-type: none"> Individual has a diagnosis of hemophilia A or B with inhibitors to Factor VIII or Factor IX; AND Individual is using for one of the following: Treatment of bleeding episodes; <p>OR</p> <ul style="list-style-type: none"> Peri-procedural operative management for surgical, invasive, or interventional radiology procedures; <p>OR</p> <ul style="list-style-type: none"> Routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Criteria for Continuation Therapy <p>Continuation requests for FEIBA (Anti-inhibitor Coagulant Complex) may be approved if the following criteria are met:</p> <ul style="list-style-type: none"> Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes). Conditions Not Covered | | |

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| <p>FEIBA (Anti-inhibitor Coagulant Complex) may not be approved for the following:</p> <ul style="list-style-type: none"> 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; <p>OR</p> <ul style="list-style-type: none"> When the above criteria are not met and for all other indications. Authorization Duration Initial Approval Duration: Up to 12 months Reauthorization Approval Duration: Up to 12 months <p>Factor VIIa Recombinant (NovoSeven RT®)</p> <ul style="list-style-type: none"> Criteria For Initial Approval <p>Initial requests for NovoSeven RT (Factor VIIa recombinant) may be approved if the following criteria are met:</p> <ul style="list-style-type: none"> Individual has one of the following diagnoses: Hemophilia A or B with inhibitors to Factor VIII or Factor IX; <p>OR</p> <ul style="list-style-type: none"> Acquired hemophilia; <p>OR</p> <ul style="list-style-type: none"> Congenital Factor VII deficiency; AND <ul style="list-style-type: none"> Individual is using for one of the following: Individual is using for treatment of bleeding episodes; <p>OR</p> <ul style="list-style-type: none"> Individual is using in the prevention of bleeding in surgical interventions or invasive procedures; <p>OR</p> <ul style="list-style-type: none"> Individual has a diagnosis of Glanzmann's thrombasthenia; AND Individual is using for the treatment of bleeding episodes and peri-operative management related to diagnosis; AND Individual has documented refractoriness to platelet transfusions with or without antibodies to platelets. <ul style="list-style-type: none"> Criteria For Continuation of Therapy <p>Continuation requests for NovoSeven RT (Factor VIIa recombinant) may be approved if the following criteria are met:</p> <ul style="list-style-type: none"> Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes). | | |

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| <ul style="list-style-type: none"> Conditions Not Covered Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive): NovoSeven RT (Factor VIIa recombinant) may not be approved when the above criteria are not met and for all other indications. Authorization Duration <ul style="list-style-type: none"> Initial Approval Duration: Up to 12 months Reauthorization Approval Duration: Up to 12 months <p>Human plasma-derived Fibrinogen concentrate (RiaSTAP®) or Human fibrinogen (Fibryga®)</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Individual has a diagnosis of congenital fibrinogen deficiency (afibrinogenemia or hypofibrinogenemia); AND Individual is using for the treatment of acute bleeding episodes. 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: <ul style="list-style-type: none"> Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes). 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: Individual has a diagnosis of dysfibrinogenemia; OR When the above criteria are not met and for all other indications. Authorization Duration <ul style="list-style-type: none"> Initial Approval Duration: Up to 12 months Reauthorization Approval Duration: Up to 12 months | | |

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| <p>Factor VIIa Recombinant (SevenFact®)</p> <ul style="list-style-type: none"> Criteria For Initial Approval Initial requests for SevenFact (Factor VIIa Recombinant) may be approved if the following criteria are met: <ul style="list-style-type: none"> Individual is 12 years of age or older; AND Individual has a diagnosis of hemophilia A or B with inhibitors to Factor VIII or Factor IX; AND Individual is using for the treatment and control of bleeding episodes. Criteria For Continuation of Therapy Continuation requests for SevenFact (Factor VIIa Recombinant) may be approved if the following criteria are met: <ul style="list-style-type: none"> Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes). Conditions Not Covered Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive): <ul style="list-style-type: none"> SevenFact (Factor VIIa Recombinant) may not be approved for the following: Individual is using for the treatment of congenital factor VII deficiency; OR 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 When the above criteria are not met and for all other indications. Authorization Duration <ul style="list-style-type: none"> Initial Approval Duration: Up to 12 months Reauthorization Approval Duration: Up to 12 months | | |
| <p>Factor XIII (Tretten® or Corifact®)</p> <ul style="list-style-type: none"> Criteria For Initial Approval Initial requests for Corifact (Human Plasma-derived, Factor XIII) may be approved if the following criteria are met: <ul style="list-style-type: none"> Individual has a diagnosis of Factor XIII deficiency; AND | | |

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| <ul style="list-style-type: none"> Individual is using for routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes; OR Individual is using for peri-procedural management for surgical, invasive or interventional radiology procedures. <p>Initial requests for Tretten (Recombinant Factor XIII A-Subunit) may be approved if the following criteria are met:</p> <ul style="list-style-type: none"> Individual has a diagnosis of congenital Factor XIII A-Subunit deficiency; AND Individual is using as routine prophylaxis for bleeding. Criteria For Continuation of Therapy <p>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:</p> <ul style="list-style-type: none"> Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes). Conditions Not Covered <p>Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):</p> <ul style="list-style-type: none"> Corifact (Human Plasma-derived, Factor XIII) may not be approved for the following: When the above criteria are not met and for all other indications. Tretten (Recombinant Factor XIII A-Subunit) may not be approved for the following: Individual with congenital Factor XIII B-subunit deficiency; OR When the above criteria are not met and for all other indications. | | |
| <p>Hympavzi (marstacimab-hncq)</p> <ul style="list-style-type: none"> Criteria For Initial Approval <p>Initial requests for Hympavzi (marstacimab-hncq) may be approved if the following criteria are met:</p> <ul style="list-style-type: none"> Individual is 12 years of age or older; AND 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 Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; OR | | |

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| <ul style="list-style-type: none"> Individual is 12 years of age or older; AND 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 Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; OR <ul style="list-style-type: none"> Individual is 12 years of age or older; AND 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 Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND Individual has one of the following: <ul style="list-style-type: none"> One or more episodes of spontaneous bleeding into joint; OR One or more episodes of severe, life-threatening, or spontaneous bleeding as determined by the prescriber; OR 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. <ul style="list-style-type: none"> Criteria For Continuation of Therapy Continuation requests for Hymoviz (emicizumab-kxwh) may be approved if the following criteria are met: <ul style="list-style-type: none"> Individual has a diagnosis of hemophilia A or hemophilia B; AND Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes). Conditions Not Covered Hymoviz (emicizumab-kxwh) may not be approved when the above criteria are not met and for all other indications. <p>Alhemo (concizumab-mtci) Criteria For Initial Approval</p> <p>Initial requests for Alhemo (concizumab-mtci) may be approved if the following criteria are met:</p> <ul style="list-style-type: none"> Individual is 12 years of age or older; AND 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 Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; OR <ul style="list-style-type: none"> Individual is 12 years of age or older; AND | | |

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| <ul style="list-style-type: none"> 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 Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; OR <ul style="list-style-type: none"> Individual is 12 years of age or older; AND 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 Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND Individual has one of the following: <ul style="list-style-type: none"> One or more episodes of spontaneous bleeding into joint; OR One or more episodes of severe, life-threatening, or spontaneous bleeding as determined by the prescriber; OR 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. <ul style="list-style-type: none"> Criteria For Continuation of Therapy <p>Continuation requests for Alhemo (concizumab-mtci) may be approved if the following criteria are met:</p> <ul style="list-style-type: none"> Individual has a diagnosis of hemophilia A or hemophilia B; AND Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes). <ul style="list-style-type: none"> Conditions Not Covered <p>Alhemo (concizumab-mtci) may not be approved when the above criteria are not met and for all other indications.</p> | | |

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| Reference Information <ol style="list-style-type: none"> Centers for Disease Control and Prevention. Hemophilia Facts. Available at: http://www.cdc.gov/ncbddd/hemophilia/facts.html. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: September 29, 2022. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically. National Hemophilia Foundation (NHF). Available at: http://www.hemophilia.org/. Accessed on September 29, 2022. National Hemophilia Foundation (NHF). Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. September 2020. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medicaland-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/MASAC-Recommendations-Concerning-Products-Licensedfor-the-Treatment-of-Hemophilia-and-Other-Bleeding-Disorders. Accessed on September 29, 2022. Srivastava A, Santagostino E, Dougall A, et al. World Federation of Hemophilia. Guidelines for the management of hemophilia. Haemophilia. 3rd edition. August 2020. Available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/hae.14046. Accessed on September 29, 2022. <p>Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.</p> <p>No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.</p> <p>© CPT Only – American Medical Association</p> | | |

Medical Policy

Healthcare Services Department

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| Policy Name | Policy Number | Scope | |
| Select Clotting Agents for Bleeding Disorders | MP-RX-FP-82-23 | <input checked="" type="checkbox"/> MMM MA | <input checked="" type="checkbox"/> MMM Multihealth |

| Policy History | | | |
|-------------------------------|---|----------------------|-----------------------------|
| Revision Type | Summary of Changes | P&T Approval Date | UM/CMPC Approval Date |
| Annual Review 4/29/2025 | Add Alhemo and Hymavzi 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 Hymavzi. | 6/9/2025 | 6/19/2025 |
| 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 |