Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Agents for Hemophilia B	**MP-RX-FP-03-23**	☒ **MMM MA** ☒ **MMM MultiHealth**	**11/30/2023**	**7/1/2026**
			Last Review Date:	**Frequently Revision:**
			7/1/2026	**Annual**

Service Category:

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

Service Description:

This document addresses the use of Factor IX Human, Purified [Alphanine® SD], Factor IX Complex Human [Profilnine® SD], Coagulation Factor IX Recombinant [Rixubis®, BeneFIX®, IXINITY®], Factor IX Fc Fusion Protein Recombinant [Alprolix®], Factor IX Albumin Fusion Protein Recombinant [Idelvion®], Coagulation Factor IX Recombinant, GlycoPEGylated [Rebinyn®], drugs approved by the Food and Drug Administration (FDA) for the treatment of Hemophilia B.

Background Information:

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:

- Coagulation Factor IX, Human plasma-derived:
  - AlphaNine® SD,
- Factor IX Complex, human plasma-derived:
  - Profilnine® SD
- Factor IX Recombinant:
  - Rixubis®
  - Benefix®
  - Ixinity®
- Coagulation Factor IX, Long-Acting
  - Recombinant, Albumin Fusion Protein: Idelvion®
  - Recombinant coagulation factor IX, Fc Fusion Protein: Alprolix®
  - Recombinant coagulation factor IX, GlycoPEGylated: Rebinyn®

Requests for Qfitlia™ (fitusiran) are reviewed under the Select Clotting Agents policy.

Hereditary hemophilia B is the second most common type of hemophilia after hemophilia A (four times less common than hemophilia A). Although it is usually inherited, about one third of cases are caused by spontaneous mutations. Hemophilia A and B are clinically indistinguishable from one another, except by factor analysis. Hemophilia B is related to mutations in the gene coding for coagulation Factor IX (CDC 2014).

The U.S. National Hemophilia Foundation (NHF) and the World Federation of Hemophilia (Srivastava, 2020) both note there is a relationship of bleeding severity to the clotting factor level. Both entities list "severe" hemophilia as a clotting factor level < 1 IU/dl or < 1% of normal. A "mild" bleeding severity is identified as a

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clotting factor level of 5-40 IU/dl or 5 to < 40% of normal. A bleeding episode for individuals with mild risk includes severe bleeding with major trauma or surgery. Individuals with 1-5 IU/dl or 1-5% of normal are considered "moderate" risk for occasional spontaneous bleeding and prolonged bleeding with minor trauma or surgery (Srivastava, 2013).

Hemophilia severity:

- Severe hemophilia – Severe hemophilia is defined as < 1 percent factor activity, which corresponds to < 1 IU/dL.
- Moderate hemophilia – Moderate hemophilia is defined as a factor activity level ≥ 1 percent of normal and < 5 percent of normal, corresponding to ≥ 1 and < 5 IU/dL.
- Mild hemophilia – Mild hemophilia is defined as a factor activity level ≥ 5 percent of normal and < 40 percent of normal (≥ 5 and < 40 IU/dL).

World Federation of Hemophilia 2020 Guidelines for treatment of hemophilia state that prophylaxis prevents bleeding and joint destruction, and that prophylaxis should enable those with hemophilia to lead healthy and active lives. Moreover, the updated 2020 guidelines proposes that the definition of prophylaxis be based on outcomes rather than doses or timing of initiation, and treatment 2 regimens that take into account the hemophilic phenotype of the individual in addition to factor levels. However, more studies are needed to determine if all individuals should remain on therapy as adults (that is, those with severe hemophilia vs. moderate or mild). The WFH 2020 guidelines have been endorsed by several societies worldwide, including the U.S. NHF. Short-term prophylaxis (of 4 to 8 weeks) may interrupt the bleeding cycle and benefit individuals with repeated bleeding into target joints. Prophylaxis does not reverse existing joint damage but reduces bleeding and may slow progression of joint damage. Prophylactic clotting factor administration is recommended prior to the individual engaging in activities with higher risk of injury. Randomized trials of prophylactic therapy of hemophilia have demonstrated a decreased incidence of arthropathy (Gringeri, 2011; Manco-Johnson, 2007).

Approved Indications

Product Category	Product	Factor Type / Formulation	FDA-Approved Indication	Note
Coagulation Factor IX, Human plasma-derived	**AlphaNine SD**	Coagulation Factor IX, Human; plasma-derived	Indicated for the prevention and control of bleeding in patients with Factor IX deficiency due to hemophilia B.	The label does not separately list routine prophylaxis or perioperative management as distinct indications, although dosing guidance includes hemorrhagic events and surgery.
Factor IX Complex, human plasma-derived	**Profilnine SD**	Factor IX Complex; plasma-derived; contains factors IX, II, X, and low levels of factor VII	Indicated for the prevention and control of bleeding in patients with Factor IX deficiency, hemophilia B.	Not indicated for treatment of Factor VII deficiency. Pediatric safety and effectiveness are not established in the PI.

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Factor IX Recombinant	**Rixubis**	Coagulation Factor IX, Recombinant	Indicated in adults and children with hemophilia B for: on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.	Not indicated for induction of immune tolerance in patients with hemophilia B.
Factor IX Recombinant	**BeneFIX**	Coagulation Factor IX, Recombinant	Indicated in adults and children with hemophilia B, congenital Factor IX deficiency or Christmas disease, for: on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.	Not indicated for induction of immune tolerance in patients with hemophilia B.
Factor IX Recombinant	**IXINITY**	Coagulation Factor IX, Recombinant	Indicated in adults and children with hemophilia B for: on-demand treatment and control of bleeding episodes, perioperative management, and routine prophylaxis to reduce the frequency of bleeding episodes.	Not indicated for induction of immune tolerance in patients with hemophilia B.
Coagulation Factor IX – Long-Acting	**Idelvion**	Coagulation Factor IX, Recombinant, Albumin Fusion Protein	Indicated in children and adults with hemophilia B, congenital Factor IX deficiency, for: on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.	Not indicated for induction of immune tolerance in patients with hemophilia B.

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Coagulation Factor IX – Long-Acting	**Alprolix**	Coagulation Factor IX, Recombinant, Fc Fusion Protein	Indicated in adults and children with hemophilia B for: on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.	Not indicated for induction of immune tolerance in patients with hemophilia B.
Coagulation Factor IX – Long-Acting	**Rebinyn**	Coagulation Factor IX, Recombinant, GlycoPEGylated	Indicated in adults and children with hemophilia B, congenital Factor IX deficiency, for: on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.	Not indicated for immune tolerance induction in patients with hemophilia B.

Other Uses

A. None.

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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.

Alphanine SD® (Human plasma-derived, Coagulation Factor IX)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of hemophilia B (also called factor IX deficiency or Christmas disease); **AND**
ii. Individual is using for the treatment of bleeding episodes;
OR
iii. Individual has a diagnosis of moderate to severe hemophilia B (defined as 5 IU/dL or less endogenous Factor IX) (Rezende 2024); **AND**
iv. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
OR
v. Individual has a diagnosis of mild hemophilia B (defined as endogenous Factor IX less than 40 IU/dL [less than 40%], but greater than 5 IU/dL) (NHF, Srivastava 2020); **AND**
vi. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
vii. Individual has one of the following:
   A. One or more episodes of spontaneous bleeding into joint; **OR**
   B. One or more episodes severe, life-threatening, or spontaneous bleeding as determined by prescriber; **OR**
   C. Severe phenotype hemophilia determined by the individual's risk factors that increase the risk of a clinically significant bleed, including but not limited to, participation in activities likely to cause injury/trauma, procoagulant and anticoagulant protein levels, comorbid conditions affecting functional ability and physical coordination, or history of a clinically significant bleed.

B. Criteria For Continuation of Therapy

i. MMM considers continuation Alphanine SD therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when all of the following criteria is met:
   A. Individual has a diagnosis of hemophilia B; **AND**
   B. Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes).

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C. Authorization Duration

i. Initial Approval Duration: 1 year
ii. Reauthorization Approval Duration: 1 year

D. Conditions Not Covered

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

Alphanine SD may not be approved for the following:

i. Reversal of anticoagulation due to vitamin K antagonists or other anticoagulants; **OR**
ii. Treatment of individuals with hemophilia A with inhibitors to factor VIII; **OR**
iii. Replacement therapy of other clotting factors which include factors II, VII, and X; **OR**
iv. Treatment of hemorrhagic states caused by reduced production of liver-dependent coagulation factors, including hepatitis or cirrhosis; **OR**
v. Immune tolerance induction in patients with hemophilia B**; OR**
vi. When the above criteria are not met and for all other indications

Profilnine SD® (Human plasma-derived, Factor IX Complex)

A. Criteria for Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of hemophilia B (also called factor IX deficiency or Christmas disease); **AND**
ii. Individual is using for the treatment of bleeding episodes,
OR
iii. Individual has a diagnosis of moderate to severe hemophilia B (defined as 5 IU/dL or less endogenous Factor IX) (Rezende 2024); **AND**
iv. Individual is using as routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
OR
v. Individual has a diagnosis of mild hemophilia B (defined as endogenous Factor IX less than 40 IU/dL [less than 40%], but greater than 5 IU/dL) (NHF, Srivastava 2020); **AND**
vi. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
vii. Individual has one of the following:
    A. One or more episodes of spontaneous bleeding into joint; **OR**
    B. One or more episodes of severe, life-threatening, or spontaneous bleeding as determined by the prescriber; **OR**
    C. Severe phenotype hemophilia determined by the individual's risk factors that increase the risk of a clinically significant bleed, including but not limited to, participation in activities likely to cause injury/trauma, procoagulant and anticoagulant protein levels, comorbid

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conditions affecting functional ability and physical coordination, or history of a clinically significant bleed.

B. Criteria for Continuation of Therapy

i. MMM considers continuation Profilnine SD (Human plasma-derived, Factor IX Complex) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when all of the following criteria is met:
   A. Individual has a diagnosis of hemophilia B; **AND**
   B. Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes).

C. Authorization Duration

i. Initial Approval Duration: 1 year
ii. Reauthorization Approval Duration: 1 year

D. Conditions Not Covered

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

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

Benefix®, Ixinity®, Rixubis® (Recombinant Factor IX)

A. Criteria for Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of hemophilia B (also called factor IX deficiency or Christmas disease); **AND**
ii. Individual is using for one of the following:
   A. The treatment of bleeding episodes; **OR**
   B. Peri-procedural management for surgical, invasive or interventional radiology procedures;

OR

iii. Individual has a diagnosis of moderate to severe hemophilia B (defined as 5 IU/dL or less endogenous Factor IX) (Rezende 2024); AND
iv. Individual is using as routine prophylaxis to prevent or reduce the frequency of bleeding episodes;

OR

v. Individual has a diagnosis of mild hemophilia B (defined as endogenous Factor IX less than 40 IU/dL [less than 40%], but greater than or equal to 5 IU/dL) (NHF, Srivastava 2020); **AND**
vi. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**

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vii. Individual has one of the following:
   A. One or more episodes of spontaneous bleeding into joint; **OR**
   B. One or more episodes of severe, life-threatening, or spontaneous bleeding as determined by the prescriber; **OR**
   C. Severe phenotype hemophilia determined by the individual's risk factors that increase the risk of a clinically significant bleed, including but not limited to, participation in activities likely to cause injury/trauma, procoagulant and anticoagulant protein levels, comorbid conditions affecting functional ability and physical coordination, or history of a clinically significant bleed.

B. Criteria for Continuation of Therapy

MMM considers continuation Benefix, Ixinity, Rixubis (Recombinant Factor IX therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when all of the following criteria is met:

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

C. Authorization Duration

i. Initial Approval Duration: 1 year
ii. Reauthorization Approval Duration: 1 year

D. Conditions Not Covered

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

i. Treatment of other factor deficiencies (for example factors II, VII, VIII and X); **OR**
ii. Treatment of individuals with hemophilia A with inhibitors to factor VIII; **OR**
iii. To reverse coumarin-induced anticoagulation; **OR**
iv. Treatment of bleeding due to low levels of liver-dependent coagulation factors; **OR**
v. Using for the induction of immune tolerance in individuals with hemophilia B; **OR**
vi. When the above criteria are not met and for all other indications.

Idelvion® (Recombinant Long-Acting, Albumin Fusion Protein Coagulation Factor IX), Alprolix® (Recombinant, Fc Fusion Protein Coagulation Factor IX), or Rebinyn® (Recombinant, glycoPEGylated Coagulation Factor IX)

A. Criteria for Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of moderate to severe hemophilia B (also called factor IX deficiency or Christmas disease); **AND**

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ii. Individual has 5 IU/dL or less endogenous Factor IX (Rezende 2024); **AND**
iii. Individual is using for one of the following:
   A. The treatment of 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

iv. Individual has a diagnosis of mild to moderate hemophilia B; **AND**
v. Individual has endogenous Factor IX level less than 40 IU/dL (less than 40%) but greater than or equal to 1 IU/dL (NHF,Srivastava 2020); **AND**
vi. Individual is using for one of the following:
   A. Individual is using for the treatment of bleeding episodes; **OR**
   B. Individual is using for peri-procedural management for surgical, invasive or interventional radiology procedures; **OR**
   C. Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes for one of the following:
      1. Individual has had one or more episodes of spontaneous bleeding into joint; **OR**
      2. Individual has had one or more episodes of severe, life-threatening, or 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

i. MMM considers continuation Idelvion (Recombinant Long-Acting, Albumin Fusion Protein Coagulation Factor IX), Alprolix (Recombinant, Fc Fusion Protein Coagulation Factor IX), or Rebinyn (Recombinant, glycoPEGylated Coagulation Factor IX) necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when all of the following criteria is met:
   A. Individual has a diagnosis of hemophilia B; **AND**
   B. Individual has had a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes).

C. Authorization Duration

i. Initial Approval Duration: 1 year
ii. Reauthorization Approval Duration: 1 year

D. Conditions Not Covered

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

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i. Using for the induction of immune tolerance in individuals with hemophilia B; **OR**
ii. When the above criteria are not met and for all other indication.

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Limits or Restrictions:

A. Therapeutic Alternatives

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

i. N/A

B. Quantity Limitations

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

Dosing, frequency, duration of therapy, preparation, reconstitution, administration instructions, and dose adjustments vary by product and should be individualized based on the severity of Factor IX deficiency, location and extent of bleeding, clinical condition, age, weight, pharmacokinetic response, Factor IX activity levels, and clinical response.

For the most up-to-date FDA-approved prescribing information, refer to the DailyMed website at https://dailymed.nlm.nih.gov/dailymed/ or the respective product prescribing information/product website listed below.

Product Category	Product / Prescribing Information Source
Coagulation Factor IX, Human plasma-derived	• **AlphaNine® SD:** https://www.alphaninesd.com/en/product-information
Factor IX Complex, human plasma-derived	• **Profilnine® SD:** Refer to DailyMed or FDA-approved prescribing information.
Factor IX Recombinant	• **RIXUBIS®:** https://www.rixubis.com • **BeneFIX®:** https://www.benefix.com • **IXINITY®:** https://www.ixinity.com
Coagulation Factor IX, Long-Acting	• **IDELVION®:** https://www.idelvion.com • **ALPROLIX®:** https://www.alprolix.com • **REBINYN®:** https://www.rebinyn.com

Coverage of the requested dose and frequency is subject to FDA-approved prescribing information, accepted compendia, evidence-based clinical guidelines, and medical necessity review.

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Codes Information:

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.

Coagulation Factor IX, Human plasma-derived (Alphanine SD)

ICD-10 Diagnostic Codes:

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

HCPCS Codes:

Codes	Description
J7193	Factor IX (Anti-hemophilic factor, purified, non-recombinant) per IU [AlphaNine SD]

Factor IX Complex Human (Profilnine SD)

ICD-10 Diagnostic Codes:

ICD-10	Description
D67	Hereditary factor IX deficiency [hemophilia B]
Z29.89	Encounter for other specified prophylactic measures
Z79.899	Other long term (current) drug therapy [prophylactic]

HCPCS Codes:

HCPCS	Description
J7194	Factor IX complex, per IU [Profilnine SD]

Factor IX Recombinant (Benefix, Ixinity, Rixubis)

ICD-10 Diagnostic Codes:

ICD-10	Description
D67	Hereditary factor IX deficiency [hemophilia B]
Z29.89	Encounter for other specified prophylactic measures
Z79.899	Other long term (current) drug therapy [prophylactic]

HCPCS Codes:

HCPCS	Description
J7200	Injection, factor IX, (Anti-hemophilic factor, recombinant), Rixubis, per IU
J7195	Injection, factor IX (Anti-hemophilic factor, recombinant) per IU, not otherwise specified [Benefix, Ixinity]

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J7213	Injection, coagulation factor ix (recombinant) [Ixinity], 1 IU

Coagulation Factor IX—Long Acting Recombinant, Albumin Fusion Protein (Idelvion); Recombinant Coagulation Factor IX, Fc Fusion Protein (Alprolix); Recombinant Coagulation Factor IX, GlycoPEGylated (Rebinyn)

ICD-10 Diagnostic Codes:

ICD-10	Description
D67	Hereditary factor IX deficiency [hemophilia B]
Z29.89	Encounter for other specified prophylactic measures
Z79.899	Other long term (current) drug therapy [prophylactic]

HCPCS Codes:

HCPCS	Description
J7201	Injection, factor IX, Fc fusion protein (recombinant), Alprolix, 1 IU
J7202	Injection, factor IX, albumin fusion protein, (recombinant), Idelvion, 1 IU
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1IU

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11. Wyeth Pharmaceuticals LLC / Pfizer. BeneFIX® [Coagulation Factor IX (Recombinant)] prescribing information. Accessed April 28, 2026.
12. Medexus Pharma, Inc. IXINITY® [Coagulation Factor IX (Recombinant)] prescribing information. U.S. Food and Drug Administration. Accessed April 28, 2026.
13. CSL Behring. IDELVION® [Coagulation Factor IX (Recombinant), Albumin Fusion Protein] prescribing information. U.S. Food and Drug Administration. Accessed April 28, 2026.
14. Bioverativ Therapeutics Inc. / Sanofi. ALPROLIX® [Coagulation Factor IX (Recombinant), Fc Fusion Protein] prescribing information. U.S. Food and Drug Administration. Accessed April 28, 2026. Accessed April 28, 2026.
15. Novo Nordisk Inc. REBINYN® [Coagulation Factor IX (Recombinant), GlycoPEGylated] prescribing information. Accessed April 28, 2026.
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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.

Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Removed Qfitlia™ (fitusiran) clinical criteria from this policy and added a cross-reference note indicating that requests for Qfitlia are reviewed under the Select Clotting Agents medical policy. Added FDA-approved indications per drug/product category. Updated Conditions Not Covered language to align with current prescribing information, including exclusions related to anticoagulation reversal, treatment of other clotting factor deficiencies, hemophilia A with Factor VIII inhibitors, liver-dependent coagulation factor deficiencies, and immune tolerance induction, as applicable. Updated Quantity Limitations section to clarify that dosing, frequency, duration, preparation, administration, and dose adjustments vary by product and should be based on current FDA-approved prescribing information, DailyMed, respective product websites, accepted compendia, evidence-based guidelines, and medical necessity review. Coding reviewed: Removed ICD-10-CM D68.311 from AlphaNine SD, BeneFIX, IXINITY, RIXUBIS, IDELVION, ALPROLIX, and REBINYN. Removed ICD-10-CM Z29.8 and replaced with Z29.89 for AlphaNine SD, Profilnine SD, BeneFIX, IXINITY, RIXUBIS, IDELVION, ALPROLIX, and REBINYN. Wording and formatting changes. Administrative update to incorporate new template.	6/19/2026	7/1/2026
Focus Review	Addition of Qfitlia clinical authorization criteria.	7/21/2025	8/8/2025
Annual Review	Added Duration of Therapy and Quantity Limits section; Wording, and formatting changes; Coding Reviewed: No changes.	2/18/2025	3/6/2025
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023