



# Hemophilia Factor IX Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
11-01-2025

**Date of Origin**

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3500 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Benefix ; Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj ; coagulation factor ix (recombinant) for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Alphanine sd	coagulation factor ix for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y	N		
Profilnine	factor ix complex for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	M ; N ; O ; Y	N		

## POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Benefix ; Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj ; coagulation factor ix (recombinant) for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000	1	mL	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
		UNIT ; 500 UNIT							

### ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
851000284021	Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000283521	Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3500 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000284521	Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			

### CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Alphanine sd	coagulation factor ix for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Benefix ; Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj ; coagulation factor ix (recombinant) for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3500 UNIT ; 500 UNIT	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Profilnine	factor ix complex for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

### CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Alphanine sd	coagulation factor ix for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Benefix ; Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj ; coagulation factor ix (recombinant) for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3500 UNIT ; 500 UNIT	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Profilnine	factor ix complex for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

**PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL**

Module	Clinical Criteria for Approval						
	<table border="1" data-bbox="235 220 950 499"> <thead> <tr> <th data-bbox="235 220 592 258">Preferred Agents</th> <th data-bbox="592 220 950 258">Non-Preferred Agents</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 258 592 499">           AlphaNine SD            Alprolix            BeneFIX            Idelvion            Ixinity            Profilnine            Rebinyn            Rixubis         </td> <td data-bbox="592 258 950 499"></td> </tr> </tbody> </table> <p data-bbox="256 535 488 569"><b>Initial Evaluation</b></p> <p data-bbox="256 604 1105 638"><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol data-bbox="280 674 1357 735" style="list-style-type: none"> <li>ONE of the following:       <ol style="list-style-type: none"> <li>The requested agent is eligible for continuation of therapy AND the following:</li> </ol> </li> </ol> <table border="1" data-bbox="235 772 950 846"> <thead> <tr> <th data-bbox="235 772 950 810">Agents Eligible for Continuation of Therapy</th> </tr> </thead> <tbody> <tr> <td data-bbox="235 810 950 846">All target agents are eligible for continuation of therapy</td> </tr> </tbody> </table> <ol data-bbox="354 888 1417 1942" style="list-style-type: none"> <li>The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed <b>OR</b></li> <li><b>BOTH</b> of the following:       <ol style="list-style-type: none"> <li>The patient has a diagnosis of hemophilia B (also known as Factor IX deficiency, Christmas disease) AND ONE of the following:           <ol style="list-style-type: none"> <li>The patient is currently experiencing a bleed AND BOTH of the following:               <ol style="list-style-type: none"> <li>The patient is out of medication <b>AND</b></li> <li>The patient needs to receive a ONE TIME emergency supply of medication <b>OR</b></li> </ol> </li> <li><b>BOTH</b> of the following:               <ol style="list-style-type: none"> <li>The requested agent is being used for ONE of the following:                   <ol style="list-style-type: none"> <li>Prophylaxis <b>OR</b></li> <li>On-demand use for bleeds <b>OR</b></li> <li>Peri-operative management of bleeding <b>AND</b></li> </ol> </li> <li>ONE of the following:                   <ol style="list-style-type: none"> <li>The requested agent is a preferred agent <b>OR</b></li> <li>The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member <b>OR</b></li> <li>The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] <b>OR</b></li> <li>The patient has tried and had an inadequate response to ALL of the preferred agents [chart notes are required] <b>OR</b></li> <li>ALL of the preferred agents were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] <b>OR</b></li> <li>The patient has an intolerance or hypersensitivity to ALL of the preferred agents [chart notes are required] <b>OR</b></li> </ol> </li> </ol> </li> </ol> </li> </ol> </li> </ol>	Preferred Agents	Non-Preferred Agents	AlphaNine SD Alprolix BeneFIX Idelvion Ixinity Profilnine Rebinyn Rixubis		Agents Eligible for Continuation of Therapy	All target agents are eligible for continuation of therapy
Preferred Agents	Non-Preferred Agents						
AlphaNine SD Alprolix BeneFIX Idelvion Ixinity Profilnine Rebinyn Rixubis							
Agents Eligible for Continuation of Therapy							
All target agents are eligible for continuation of therapy							

Module	Clinical Criteria for Approval
	<p>G. The patient has an FDA labeled contraindication to ALL of the preferred agents [chart notes are required] <b>OR</b></p> <p>H. ALL of the preferred agents are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; <b>OR</b> cause a significant barrier to the patient’s adherence of care; <b>OR</b> worsen a comorbid condition; <b>OR</b> decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities; <b>OR</b> cause an adverse reaction or cause physical or mental harm [chart notes are required] <b>OR</b></p> <p>I. ALL of the preferred agents are not in the best interest of the patient based on medical necessity [chart notes are required] <b>OR</b></p> <p>J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ALL of the preferred agents and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] <b>AND</b></p> <p>2. If the patient has an FDA labeled indication, then ONE of the following:</p> <p>A. The patient’s age is within FDA labeling for the requested indication for the requested agent <b>OR</b></p> <p>B. There is support for using the requested agent for the patient’s age for the requested indication <b>AND</b></p> <p>2. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., prescriber working in a hemophilia treatment center [HTC], hematologist with hemophilia experience) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis <b>AND</b></p> <p>3. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></p> <p>4. The prescriber must provide the actual prescribed dose with ALL of the following:</p> <p>A. Patient’s weight <b>AND</b></p> <p>B. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) <b>AND</b></p> <p>C. Inhibitor status <b>AND</b></p> <p>D. Intended use/regimen: prophylaxis, on-demand, peri-operative <b>AND</b></p> <p>5. ONE of the following:</p> <p>A. The patient will NOT be using the requested agent in combination with another Factor IX agent included in this program <b>OR</b></p> <p>B. There is support for the use of more than one unique Factor IX agent (medical records required)</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>BCBSIL, BCBSMT, and BCBSTX: 12 months</p> <p>BCBSNM:</p> <p>One time emergency use: 3 months</p>

Module	Clinical Criteria for Approval
	<p>Peri-operative dosing: 3 months</p> <p>On-demand: 3 months</p> <p>Prophylaxis: up to 12 months, minimum of 3 months</p> <p>ALL other plans:</p> <p>One time emergency use: up to 2 weeks</p> <p>Peri-operative dosing: 1 time per request</p> <p>On-demand: up to 3 months</p> <p>Prophylaxis: up to 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p><b>The requested agent will also be approved when ONE of the following is met:</b></p> <ol style="list-style-type: none"> <li>1. The request is for a BCBS MT Fully Insured or MT HIM member <b>AND</b> <ol style="list-style-type: none"> <li>A. The patient is under the age of 18 years old <b>AND</b></li> <li>B. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <b>AND</b></li> <li>D. There is support for an age in the patient's given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <b>OR</b></li> </ol> </li> <li>2. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> <li>A. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>B. The requested indication is a rare disease <b>AND</b></li> <li>C. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> </ol> </li> </ol> </li> <li>3. ALL of the following: <ol style="list-style-type: none"> <li>A. The member resides in Ohio <b>AND</b></li> <li>B. The plan is Fully Insured or HIM Shop (SG) <b>AND</b></li> <li>C. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>D. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> </ol> </li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<p data-bbox="469 180 1398 384">3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</p> <p data-bbox="232 422 1393 478"><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p data-bbox="232 516 1377 600"><b>Oncology compendia allowed:</b> NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p data-bbox="232 638 496 667"><b>Length of Approval:</b></p> <p data-bbox="232 707 480 737">BCBSOK: 36 months</p> <p data-bbox="232 774 566 804">ALL other plans: 12 months</p> <p data-bbox="232 842 1073 871">NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p data-bbox="248 972 513 1001"><b>Renewal Evaluation</b></p> <p data-bbox="248 1039 1094 1068"><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol data-bbox="280 1106 1403 1942" style="list-style-type: none"> <li data-bbox="280 1106 1386 1247">1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (if the current request is for a ONE TIME emergency use or the patient ONLY has previous approvals for emergency use, must use Initial Evaluation) (Note: patients not previously approved for the requested agent will require initial evaluation review) <b>AND</b></li> <li data-bbox="280 1251 1377 1360">2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., prescriber working in a hemophilia treatment center [HTC], hematologist with hemophilia experience) or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> <li data-bbox="280 1365 1354 1421">3. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li data-bbox="280 1425 1403 1625">4. The prescriber must provide the actual prescribed dose with ALL of the following: <ol data-bbox="354 1453 1403 1625" style="list-style-type: none"> <li data-bbox="354 1453 683 1482">A. Patient's weight <b>AND</b></li> <li data-bbox="354 1486 1403 1570">B. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) <b>AND</b></li> <li data-bbox="354 1575 675 1604">C. Inhibitor status <b>AND</b></li> <li data-bbox="354 1608 1341 1638">D. Intended use/regimen: (e.g., prophylaxis, on-demand, peri-operative) <b>AND</b></li> </ol> </li> <li data-bbox="280 1629 1370 1797">5. ONE of the following: <ol data-bbox="354 1661 1370 1797" style="list-style-type: none"> <li data-bbox="354 1661 1370 1745">A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand <b>OR</b></li> <li data-bbox="354 1749 1370 1797">B. There is support for the patient having more than 5 on-demand doses on hand <b>AND</b></li> </ol> </li> <li data-bbox="280 1801 1370 1942">6. ONE of the following: <ol data-bbox="354 1833 1370 1942" style="list-style-type: none"> <li data-bbox="354 1833 1370 1887">A. The patient will NOT be using the requested agent in combination with another Factor IX agent included in this program <b>OR</b></li> <li data-bbox="354 1892 1370 1942">B. There is support for the use of more than one unique Factor IX agent (medical records required)</li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>BCBSIL, BCBSMT, and BCBSTX: 12 months</p> <p>BCBSNM:</p> <p style="padding-left: 40px;">Peri-operative dosing: 3 months</p> <p style="padding-left: 40px;">On-demand: 3 months</p> <p style="padding-left: 40px;">Prophylaxis: up to 12 months, minimum of 3 months</p> <p>ALL other plans:</p> <p style="padding-left: 40px;">Peri-operative dosing: 1 time per request</p> <p style="padding-left: 40px;">On-demand: up to 3 months</p> <p style="padding-left: 40px;">Prophylaxis: up to 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

## QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Quantity Limit for the requested agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: <ol style="list-style-type: none"> <li>A. The requested quantity (dose) is within the FDA labeled dosing <b>AND</b></li> <li>B. The requested quantity (number of doses) is appropriate based on intended use (e.g., prophylaxis, on-demand, peri-operative) <b>OR</b></li> </ol> </li> <li>2. There is support for exceeding the program quantity limit (dose and number of doses) (medical records required)</li> </ol> <p><b>Length of Approval:</b></p> <p>BCBSIL: 12 months</p> <p>ALL other plans:</p> <ul style="list-style-type: none"> <li>• For initial one-time emergency use: up to 2 weeks</li> <li>• Prophylaxis: up to 12 months</li> <li>• Both initial and renewal Peri-operative dosing: 1 time per request</li> <li>• Both initial and renewal On-demand: up to 3 months</li> </ul>