



Coagulation Factor VIIa 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
Sevenfact	coagulation factor viia (recom)-jncw for inj	1 MG ; 2 MG ; 5 MG	M ; N ; O ; Y	N		
Novoseven rt	coagulation factor viia (recomb) for inj	1 MG ; 2 MG ; 5 MG ; 8 MG	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
Sevenfact	coagulation factor viia (recom)-jncw for inj	1 MG ; 2 MG ; 5 MG	1	mL	30	DAYS	Dependent on patient weight and number of doses		

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
8510002620	Novoseven rt	coagulation factor viia (recomb) for inj	1 MG ; 2 MG ; 5 MG ; 8 MG	Dependent on patient weight and number of doses			
8510002640	Sevenfact	coagulation factor viia (recom)-jncw for inj	1 MG ; 2 MG ; 5 MG	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
Novoseven rt	coagulation factor viia (recomb) for inj	1 MG ; 2 MG ; 5 MG ; 8 MG	IL HMO Performance Annual ; Balanced ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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
Sevenfact	coagulation factor viia (recom)-jncw for inj	1 MG ; 2 MG ; 5 MG	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
Novoseven rt	coagulation factor viia (recomb) for inj	1 MG ; 2 MG ; 5 MG ; 8 MG	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 ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Sevenfact	coagulation factor viia (recom)-jncw for inj	1 MG ; 2 MG ; 5 MG	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		
NovoSeven RT	<p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The requested agent is eligible for continuation of therapy AND the following: <table border="1" data-bbox="235 1270 950 1348"> <tr> <td>Agents Eligible for Continuation of Therapy</td> </tr> <tr> <td>All target agents are eligible for continuation of therapy</td> </tr> </table> 1. 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 OR B. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of hemophilia A AND BOTH of the following: <ol style="list-style-type: none"> 1. The patient has inhibitors to Factor VIII AND 2. The requested agent is being used for ONE of the following: <ol style="list-style-type: none"> A. On-demand use for bleeds AND ONE of the following: <ol style="list-style-type: none"> 1. 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 OR 2. There is support for the patient having more than 5 on-demand doses on hand OR 	Agents Eligible for Continuation of Therapy	All target agents are eligible for continuation of therapy
Agents Eligible for Continuation of Therapy			
All target agents are eligible for continuation of therapy			

Module	Clinical Criteria for Approval
	<ul style="list-style-type: none"> B. Prophylaxis AND BOTH of the following: <ul style="list-style-type: none"> 1. ONE of the following: <ul style="list-style-type: none"> A. The patient has tried and had an inadequate response to Immune Tolerance Induction (ITI) (Immune Tolerance Therapy [ITT]) OR B. The patient has an inhibitor level greater than or equal to 200 BU (lab records required) OR C. The patient is not a candidate for ITI AND 2. The patient will NOT be using the requested agent in combination with Hemlibra OR C. Peri-operative management of bleeding OR D. As a component of Immune Tolerance Induction (ITI)/Immune Tolerance Therapy (ITT) AND ONE of the following: <ul style="list-style-type: none"> 1. The patient has NOT had more than 33 months of ITT/ITI therapy OR 2. There is support for the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical records required) OR <p>B. The patient has a diagnosis of hemophilia B AND BOTH of the following:</p> <ul style="list-style-type: none"> 1. The patient has inhibitors to Factor IX AND 2. The requested agent is being used for ONE of the following: <ul style="list-style-type: none"> A. On-demand use for bleeds AND ONE of the following: <ul style="list-style-type: none"> 1. 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 OR 2. There is support for the patient having more than 5 on-demand doses on hand OR B. Prophylaxis AND ONE of the following: <ul style="list-style-type: none"> 1. The patient has tried and had an inadequate response to Immune Tolerance Induction (ITI) (Immune Tolerance Therapy [ITT]) OR 2. The patient has an inhibitor level greater than or equal to 200 BU (lab records required) OR 3. The patient is not a candidate for ITI AND C. Peri-operative management of bleeding OR D. As a component of Immune Tolerance Induction (ITI)/Immune Tolerance Therapy (ITT) AND ONE of the following: <ul style="list-style-type: none"> 1. The patient has NOT had more than 33 months of ITT/ITI therapy OR 2. There is support for the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months

Module	Clinical Criteria for Approval
	<p style="text-align: right;">and needs further treatment to eradicate inhibitors) (medical records required) OR</p> <p>C. The patient has a diagnosis of congenital Factor VII deficiency AND the requested agent will be used for ONE of the following:</p> <ol style="list-style-type: none"> 1. On-demand use for bleeds AND ONE of the following: <ol style="list-style-type: none"> 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 OR B. There is support for the patient having more than 5 on-demand doses on hand OR 2. Prophylaxis OR 3. Perioperative use OR <p>D. The patient has a diagnosis of Glanzmann's thrombasthenia AND BOTH of the following:</p> <ol style="list-style-type: none"> 1. The patient is refractory to platelet transfusions AND 2. The requested agent will be used for ONE of the following: <ol style="list-style-type: none"> A. On-demand use for bleeds AND ONE of the following: <ol style="list-style-type: none"> 1. 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 OR 2. There is support for the patient having more than 5 on-demand doses on hand OR B. Perioperative use OR <p>E. The patient has a diagnosis of acquired hemophilia AND the requested agent will be used for ONE of the following:</p> <ol style="list-style-type: none"> 1. On-demand use for bleeds AND ONE of the following: <ol style="list-style-type: none"> 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 OR B. There is support for the patient having more than 5 on-demand doses on hand OR 2. Perioperative use OR <p>F. The patient has another FDA approved indication for the requested agent and route of administration AND</p> <ol style="list-style-type: none"> 2. If the patient has an FDA approved indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication OR <p>C. The patient has another indication that is supported in compendia for the requested agent and route of administration AND</p> <ol style="list-style-type: none"> 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 AND 3. The patient will NOT be using the requested agent in combination with another Factor VIIa agent AND 4. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Compendia Allowed: AHFS, or DrugDex 1, 2a, or 2b level of evidence</p>

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	<p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>BCBSIL, BCBSMT, and BCBSTX: 12 months</p> <p>BCBSNM: Prophylaxis: 12 months ALL other indications: 3 months</p> <p>ALL other plans: Peri-operative dosing: 1 time per request, On-demand: up to 3 months, Prophylaxis: up to 12 months, ITT/ITI: up to 6 months (or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest), all other indications: 3 months</p> <p>NOTE: If Quantity Limit applies, please see Quantity Limit criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS MT Fully Insured or MT HIM member AND <ol style="list-style-type: none"> A. The patient is under the age of 18 years old AND B. The patient does NOT have any FDA labeled contraindications to the requested agent AND 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] AND 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] OR 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"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 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

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	<p>blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</p> <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: 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>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>		
Sevenfact	<p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The requested agent is eligible for continuation of therapy AND the following: <table border="1" data-bbox="235 905 950 982"> <tr> <td>Agents Eligible for Continuation of Therapy</td> </tr> <tr> <td>All target agents are eligible for continuation of therapy</td> </tr> </table> B. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of hemophilia A AND BOTH of the following: <ol style="list-style-type: none"> 1. The patient has inhibitors to Factor VIII AND 2. The requested agent is being used for on-demand use for bleeds OR B. The patient has a diagnosis of hemophilia B AND BOTH of the following: <ol style="list-style-type: none"> 1. The patient has inhibitors to Factor IX AND 2. The requested agent is being used for on-demand use for bleeds OR C. The patient has another FDA approved indication for the requested agent and route of administration AND 2. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication AND 2. 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 OR 3. 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 AND 4. The patient will NOT be using the requested agent in combination with another Factor VIIa agent AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent AND 6. ONE of the following:	Agents Eligible for Continuation of Therapy	All target agents are eligible for continuation of therapy
Agents Eligible for Continuation of Therapy			
All target agents are eligible for continuation of therapy			

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	<p>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 OR</p> <p>B. There is support for the patient having more than 5 on-demand doses on hand</p> <p>Length of Approval:</p> <ul style="list-style-type: none"> • BCBSOK: 36 months • BCBSIL, BCBSMT, and BCBSTX: 12 months • BCBSNM: at least 3 months • ALL other plans: up to 3 months <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS MT Fully Insured or MT HIM member AND <ol style="list-style-type: none"> A. The patient is under the age of 18 years old AND B. The patient does NOT have any FDA labeled contraindications to the requested agent AND 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] AND 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] OR 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"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 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

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	<p>blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</p> <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: 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>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 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
NovoSeven RT	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: <ol style="list-style-type: none"> A. The requested dose is within the FDA labeled dosing AND B. The requested quantity (number of doses) is appropriate based on intended use (e.g., on-demand, prophylaxis, perioperative) OR 2. There is support for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required) <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>ALL other plans: Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest up to 3 months for all other diagnoses</p>
Sevenfact	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: <ol style="list-style-type: none"> A. The requested dose is within the FDA labeled dosing AND B. The requested quantity (number of doses) is appropriate based on intended use (e.g., on-demand) OR 2. There is support for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required) <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>ALL other plans: up to 3 months</p>