



Qfitlia Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
02-01-2026

Date of Origin
05-15-2025

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Qfitlia	fitusiran sodium subcutaneous soln	20 MG/0.2ML	M ; N ; O ; Y	N		
Qfitlia	fitusiran sodium subcutaneous soln auto-inj	50 MG/0.5ML	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
Qfitlia	fitusiran sodium subcutaneous soln	20 MG/0.2 ML	1	Vial	28				
Qfitlia	fitusiran sodium subcutaneous soln auto-inj	50 MG/0.5 ML	1	Pen	28				

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Qfitlia	fitusiran sodium subcutaneous soln	20 MG/0.2ML	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 HMO Performance Quarterly ; 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
Qfitlia	fitusiran sodium subcutaneous soln auto-inj	50 MG/0.5ML	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 HMO Performance Quarterly ; 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
Qfitlia	fitusiran sodium subcutaneous soln	20 MG/0.2ML	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 HMO Performance Quarterly ; 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
Qfitlia	fitusiran sodium subcutaneous soln auto-inj	50 MG/0.5ML	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 HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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		
	<p>Initial Evaluation</p> <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" style="margin-left: 40px;"> <thead> <tr> <th>Agents Eligible for Continuation of Therapy</th> </tr> </thead> <tbody> <tr> <td>Qfitlia</td> </tr> </tbody> </table> B. ALL 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 (factor VIII deficiency) AND ALL of the following: <ol style="list-style-type: none"> 1. The patient has diagnosis of congenital factor VIII deficiency confirmed by blood coagulation testing AND 2. The requested agent will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes AND 3. The requested agent will be used for ONE of the following: <ol style="list-style-type: none"> A. Primary prophylaxis in patients with severe factor VIII deficiency (factor VIII level of less than 1%) OR B. Secondary prophylaxis in patients with at least TWO episodes of spontaneous bleeding into joints AND 4. ONE of the following: <ol style="list-style-type: none"> A. The patient has factor VIII inhibitors AND BOTH of the following: <ol style="list-style-type: none"> 1. Previous prophylaxis therapy AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient has tried and had an inadequate response to Immune Tolerance Induction (ITI) OR B. The patient has an inhibitor level greater than or equal to 200 BU (medical records required) OR C. There is support for why the patient is NOT a candidate for ITI OR 	Agents Eligible for Continuation of Therapy	Qfitlia
Agents Eligible for Continuation of Therapy			
Qfitlia			

Module	Clinical Criteria for Approval
	<p data-bbox="760 184 1386 237">B. The patient does NOT have factor VIII inhibitors AND ONE of the following:</p> <ol data-bbox="854 243 1417 1858" style="list-style-type: none"> <li data-bbox="854 243 1417 352">1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR <li data-bbox="854 359 1417 468">2. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR <li data-bbox="854 474 1417 615">3. The patient has tried and had an inadequate response to TWO prerequisite agents (i.e. Hemlibra AND an antihemophilic factor VIII agent) [chart notes required] OR <li data-bbox="854 621 1417 789">4. TWO prerequisite agents (i.e. Hemlibra AND an antihemophilic factor VIII agent) were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR <li data-bbox="854 795 1417 936">5. The patient has an intolerance or hypersensitivity to TWO prerequisite agents (i.e. Hemlibra AND an antihemophilic factor VIII agent) [chart notes required] OR <li data-bbox="854 942 1417 1052">6. The patient has an FDA labeled contraindication to BOTH Hemlibra AND ALL antihemophilic factor VIII agents [chart notes required] OR <li data-bbox="854 1058 1417 1455">7. TWO prerequisite agents (i.e. Hemlibra AND an antihemophilic factor VIII agent) are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR <li data-bbox="854 1461 1417 1602">8. TWO prerequisite agents (i.e. Hemlibra AND an antihemophilic factor VIII agent) are not in the best interest of the patient based on medical necessity [chart notes required] OR <li data-bbox="854 1608 1417 1858">9. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as TWO prerequisite agents (i.e. Hemlibra AND an antihemophilic factor VIII agent) and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND <p data-bbox="570 1864 1235 1917">B. The patient has a diagnosis of Hemophilia B (factor IX deficiency) AND ALL of the following:</p> <ol data-bbox="646 1923 1417 1976" style="list-style-type: none"> <li data-bbox="646 1923 1417 1976">1. The patient has diagnosis of congenital factor IX deficiency confirmed by blood coagulation testing AND

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	<ol style="list-style-type: none"> 2. The requested agent will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes AND 3. The requested agent will be used for ONE of the following: <ol style="list-style-type: none"> A. Primary prophylaxis in patients with severe factor IX deficiency (factor IX level \leq 2%) OR B. Secondary prophylaxis in patients with at least TWO episodes of spontaneous bleeding into joints AND 4. ONE of the following: <ol style="list-style-type: none"> A. The patient has factor IX inhibitors AND BOTH of the following: <ol style="list-style-type: none"> 1. Previous prophylaxis therapy AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient has tried and had an inadequate response to Immune Tolerance Induction (ITI) OR B. The patient has an inhibitor level greater than or equal to 200 BU (medical records required) OR C. There is support for why the patient is NOT a candidate for ITI OR B. The patient does NOT have factor IX inhibitors AND ONE of the following: <ol style="list-style-type: none"> 1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR 2. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR 3. The patient has tried and had an inadequate response to an antihemophilic Factor IX agent [chart notes required] OR 4. ONE antihemophilic Factor IX agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 5. The patient has an intolerance or hypersensitivity to an antihemophilic Factor IX agent [chart notes required] OR 6. The patient has an FDA labeled contraindication to ALL antihemophilic Factor IX agents [chart notes required] OR 7. ONE antihemophilic Factor IX agent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR 8. ONE antihemophilic Factor IX agent is not in the best interest of the patient based

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	<p>on medical necessity [chart notes required] OR</p> <p>9. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE antihemophilic Factor IX agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND</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 OR</p> <p>B. There is support for using the requested agent for the patient's age for the requested indication AND</p> <p>3. The patient does NOT have a co-existing thrombophilic disorder or a history of, or risk factors predisposing to, thrombosis AND</p> <p>4. The requested agent will NOT be used for the treatment of breakthrough bleeding AND</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, hematologist with hemophilia experience), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>3. The requested agent will NOT be used in combination with immune tolerance induction with clotting factor products (i.e., factor VIII or factor IX concentrates) as prophylactic therapy, hemophilia bypassing agent prophylaxis (i.e., factor VIIa or anti-inhibitor coagulant complex), or emicizumab for hemophilia A with inhibitors (Note: Factor VIII or factor IX products can be administered for the treatment of breakthrough bleeds when occurring more than 7 days after initiation of QFITLIA) AND</p> <p>4. The patient has an antithrombin (AT) activity level of $\geq 60\%$ at baseline (e.g., prior to therapy with the requested agent) and AT-activity will be monitored regularly as outlined in the FDA labeling AND</p> <p>5. The patient does NOT have hepatic impairment (Child-Pugh Class A, B, and C)</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>BCBSIL, BCBSMT, and BCBSTX: 12 months</p> <p>ALL other plans: 6 months</p> <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> <p>1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following:</p> <p>A. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>B. The requested indication is a rare disease AND</p> <p>C. ONE of the following:</p> <p>1. The patient has another FDA labeled indication for the requested agent and route of administration OR</p> <p>2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR</p> <p>2. ALL of the following:</p> <p>A. The member resides in Ohio AND</p> <p>B. The plan is Fully Insured or HIM Shop (SG) AND</p>

Module	Clinical Criteria for Approval
	<p>C. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>D. ONE of the following:</p> <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 blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <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> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient has had improvement or stabilization with the requested agent as indicated by the number of breakthrough bleeding episodes (medical records required) OR B. There is support for the continued use of the requested agent (medical records required) AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., prescriber working in a hemophilia treatment center, hematologist with hemophilia experience), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. The requested agent will NOT be used in combination with immune tolerance induction with clotting factor products (i.e., factor VIII or factor IX concentrates) as prophylactic therapy, hemophilia bypassing agent prophylaxis (i.e., factor VIIa or anti-inhibitor coagulant complex), or Efficizumab for hemophilia A with inhibitors (Note: Factor VIII or factor IX products can be administered for the treatment of breakthrough bleeds when occurring more than 7 days after initiation of QFITLIA) <p>Length of Approval:</p>

Module	Clinical Criteria for Approval
	BCBSOK: 36 months ALL other plans: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<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 OR 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR C. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication <p>Length of Approval:</p> <p>INITIAL</p> <ul style="list-style-type: none"> • BCBSIL: 12 months • ALL other plans: 6 months <p>RENEWAL: 12 months</p>