



# Rivfloza Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
11-01-2025

**Date of Origin**  
11-09-2023

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Rivfloza	nedosiran sodium subcutaneous soln	80 MG/0.5ML	M ; N ; O ; Y	N		
Rivfloza	nedosiran sodium subcutaneous soln pref syr	128 MG/0.8ML	M ; N ; O ; Y	N		
Rivfloza	nedosiran sodium subcutaneous soln pref syr	160 MG/ML	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
Rivfloza	nedosiran sodium subcutaneous soln	80 MG/0.5 ML	2	Vials	30	DAYS			
Rivfloza	nedosiran sodium subcutaneous soln pref syr	128 MG/0.8 ML	1	Syringe	30	DAYS			
Rivfloza	nedosiran sodium subcutaneous soln pref syr	160 MG/ML	1	Syringe	30	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Rivfloza	nedosiran sodium subcutaneous soln	80 MG/0.5ML	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
Rivfloza	nedosiran sodium subcutaneous soln pref syr	128 MG/0.8ML	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
Rivfloza	nedosiran sodium subcutaneous soln pref syr	160 MG/ML	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
Rivfloza	nedosiran sodium subcutaneous soln	80 MG/0.5ML	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

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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
Rivfloza	nedosiran sodium subcutaneous soln pref syr	160 MG/ML	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
Rivfloza	nedosiran sodium subcutaneous soln pref syr	128 MG/0.8ML	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
	<p><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>The patient has a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by ONE of the following:</li> </ol>

Module	Clinical Criteria for Approval
	<ul style="list-style-type: none"> <li>A. Genetic testing of the <i>AGXT</i> gene indicates a pathogenic mutation <b>OR</b></li> <li>B. Liver biopsy demonstrates absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity <b>AND</b></li> </ul> <p>2. The requested agent will be used to lower urinary oxalate levels <b>AND</b></p> <p>3. The patient has an estimated GFR (eGFR) greater than or equal to 30 mL/min/1.73<sup>2</sup> <b>AND</b></p> <p>4. If the patient has an FDA labeled indication, then ONE of the following:</p> <ul style="list-style-type: none"> <li>A. The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></li> <li>B. There is support for using the requested agent for the patient's age for the requested indication <b>AND</b></li> </ul> <p>5. ONE of the following:</p> <ul style="list-style-type: none"> <li>A. The patient does NOT have hypocitraturia, elevated urinary supersaturation of calcium oxalate, or increasing stone burden <b>OR</b></li> <li>B. The patient has tried and had an inadequate response to potassium citrate or sodium citrate <b>OR</b></li> <li>C. The patient has an intolerance or hypersensitivity to potassium citrate or sodium citrate therapy <b>OR</b></li> <li>D. The patient has an FDA labeled contraindication to BOTH potassium citrate AND sodium citrate <b>AND</b></li> </ul> <p>6. ONE of the following:</p> <ul style="list-style-type: none"> <li>A. The patient has an <i>AGXT</i> mutation known to be unresponsive to therapy with pyridoxine (vitamin B6) <b>OR</b></li> <li>B. The patient has tried and had an inadequate response to pyridoxine (vitamin B6) for at least 3 months <b>AND</b> ONE of the following: <ul style="list-style-type: none"> <li>1. The patient is unresponsive to pyridoxine (vitamin B6) (unresponsive defined as less than or equal to 30% decrease in urine oxalate after 3 months of treatment with maximally tolerated pyridoxine) <b>OR</b></li> <li>2. The patient is responsive to pyridoxine (vitamin B6) (responsive defined as greater than 30% decrease in urine oxalate after 3 months of treatment with maximally tolerated pyridoxine) <b>AND</b> will continue treatment with pyridoxine (vitamin B6) in combination with the requested agent <b>OR</b></li> </ul> </li> <li>C. The patient has an intolerance or hypersensitivity to pyridoxine (vitamin B6) therapy <b>OR</b></li> <li>D. The patient has an FDA labeled contraindication to pyridoxine (vitamin B6) <b>AND</b></li> </ul> <p>7. The patient has NOT received a liver transplant <b>AND</b></p> <p>8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, geneticist, nephrologist, urologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></p> <p>9. The patient will NOT be using the requested agent in combination with another urinary oxalate reducing agent (e.g., lumasiran) <b>AND</b></p> <p>10. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSMT: 12 months</p> <p>ALL other plans: 6 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> <ul style="list-style-type: none"> <li>1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following:</li> </ul>

Module	Clinical Criteria for Approval
	<p>A. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></p> <p>B. The requested indication is a rare disease <b>AND</b></p> <p>C. ONE of the following:</p> <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> <p>2. ALL of the following:</p> <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> <li>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]</li> </ol> </li> </ol> <p><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p><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><b>Length of Approval:</b></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><b>Renewal Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>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] <b>AND</b></li> <li>2. The patient has had clinical benefit with the requested agent (e.g., decrease in urinary oxalate levels) <b>AND</b></li> <li>3. The patient has an estimated GFR (eGFR) greater than or equal to 30 mL/min/1.73<sup>2</sup> <b>AND</b></li> <li>4. ONE of the following: <ol style="list-style-type: none"> <li>A. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has an AGXT mutation known to be unresponsive to therapy with pyridoxine (vitamin B6) <b>OR</b></li> </ol> </li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> <li>2. The patient will continue treatment with pyridoxine (vitamin B6) in combination with the requested agent <b>OR</b></li> <li>3. The patient was unresponsive to pyridoxine (vitamin B6) (unresponsive defined as less than or equal to 30% decrease in urine oxalate after 3 months of treatment with maximally tolerated pyridoxine) <b>OR</b> <ol style="list-style-type: none"> <li>B. The patient has an intolerance or hypersensitivity to pyridoxine (vitamin B6) therapy <b>OR</b></li> <li>C. The patient has an FDA labeled contraindication to pyridoxine (vitamin B6) <b>AND</b></li> </ol> </li> <li>5. The patient has NOT received a liver transplant <b>AND</b></li> <li>6. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., gastroenterologist, geneticist, nephrologist, urologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis <b>AND</b></li> <li>7. The patient will NOT be using the requested agent in combination with another urinary oxalate reducing agent (e.g., lumasiran) <b>AND</b></li> <li>8. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Length of Approval:</b></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
	<p><b>Quantity limit for the Target 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 <b>OR</b></li> <li>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> <li>A. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication <b>OR</b></li> </ol> </li> <li>B. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>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</li> </ol> </li> </ol> </li> </ol> <p><b>Length of Approval:</b></p> <p><b>BCBSIL:</b> 12 months</p> <p><b>ALL other plans:</b> 6 months (Initial); 12 months (Renewal)</p>