

## PRIOR AUTHORIZATION REQUEST FORM PRIMARY HYPEROXALURIA TYPE 1

For authorization, please answer each question and fax this form PLUS chart notes back to the U of U Health Plans Prior Authorization Department at 801-213-1547.

Failure to submit clinical documentation to support this request will result in a dismissal of the request.

If you have medical pharmacy prior authorization questions, please call for assistance: Individual Exchange: 833-981-0214, Commercial Groups: 833-981-0213, MHC: 844-262-1500

<ul> <li>Metabolic testing shows elevated urinary oxalate excretion persistently &gt; 0.7mmol/1.73m²/day OR for those less than 6 years of age a urinary oxalate/serum creatinine ratio &gt; the ULN for the member's age</li> <li>Genetic testing confirms a mutation in the alanine glyoxylate aminotransferase (AGXT) gene</li> <li>Has the member received a liver transplant?</li> <li>Does the member have an estimated glomerular filtration rate (eGFR) &gt; 30mL/min/1.73m²?</li> <li>Has the prescriber educated the member about diet, such as avoiding oxalate rich foods (e.g. chocolate, leafy green vegetables, black teas, nuts, star fruit)?</li> </ul>	Dis	sclaimer: Prior authorization request for	ms are subject to change in acco	rdance	with Fede	eral and State notice requirements.				
Office Phone:  Office Phone:  Office Fax:  Office Contact:  Height/Weight:  Member must try formulary preferred drugs before a request for a non-preferred drug may be considered. If treatment with preferred products has not been successful, you must submit which preferred products have been tried, dates of treatment, our reason for failure. Reasons for failure must meet the Health Plan medical necessity criteria.  Product being requested: □ Oxlumo™ (lumasiran), □ Rivfloza™ (nedosiran)  Please note: the preferred medication will be determined based on Medical Necessity Assessment  Dosing/Frequency:  If the request is for reauthorization, proceed to reauthorization section.  Questions  Yes No Comments/Notes  1. Is the request made by, or in consultation with, a physician who specializes in the treatment of primary hyperoxaluria type 1 (PH1)?  2. Does the member have a diagnosis of PH1 confirmed by both of the following:  • Metabolic testing shows elevated urinary oxalate excretion persistently > 0.7mmol/1.73m²/day OR for those less than 6 years of age a urinary oxalate/serum creatinine ratio > the ULN for the member's age  • Genetic testing confirms a mutation in the alanine glyoxylate aminotransferase (AGXT) gene  3. Has the member received a liver transplant?  4. Does the member have an estimated glomerular filtration rate (eGFR) > 30mL/min/1.73m²?  5. Has the prescriber educated the member about diet, such as avoiding oxalate rich foods (e.g. chocolate, leafy green vegetables, black teas, nuts, star fruit)?  6. Has the member tried and failed, or has a contraindication/intolerance to, large fluid intake resulting in a	Da	te:	Member Name:		ID#:					
Height/Weight:  Member must try formulary preferred drugs before a request for a non-preferred drug may be considered. If treatment with preferred products has not been successful, you must submit which preferred products have been tried, dates of treatment, and reason for failure. Reasons for failure must meet the Health Plan medical necessity criteria.  Product being requested: □ Oxlumo™ (lumasiran), □ Rivfloza™ (nedosiran) Please note: the preferred medication will be determined based on Medical Necessity Assessment  Dosing/Frequency:    If the request is for reauthorization, proceed to reauthorization section.    Questions	DC	DB:	Gender:		Phy	sician:				
Member must try formulary preferred drugs before a request for a non-preferred drug may be considered. If treatment with preferred products has not been successful, you must submit which preferred products have been tried, dates of treatment, and reason for failure. Reasons for failure must meet the Health Plan medical necessity criteria.  Product being requested: □ Oxlumo™ (lumasiran), □ Rivfloza™ (nedosiran) Please note: the preferred medication will be determined based on Medical Necessity Assessment  Dosing/Frequency:    If the request is for reauthorization, proceed to reauthorization section.    Questions   Yes   No   Comments/Notes	Of	fice Phone:	Office Fax:		Offi	ce Contact:				
preferred products has not been successful, you must submit which preferred products have been tried, dates of treatment, and reason for failure. Reasons for failure must meet the Health Plan medical necessity criteria.  Product being requested: □ Oxlumo™ (lumasiran), □ Rivfloza™ (nedosiran) Please note: the preferred medication will be determined based on Medical Necessity Assessment  Dosing/Frequency:    If the request is for reauthorization, proceed to reauthorization section.    Questions   Yes   No   Comments/Notes	He	ight/Weight:		HCPCS Code:						
Questions  1. Is the request made by, or in consultation with, a physician who specializes in the treatment of primary hyperoxaluria type 1 (PH1)?  2. Does the member have a diagnosis of PH1 confirmed by both of the following:  ■ Metabolic testing shows elevated urinary oxalate excretion persistently > 0.7mmol/1.73m²/day OR for those less than 6 years of age a urinary oxalate/serum creatinine ratio > the ULN for the member's age  ■ Genetic testing confirms a mutation in the alanine glyoxylate aminotransferase (AGXT) gene  3. Has the member received a liver transplant?  4. Does the member have an estimated glomerular filtration rate (eGFR) > 30mL/min/1.73m²?  5. Has the prescriber educated the member about diet, such as avoiding oxalate rich foods (e.g. chocolate, leafy green vegetables, black teas, nuts, star fruit)?  6. Has the member tried and failed, or has a contraindication/intolerance to, large fluid intake resulting in a	pro rec Pro Ple	eferred products has not been successfunctions for failure. Reasons for failure municoduct being requested: ☐ Oxlumo™ (luberase note: the preferred medication will existing/Frequency:	ll, you must submit which prefer st meet the Health Plan medical masiran), □ Rivfloza™ (nedosira be determined based on Medica	red prod necessi an) I Necess	ducts have ty criteria	e been tried, dates of treatment, and i.				
1. Is the request made by, or in consultation with, a physician who specializes in the treatment of primary hyperoxaluria type 1 (PH1)?  2. Does the member have a diagnosis of PH1 confirmed by both of the following:  • Metabolic testing shows elevated urinary oxalate excretion persistently > 0.7mmol/1.73m²/day OR for those less than 6 years of age a urinary oxalate/serum creatinine ratio > the ULN for the member's age  • Genetic testing confirms a mutation in the alanine glyoxylate aminotransferase (AGXT) gene  3. Has the member received a liver transplant?  4. Does the member have an estimated glomerular filtration rate (eGFR) > 30mL/min/1.73m²?  5. Has the prescriber educated the member about diet, such as avoiding oxalate rich foods (e.g. chocolate, leafy green vegetables, black teas, nuts, star fruit)?  6. Has the member tried and failed, or has a contraindication/intolerance to, large fluid intake resulting in a	If the request is for reauthorization, proceed to reauthorization section.									
specializes in the treatment of primary hyperoxaluria type 1 (PH1)?  2. Does the member have a diagnosis of PH1 confirmed by both of the following:  • Metabolic testing shows elevated urinary oxalate excretion persistently > 0.7mmol/1.73m²/day OR for those less than 6 years of age a urinary oxalate/serum creatinine ratio > the ULN for the member's age  • Genetic testing confirms a mutation in the alanine glyoxylate aminotransferase (AGXT) gene  3. Has the member received a liver transplant?  4. Does the member have an estimated glomerular filtration rate (eGFR) > 30mL/min/1.73m²?  5. Has the prescriber educated the member about diet, such as avoiding oxalate rich foods (e.g. chocolate, leafy green vegetables, black teas, nuts, star fruit)?  6. Has the member tried and failed, or has a contraindication/intolerance to, large fluid intake resulting in a		Questions		Yes	No	Comments/Notes				
of the following:  • Metabolic testing shows elevated urinary oxalate excretion persistently > 0.7mmol/1.73m²/day OR for those less than 6 years of age a urinary oxalate/serum creatinine ratio > the ULN for the member's age • Genetic testing confirms a mutation in the alanine glyoxylate aminotransferase (AGXT) gene  3. Has the member received a liver transplant?  4. Does the member have an estimated glomerular filtration rate (eGFR) > 30mL/min/1.73m²?  5. Has the prescriber educated the member about diet, such as avoiding oxalate rich foods (e.g. chocolate, leafy green vegetables, black teas, nuts, star fruit)?  6. Has the member tried and failed, or has a contraindication/intolerance to, large fluid intake resulting in a	1.	specializes in the treatment of prim								
<ul> <li>4. Does the member have an estimated glomerular filtration rate (eGFR) &gt; 30mL/min/1.73m<sup>2</sup>?</li> <li>5. Has the prescriber educated the member about diet, such as avoiding oxalate rich foods (e.g. chocolate, leafy green vegetables, black teas, nuts, star fruit)?</li> <li>6. Has the member tried and failed, or has a contraindication/intolerance to, large fluid intake resulting in a</li> </ul>	2.	<ul> <li>Metabolic testing shows elevate excretion persistently &gt; 0.7mm less than 6 years of age a urina ratio &gt; the ULN for the member</li> <li>Genetic testing confirms a mut</li> </ul>	ted urinary oxalate nol/1.73m²/day OR for those ry oxalate/serum creatinine r's age			Please provide documentation				
(eGFR) > 30mL/min/1.73m²?  5. Has the prescriber educated the member about diet, such as avoiding oxalate rich foods (e.g. chocolate, leafy green vegetables, black teas, nuts, star fruit)?  6. Has the member tried and failed, or has a contraindication/intolerance to, large fluid intake resulting in a	3.	<u> </u>								
avoiding oxalate rich foods (e.g. chocolate, leafy green vegetables, black teas, nuts, star fruit)?  6. Has the member tried and failed, or has a contraindication/intolerance to, large fluid intake resulting in a	4.		d glomerular filtration rate			Please provide documentation				
contraindication/intolerance to, large fluid intake resulting in a	5.	avoiding oxalate rich foods (e.g. cho	ocolate, leafy green			Please provide documentation				
	6.	contraindication/intolerance to, lar	ge fluid intake resulting in a			Please provide documentation				

7.	Has the member tried and failed, is currently taking, or has a			Please provide documentation				
	contraindication/intolerance to, calcium-oxalate crystallization			-				
	inhibitors (e.g. potassium citrate-citric acid, orthophosphate,							
	magnesium oxide)?							
8.	Has the member tried and failed, is currently taking, or has a			Please provide documentation				
	contraindication/intolerance to, pyridoxine (Vitamin B6) for $\geq 3$							
	months without a positive response (defined as a reduction of							
	> 30% in urinary oxalate excretion)?							
REAUTHORIZATION								
1.	Is the request for reauthorization of therapy?							
2.	Has the member had a positive response to therapy with a			Please provide documentation				
	significant reduction from baseline in urinary oxalate levels or							
	for those <6 years of age a decrease in urinary oxalate/serum							
	creatinine ratio?							
3.	Has the member experienced unacceptable drug toxicity to							
	therapy?							
4.	Has the member received a liver transplant?							
W	hat medications and/or treatment modalities have been tried in	the pa	st for this	condition? Please document				
name of treatment, reason for failure, treatment dates, etc.								
Additional information:								
Physician Signature:								

\*\* Failure to submit clinical documentation to support this request will result in a dismissal of the request.\*\*

Policy PHARM-M035

Origination Date: 12/20/2020 Reviewed/Revised Date: 03/27/2024 Next Review Date: 03/27/2025 Current Effective Date: 04/01/2024

## **Confidentiality Notice**

This document and any accompanying document contain confidential information and is intended for the use of the individual or entity named on this transmission sheet. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of this information is strictly prohibited and the document should be returned to this office immediately. If you have received this facsimile in error, please notify us by telephone immediately and destroy document received.