University of Michigan Health Plan

DRUG DETERMINATION POLICY

Title: DDP-51 Oxlumo

Effective Date: 10/22/25

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by UM Health Plan and may not be covered by all UM Health Plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact UM Health Plan Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Oxlumo is used to lower urinary oxalate levels in adults and children with type 1 primary hyperoxaluria. High oxalate levels can cause kidney stones, renal inflammation, and fibrosis. If persistent and left untreated, it can lead to end-stage renal disease. These criteria were developed and implemented to ensure appropriate use for the intended diagnosis, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. General Considerations:

A. Appropriate medication use [must meet all listed below]:

1. Diagnosis: meets standard diagnostic criteria that designates signs, symptoms, and test results to support specific diagnosis.

2. Food and Drug Administration (FDA) approval status [must meet one listed below]:

a. FDA approved: product, indication, and/or dosage regimen.

b. Non-FDA approved use: Compendium support (Lexicomp®) for use of a drug for a non-FDA approved indication or dosage regimen.

3. Place in therapy: sequence of therapy supported by national or internationally accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

B. Pharmaceutical sample use: The Plan does not recognize samples as a medication trial or for continuation of therapy.

C. Adherence to requested medication required for re-approval [must meet one listed below]:

1. Medications processed on the medical benefit: consistent utilization history documented in claims history or chart notes.

2. Medications processed at the pharmacy benefit: consistent fill history electronically or verbally from pharmacy.

D. Place in therapy: sequence of therapy supported by national or international accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

E. Exclusions for any of the following conditions:

1. Secondary causes of hyperoxaluria include excessive dietary consumption of oxalate, gastric bypass surgery, inflammatory bowel disease, or other intestinal disorders.

2. Patient underwent or scheduled to have a liver and/or kidney transplant.

II. Type 1 Primary Hyperoxaluria [must meet all listed below]:

A. Prescriber: Nephrologist.

B. Diagnosis and severity.

1. Type 1 Primary Hyperoxaluria [must meet all listed below]:

a. Signs and symptoms: recurrent kidney stones, urolithiasis, infantile oxalosis, renal failure, nephrocalcinosis with decreased glomerular filtration rate (GFR) and presence of oxalate crystals or stones.

b. Genetic testing: confirming homozygous or compound heterozygous AGXT mutation.

2. Documentation of laboratory levels confirming Type 1 Primary Hyperoxaluria [must meet one listed below]:

a. Urine oxalate: greater than the upper limit of normal (refer to Appendix II).

b. Urine oxalate/creatinine: greater than the normal range based on patient's age (refer to Appendix II).

C. Dosage and administration.

Pediatric	**Loading dose SQ**	**Maintenance dose SQ**
< 10 kg	6 mg/kg once monthly x 3 doses	3 mg/kg once monthly 1 month after loading doses
10 to < 20 kg	6 mg/kg once monthly x 3 doses	6 mg/kg once every three months 1 month after loading doses
≥ 20 kg	3 mg/kg once monthly x 3 doses	3 mg/kg every 3 months 1 month after loading doses
Adult	**Loading dose SQ**	**Maintenance dose SQ**
	3mg/kg once monthly x 3 doses	3 mg/kg every 3 months 1 month after loading doses

D. Approval.

1. Initial: six months.
2. Re-approval: six months [must meet all listed below]:
    a. Improvement in urine oxalate level and/or urine oxalate/creatinine ratio from baseline.
    b. Documentation of reduced signs and symptoms of type 1 primary hyperoxaluria.

4.0 Coding:

COVERED CODES				
Code	**Brand**	**Generic**	**Billing (1u)**	**Prior Approval Required**
J0224	Oxlumo	lumasiran	0.5 mg	Y

5.0 References, Citations & Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Oxlumo accessed September 2025.
2. Liebow A, Li X, Racie T, et al. An investigational RNAi therapeutic targeting glycolate oxidase reduces oxalate production in models of primary hyperoxaluria. J Am Soc Nephrol. 2017;28:494-503.
3. Oxlumo [prescribing information]. Cambridge, MA: Alnylam Pharms, Inc.; November 2020.
4. Hoppe, B., 2012. An update on primary hyperoxaluria. Nature Reviews Nephrology, 8(8), pp.467-475.
5. Sas, D., Enders, F., Mehta, R., Tang, X., Zhao, F., Seide, B., Milliner, D. and Lieske, J., 2020. Clinical features of genetically confirmed patients with primary hyperoxaluria identified by clinical indication versus familial screening. Kidney International, 97(4), pp.786-792.
6. Groothoff JW, Metry E, Deesker L, et al. Clinical practice recommendations for primary hyperoxaluria: An expert consensus statement from erknet and OxalEurope. Nature News. https://www.nature.com/articles/s41581-022-00661-1. Published January 5, 2023. Accessed February 8, 2023.

6.0 Appendices:

See page 4.

7.0 Revision History:

Original Effective Date: 10/29/2025

Next Review Date: 11/01/2026

Revision Date	Reason for Revision
9/21	Code changed for Oxlumo
2/22	Annual review: Added compendium reference to appropriate therapy, updated references, j code updated, formatting
1/23	Annual review, added reference
8/23	Annual review: reformatted dosing to a table, added general consideration with appropriate use and exclusions
8/24	Annual review – no change
8/25	Annual review, updated reference, formatting

Appendix I: Laboratory Levels Confirming Type 1 Primary Hyperoxaluria

	Normal Reference Levels
Urinary Oxalate	<45 mg/1.73 m^2/day
Urinary Oxalate/Creatinine	
0-6 months of age	<0.175 mg/mg
6-12 months of age	<0.139 mg/mg
1-2 years of age	<0.103 mg/mg
2-3 years of age	<0.080 mg/mg
3-5 years of age	<0.064 mg/mg
5-7 years of age	<0.056 mg/mg
7-17 years of age	<0.048 mg/mg

Appendix II: Differential Diagnosis Based on Genetic Testing

Type of Primary Hyperoxaluria	**Genetic Testing Results**
Type 1	Defects in the gene that encodes the hepatic peroxisomal enzyme alanine: glyoxylate aminotransferase (AGT)
Type 2	Defects in the gene that encodes the cytosolic enzyme glyoxylate reductase/hydroxypyruvate reductase (GRHPR)
Type 3	Defects in the HOGA1 gene that encodes the liver-specific mitochondrial 4-hydroxy-2-oxoglutarate aldolase enzyme