Oxlumo® (lumasiran)
(Subcutaneous)

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I. Length of Authorization

Coverage will be provided for 6 months initially and may be renewed annually thereafter.

Coverage and policy application may be contingent on federal or state laws or regulations. In the event of a conflict between this policy and applicable federal or state laws or regulations, state law should apply.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Oxlumo 94.5 mg/0.5 mL in a single-dose vial for injection: 4 vials every month for 3 doses then every 3 months thereafter

B. Max Units (per dose and over time) [HCPS Unit]:

- 756 billable units every month for 3 doses then every 3 months thereafter

III. Initial Approval Criteria

Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e. genetic and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

Universal Criteria [1-5]

- Patient has not had a liver transplant; **AND**
- Must be prescribed by, or in consultation with, a specialist in genetics, nephrology or urology; **AND**
- Will not be used in combination with other urinary oxalate reducing agents (i.e., nedosiran, etc.); **AND**

Primary Hyperoxaluria type 1 (PH1) † Φ [1-5]

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- Patient has a definitive diagnosis of primary hyperoxaluria type 1 as evidenced by one of the following:
    - Patient has a biallelic pathogenic mutation in the alanine: glyoxylate aminotransferase (*AGXT)* gene as identified on molecular genetic testing; **OR**
    - Identification of alanine: glyoxylate aminotransferase (AGT) enzyme deficiency on liver biopsy; **AND**
- Patient has a baseline for one or more of the following:
    - Urinary oxalate excretion level (corrected for BSA)
    - Spot urinary oxalate: creatinine ratio
    - Estimated glomerular filtration rate (eGFR)
    - Plasma oxalate level

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe injection site reactions, etc.; **AND**
- Disease response as evidenced by at least one of the following:
    - Decrease in urinary oxalate excretion level (corrected for BSA) from baseline
    - Reduction in spot urinary oxalate: creatinine ratio from baseline
    - Stabilization of estimated glomerular filtration rate (eGFR)
    - Decrease in plasma oxalate level from baseline

V. Dosage/Administration [1]

<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>Primary Hyperoxaluria Type 1 (PH1)</td><td>For administration by a healthcare professional as a subcutaneous injection only.
<table>
<tr><th>Actual Body Weight</th><th>Loading Dose**</th><th>Maintenance dose**</th></tr>
<tr><td>Less than 10 kg</td><td>6 mg/kg once monthly for 3 doses</td><td>3 mg/kg once monthly</td></tr>
<tr><td>10 kg to less than 20 kg</td><td>6 mg/kg once monthly for 3 doses</td><td>6 mg/kg once every 3 months</td></tr>
<tr><td>20 kg and above</td><td>3 mg/kg once monthly for 3 doses</td><td>3 mg/kg once every 3 months</td></tr>
</table>
Note: Begin maintenance doses 1 month after the last loading dose.
**For Patients on Hemodialysis, administer Oxlumo after hemodialysis if administered on dialysis days.</td></tr>
</table>

VI. Billing Code/Availability Information

HCPCS:

- J0224 – Injection, lumasiran, 0.5 mg; 1 billable unit = 0.5 mg

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NDC:

- Oxlumo 94.5 mg/0.5 mL in a single-dose vial solution for injection: 71336-1002-xx

VII. References

1. Oxlumo [package insert]. Cambridge, MA; Alnylam Pharm., Inc., September 2023. Accessed December 2023.
2. Milliner DS, Harris PC, Sas DJ, et al. Primary Hyperoxaluria Type 1. Initial Posting: 2002 June 19 [Updated 2022 Feb 10]. In: Adam MP, Everman DB, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2023. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1283/.
3. Garrelfs SF, Frishberg Y, Hulton SA, et al; ILLUMINATE-A Collaborators. Lumasiran, an RNAi Therapeutic for Primary Hyperoxaluria Type 1. N Engl J Med. 2021 Apr 1;384(13):1216-1226. doi: 10.1056/NEJMoa2021712.
4. Hayes W, Sas DJ, Magen D, et al. Efficacy and safety of lumasiran for infants and young children with primary hyperoxaluria type 1: 12-month analysis of the phase 3 ILLUMINATE-B trial. Pediatr Nephrol. 2022 Aug 1. doi: 10.1007/s00467-022-05684-1.
5. Michael M, Groothoff JW, Shasha-Lavsky H, et al. Lumasiran for Advanced Primary Hyperoxaluria Type 1: Phase 3 ILLUMINATE-C Trial. Am J Kidney Dis. 2022 Jul 14:S0272-6386(22)00771-5. doi: 10.1053/j.ajkd.2022.05.012.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E72.53	Primary hyperoxaluria

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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