Oxlumo® (lumasiran)
(Subcutaneous)

Effective Date: 4/1/2021
Review Date: 3/4/2021, 5/12/2022, 4/13/2023, 12/14/2023, 1/4/2024, 3/13/2024, 05/07/2025, 03/10/2026

Scope: Medicaid, Commercial, Medicare

I. Length of Authorization

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

II. Dosing Limits

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

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

III. Summary of Evidence

Oxlumo (lumasiran) is a small-interfering RNA (siRNA) therapy indicated for the treatment of primary hyperoxaluria type 1 (PH1) in both pediatric and adult patients to lower urinary and plasma oxalate levels. The ILLUMINATE studies demonstrated significant reductions in urinary oxalate, with one pivotal study showing an average 65% reduction after six months compared with 12% in the placebo group, and 84% of treated patients achieving normal or near-normal oxalate levels; similar efficacy was seen in children under 6 years. The most common adverse effects are injection-site reactions such as redness, swelling, pain, itching, discoloration, and bruising.

IV. Initial Approval Criteria

Coverage is provided in the following conditions:

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

Universal Criteria [1-5]

- Member has not had a liver transplant; **AND**
- Must be prescribed by, or in consultation with, a specialist in genetics, nephrology or urology; **AND**

- Member will not use in combination with Rivfloza (nedosiran)

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

- Member has a definitive diagnosis of primary hyperoxaluria type 1 as evidenced by one of the following:
    - Member 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**
- Documentation that the member has made efforts to increase fluid intake to at least 3 L/m2 BSA per day; AND
- Concurrent use of pyridoxine OR previous trial of at least 3 months of pyridoxine with no significant improvement observed (e.g. <30% reduction in urine oxalate concentration after at least 3 months of therapy); AND
- Member 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

V. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria identified in section IV; **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

VI. Dosage/Administration [1]

Indication	Dose
Primary Hyperoxaluria Type 1 (PH1)	**For administration by a healthcare professional as a subcutaneous injection only.**

Actual Body Weight	Loading Dose**	Maintenance dose**
Less than 10 kg	6 mg/kg once monthly for 3 doses	3 mg/kg once monthly
10 kg to less than 20 kg	6 mg/kg once monthly for 3 doses	6 mg/kg once every 3 months
20 kg and above	3 mg/kg once monthly for 3 doses	3 mg/kg once every 3 months

Note: Begin maintenance doses 1 month after the last loading dose.

***For Patients on Hemodialysis, administer Oxlumo after hemodialysis if administered on dialysis days.*

VII. Billing Code/Availability Information

HCPCS:

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

NDC:

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

VIII. References

1. Oxlumo [package insert]. Cambridge, MA; Alnylam Pharm., Inc., December 2025. Accessed March 2026.
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,	Noridian Healthcare Solutions, LLC
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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:

Oxlumo was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Oxlumo according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.