Oxlumo™ (lumasiran)
(Subcutaneous)

Document Number: SHP-0579

Last Review Date: 01/04/2022
Date of Origin: 01/05/2021
Dates Reviewed: 01/2021, 04/2021, 07/2021, 01/2022

I. Length of Authorization

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

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

Coverage is provided in the following conditions:

> 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. Medical records may be submitted via direct upload through the PA web portal or by fax.

Universal Criteria [1,2,3,4]

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

Primary Hyperoxaluria type 1 (PH1) † Φ [1,2]

- 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)

† 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 a decrease in urinary oxalate excretion from baseline, a reduction in spot urinary oxalate: creatinine ratio from baseline, and/or stabilization of glomerular filtration rate

V. Dosage/Administration

<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.</td></tr>
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VI. 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

VII. References

1. Oxlumo [package insert]. Cambridge, MA; Alnylam Pharm., Inc., November 2020. Accessed November 2021.

2. Milliner DS, Harris PC, Cogal AG, et al. Primary Hyperoxaluria Type 1. https://www.ncbi.nlm.nih.gov/books/NBK1283/ .(Accessed on November 25, 2020).
3. Alnylam Pharmaceuticals. ILLUMINATE-A: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study With an Extended Dosing Period to Evaluate the Efficacy and Safety of Lumasiran in Children and Adults With Primary Hyperoxaluria Type 1. Available from: https://clinicaltrials.gov/ct2/show/NCT03681184?term=NCT03681184&draw=2&rank=1. Accessed November 25, 2020.
4. Alnylam Pharmaceuticals. ILLUMINATE-B: An Open-Label Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Lumasiran in Infants and Young Children With Primary Hyperoxaluria Type 1. Available from: https://clinicaltrials.gov/ct2/show/NCT03905694?term=NCT03905694&draw=2&rank=1. Accessed November 25, 2020.

Appendix 1 – Covered Diagnosis Codes

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

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

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 Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered 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
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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
15	KY, OH	CGS Administrators, LLC