MEDICAL MUTUAL®

Drug Policy

Policy:	**20210102-MRx (v11-22)**	**Initial Effective Date: 01/21/2021**
Code(s):	**HCPCS J0224**	**Annual Review Date: 11/21/2023**
SUBJECT:	**Oxlumo ® (Lumisiran)**	**Last Revised Date: 11/21/2023**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

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:

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**

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

- 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 a decrease in urinary oxalate excretion from baseline, a reduction in spot urinary oxalate: creatinine ratio from baseline, stabilization of glomerular filtration rate and/or a 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>
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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., October 2022. Accessed October 2022.
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. 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.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for HCPCS Codes J0224