

RX.PA. 042.MPC *Oxlumo® (lumasiran)*

PURPOSE

Oxlumo® is a HAO1-directed small interfering ribonucleic acid (siRNA) indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients. Maryland Physicians Care requires Prior Authorization for its use.

Primary Hyperoxaluria Type 1 (PH1) - Approve Oxlumo if the member meets **all** the following conditions:

A. Initial Therapy

- a. Prescribed by, or in consultation with a nephrologist, endocrinologist or a specialist with experience in managing primary hyperoxaluria
AND
- b. Diagnosis of primary hyperoxaluria type 1 and clinical documentation to confirm diagnosis based on the following:
 - i. Molecular genetic test showing mutation in the alanine:glyoxylate aminotransferase (AGXT) gene
OR
 - ii. Liver biopsy showing significantly reduced or absent alanine:glyoxylate aminotransferase (AGT) enzyme activityAND
- c. Documentation of the following:
 - i. Elevated plasma oxalate concentration
AND
 - ii. Elevated urinary oxalate excretionAND
- d. Member has pretreatment glomerular filtration rate (GFR) of ≥ 30 mL/min/1.73m²
AND
- e. Member has no documented history of liver transplant
- f. Member must be referred to the Maryland Department of Health Rare and Expensive Case Management (REM) program

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Oxlumo will be considered investigational or experimental for any other use and will not be covered.

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D. Member Currently Treated with Oxlumo (continuation of therapy):

MPC Renewal:

- a. Member has a documented positive clinical response to therapy as determined by the prescriber.
- b. Member must have documentation of decreased urinary oxalate excretion compared to baseline
- c. Member must have documentation of decreased plasma oxalate concentration compared to baseline
- d. Must have documentation that member has not received a liver transplant
- e. Prescribed by, or in consultation with a nephrologist, endocrinologist or a specialist with experience in managing primary hyperoxaluria

Renewal from Previous Insurer:

- a. Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria)
- b. Provider has a documented clinical response of the member's condition which has stabilized or improved compared to baseline.

Approval Duration:

- A. Initial Therapy: Approve for 6 months
- B. Continuation of Therapy: Approve for 1 year

| CPT Code | Description |
|----------|-----------------------------|
| J0224 | Injection, lumasiran, 0.5mg |

References:

1. Oxlumo® injection [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals Inc; November 2020.



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REVIEW HISTORY

| DESCRIPTION OF REVIEW / REVISION | DATE APPROVED |
|---|----------------|
| <i>Annual Review Change in Non-MPC renewal to renewal from previous insurer</i> | <i>02/2024</i> |
| <i>Annual Review</i> | <i>02/2023</i> |
| <i>Selected Revision Addition of MPC vs Non-MPC Renewal Criteria</i> | <i>09/2022</i> |
| <i>Annual Review and J-code update</i> | <i>02/2022</i> |
| <i>Addition of dosing requirements and off-label restrictions</i> | |
| <i>P&T Review</i> | <i>08/2021</i> |

