

lumasiran (Oxlumo)

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT

Mechanism of Action: HAO1-directed small interfering RNA (siRNA)

HCPCS:

J0224:Injection, lumasiran, 0.5 mg

How Supplied:

94.5 mg single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Primary Hyperoxaluria Type 1 (PH1)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct) may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted*)

1. Patient is starting new therapy with this drug (allowed for 1 dose). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
2. Patient is being re-initiated on this drug after being off therapy for at least 6 months (allowed for 1 dose). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
3. Additional clinical monitoring is required during administration as evidenced by one of the following:
 - a. Patient has experienced a previous severe adverse event on this drug based on documentation submitted.
 - b. Patient continues to experience moderate to severe adverse events on this drug based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
 - c. Patient is clinically unstable based on documentation submitted.
 - d. Patient is physically or cognitively unstable based on documentation submitted

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Primary Hyperoxaluria Type 1 (PH1)

Meets medical necessity if all the following are met:

Initial

1. Prescribed by or in consultation with a medical geneticist, gastroenterologist, nephrologist, or urologist
2. Diagnosis of PH1 confirmed by either of the following:
 - a. Molecular genetic test results demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene
 - b. Liver enzyme analysis results demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity
3. Not being used in combination with Rivfloza (nedosiran)

Reauthorization

1. ***Effective 6/1/2026 and after***, will require both of the following:
 - a. Patient is responding to therapy (e.g. lower oxalate in urine and blood)
 - b. Not being used in combination with Rivfloza (nedosiran)

Covered Doses:

Body weight	Loading dose, given subcutaneously	Maintenance dose, given subcutaneously (begin 1 month after the last dosing dose)
less than 10 kg	6 mg/kg once monthly for 3 doses	3 mg/kg once monthly
10 kg to <20 kg	6 mg/kg once monthly for 3 doses	6 mg/kg once quarterly (every 3 months)
≥20 kg	3 mg/kg once monthly for 3 doses	3 mg/kg once quarterly (every 3 months)

Coverage Period:

One year

ICD-10:

E72.53

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Oxlumo (lumasiran) Prescribing Information. Alnylam Pharmaceuticals, Inc., Cambridge, MA: 4/2025.

Review History

Date of Last Annual Review: 1Q2026

Changes from previous policy version:

- **Effective 6/1/2026**, reauthorization criteria will need to be met for continuation of treatment.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*