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.

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

1. Patient is receiving their first infusion of Oxlumo or is being re-initiated on Oxlumo after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Oxlumo based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Oxlumo based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. 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:

1. Prescribed by or in consultation with a medical geneticist, gastroenterologist, nephrologist, or urologist
2. ***Effective 8/1/2025 and after***, will require that diagnosis of PH1 be 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. ***Effective 8/1/2025 and after***, will require that Oxlumo not be 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:
Indefinitely

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: 9/2023.

Review History

Date of Last Annual Review: 1Q2025
Changes from previous policy version:

- Primary hyperoxaluria type 1 (PH1): ***Effective 8/1/2025 and after***, will add requirements for presence of genetic mutation to confirm diagnosis of PH1 and combination use with agents for PH1 (Rationale: pivotal trial (ILLUMINATE-A))

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