Lumosiran (Oxlumo™)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Outpatient Facility Infusion Administration* [*Prior authorization required – see section (1)] HCPCS: **J0224** per 0.5 mg

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

- Primary hyperoxaluria type 1 (PH1)

AHFS therapeutic class: Enzyme replacement/modifiers

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

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****
AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, Medi-Cal, ASO/Shared Advantage/HMO (non-direct contract),** 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.

ADMINISTRATION OF 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 injection 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.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for lumosiran (Oxlumo™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Primary hyperoxaluria type 1 (PH1)

1. Prescribed by or in consultation with a medical geneticist, gastroenterologist, nephrologist, or urologist

Covered Doses

Body weight	Loading dose, given SC	Maintenance dose, given SC (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

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for lumasiran (Oxlumo™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 94.5 mg/0.5 mL solution in a single-dose vial

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Oxlumo® (lumasiran) [Prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; 10/2022.

(7) Policy Update

Date of last review: 1Q2022
Date of next review: 1Q2023
Changes from previous policy version:

- No clinical change to policy following routine annual review.

Reviewed by P&T Committee
BSC Drug Coverage Criteria to Determine Medical Necessity