Generic Name: lumasiran

Therapeutic Class or Brand Name: Oxlumo®

Applicable Drugs: Oxlumo®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/14/2025

Date Last Reviewed / Revised: 2/14/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of primary hyperoxaluria type 1 (PH1) AND must meet all criteria listed:
   A. Diagnosis of PH1 confirmed by genetic testing (mutation of the alanine:glyoxylate aminotransferase (AGXT) gene).
   B. Documentation of urinary oxalate (UOx) excretion assessment > 0.70 mmol/1.73m^2/day OR plasma oxalate (POx) levels ≥ 20 µmol/L.
      i. OR, if the individual is ≤ 5 years of age, an elevated UOx excretion as measured by at least two spot UOx to creatinine ratios (UOx:Cr) above the age-specified upper limit of normal.
   C. Documented treatment failure of or contraindication to treatment with pyridoxine (vitamin B6) at a titrated dose (up to a maximum recommended dose of 5 mg/kg) for at least 3 months.
   D. In patients not at end-stage renal disease and/or on hemodialysis, documentation that the patient will receive hyperhydration (defined as 3.5-4 liters per day for adults, or 2-3 liters/m^2 BSA for children) concurrently with treatment with Lumasiran.
   E. Documentation of clinically significant phenotype burden consistent with PH1, characterized by active stone disease and/or nephrocalcinosis and/or renal impairment.

II. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

III. Drug is prescribed by or in consultation with a hepatologist, gastroenterologist, or urologist.

IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Prior liver transplant
- Patients requiring peritoneal dialysis

- Pregnancy or breastfeeding, unless an attestation is provided confirming that the patient and provider have discussed the risks and benefits, acknowledged the lack of data in these circumstances, and determined that treatment with lumasiran is necessary.
- Severe hepatic impairment
- Use in combination with Rivfloza

OTHER CRITERIA

- Lumasiran dosing is based on actual body weight:
  - The recommended dose of OXLUMO by subcutaneous injection is based on body weight. (2.1)

Body Weight	Loading Dose	Maintenance Dose
less than 10 kg	6 mg/kg once monthly for 3 doses	3 mg/kg once monthly, beginning 1 month after the last loading dose
10 kg to less than 20 kg	6 mg/kg once monthly for 3 doses	6 mg/kg once every 3 months (quarterly), beginning 1 month after the last loading dose
20 kg and above	3 mg/kg once monthly for 3 doses	3 mg/kg once every 3 months (quarterly), beginning 1 month after the last loading dose

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Lumasiran is available in single-dose vials of 94.5 mg/0.5 mL.
- For body weight <10kg: One vial (0.5 mL) per 30 days.
- For body weight 10 to 20 kg: Up to two vials per 30 days for the first 3 months, then up to two vials per 90 days thereafter.
- For body weight >20kg: Sufficient number of vials to yield a 3 mg/kg dose (see table below) per 30 days for the first 3 months, then per 90 days thereafter.

Patient Weight Range (kg)	Number of vials required for 3mg/kg dose
20 kg – 31.5 kg	1
31.5 kg – 63 kg	2
63 kg – 94.5 kg	3
94.5 – 126 kg	4
126 kg – 157.5 kg	5

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months, with an updated letter of medical necessity or progress notes showing improvement or maintenance with the medication from pre-treatment baseline. Cessation is recommended if there is no clinically significant improvement in the patient's urine or plasma oxalate levels, if there is deterioration of clinical condition, or if there is evidence of serious adverse event related to treatment.

APPENDIX

N/A

REFERENCES

1. Oxlumo®. Prescribing Information. Alnylam Pharmaceuticals; September 2023. Accessed December 12, 2024. https://www.alnylam.com/sites/default/files/pdfs/OXLUMO-Prescribing-Information.pdf
2. National Kidney Foundation. Primary hyperoxaluria type 1. Kidney.org. Accessed July 13, 2024. https://www.kidney.org/atoz/content/primary-hyperoxaluria-type-1.
3. Garrelfs, SF, et. al., Lumasiran, an RNAi Therapeutic for Primary Hyperoxaluria Type 1. *N Eng J Med*. 2021;384:1216-1226. doi:10.1056/NEJMoa2021712.
4. 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*. 2023;81(2):145-155.e1. doi:10.1053/j.ajkd.2022.05.012
5. Groothoff, JW, et al. Clinical practice recommendations for primary hyperoxaluria: an expert consensus statement from ERKNet and OxalEurope. *Nat Rev Nephrol* 2023;19,194–211. https://doi.org/10.1038/s41581-022-00661-1.