

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 9, 2021 May 11, 2023

## **OXLUMO® (lumasiran)**

**LENGTH OF AUTHORIZATION:** Up to one year

**REVIEW CRITERIA:**

- Patient must have a diagnosis of primary hyperoxaluria type 1 (PH1), confirmed by either a molecular or biochemical genetic test.
- Documentation of patient's weight.
- Prescribed by, or in consultation, with a specialist (e.g., geneticist, nephrologist, urologist).

**CONTINUATION OF THERAPY:**

- Patient met the above criteria; AND
- Documentation of improved clinical response (e.g., decreased urinary oxalate concentrations, decreased urinary oxalate: creatinine ratio, decreased plasma oxalate concentrations); AND
- Dosing is appropriate as per labeling or is supported by compendia.

**DOSING AND ADMINISTRATION:**

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as 94.5 mg/0.5 mL single-dose vial for injection