Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 9, 2021 May 11, 2023, July 1, 2024

Oxalosis Agents
Oxlumo® (lumasiran) and Rivfloza™ (nedosiran)

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

- Patient must be ≥ 6 years of age for Oxlumo.
- Patient must be ≥ 9 years of age for Rivfloza and have relatively preserved kidney function (e.g., eGFR ≥30 mL/min/1.73 m^2).
- Patient must have a diagnosis of primary hyperoxaluria type 1 (PH1), confirmed by one of the following:
  - Genetic testing demonstrating mutation in the alanine-glyoxylate aminotransferase (AGXT) gene; OR
  - Liver biopsy results demonstrating significantly decreased or absent alanine-glyoxylate aminotransferase (AGXT) enzyme activity.
- 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/