

**Policy Name:** Oxlumo (lumasiran)

**Policy #:**

3131P

## Purpose of the Policy

The purpose of this policy is to define coverage criteria for Oxlumo (lumasiran) for the treatment of hyperoxaluria.

## Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Oxlumo (lumasiran) under the medical benefit if the following criteria are met.

## Criteria

### 1. Coverage Criteria

- 1.1 Documented diagnosis of primary hyperoxaluria type 1 based on both of the following:
  - Confirmed genetic testing of AGXT or AGT mutation
  - Metabolic testing demonstrating ONE of the following:
    - Increased urinary oxalate excretion (greater than 1 mmol/1.73m<sup>2</sup> per day [90mg/1.73m<sup>2</sup> per day], increased urinary oxalate:creatinine ratio relative to normative values for age); OR
    - Increased plasma oxalate and glyoxylate concentrations
- 1.2 Patient does not have a history of liver or kidney transplant
- 1.3 Patient has tried pyridoxine for at least 3 months with no significant improvement
- 1.4 Ordered by, or in consultation with a nephrologist (kidney doctor) or urologist (doctor of the urinary tract) or medical gene doctor
- 1.5 Review of chart notes documenting diagnosis and confirming that patient has met all above requirements for treatment with Oxlumo by both a pharmacist and medical director

### 2. Approval Period

- 2.1 Initial: 12 months
- 2.2 Subsequent Approval: 12 months with documentation of positive response to therapy (reduction in urinary oxalate excretion, reduction in oxalate/creatinine ratio, reduction in plasma oxalate levels [prior to Oxlumo], etc)

## CPT Codes

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## HCPCS Codes

J0224

Injection, lumasiran, 0.5 mg

## References

1. Oxlumio (lumasiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals Inc; October 2022.
2. Jaklevic MC. First Drug Approved for Rare Genetic Disorder Affecting Kidneys. JAMA 2021; 325:214.
3. Sas DJ, Magen D, Hayes W, et al. Phase 3 trial of lumasiran for primary hyperoxaluria type 1: A new RNAi therapeutic in infants and young children. Genet Med 2022; 24:654.
4. Michael M, Groothoff JW, Lavsky HS, et al. Lumasiran for Advanced Primary Hyperoxaluria Type 1: Phase 3 ILLUMINATE-C Trial. Am J Kidney Dis. 2023 Feb;81(2):145-155.e1.
5. Groothoff JW, Metry E, Deesker L, et al. Clinical practice recommendations for primary hyperoxaluria: an expert consensus statement from ERKNet and OxalEurope. Nat Rev Nephrol 2023; 19:194.

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