

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 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/1.73m² per day [90mg/1.73m² 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
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References

1. Oxlumo (lumasiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals Inc; September 2023.
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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