

Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

Lumasiran (Oxlumo)

Notes:

- Quantity Limits: No
- Lumasiran (Oxlumo) vials for injection requires administration by a healthcare professional and is not approved for self-injection.

Non-Formulary **lumasiran (Oxlumo)** requires a clinical review. Appropriateness of therapy will be determined based on the following criteria:

Initiation (new start) criteria: Non-formulary **lumasiran (Oxlumo)** will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Diagnosis of primary hyperoxaluria type 1 (PH1) with documented genetic testing confirming *AGXT* mutation. Consultation with genetics is recommended
- Metabolic testing demonstrating:
 - Elevated 24-hour urine oxalate level consistent with diagnosis of PH1 **-OR-**
 - Elevated spot urine oxalate:creatinine ratio consistent with diagnosis of PH1
- Maintaining appropriate fluid intake as advised by treating physician
- Member has a pretreatment estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m²
- No history of liver or kidney transplant
- No diagnosis of primary hyperoxaluria type 2 (PH2) or type 3 (PH3)
- No clinical evidence of systemic oxalosis
- Patient is not pregnant or breastfeeding
- Restricted to Nephrologists, Pediatric Nephrologists, Urologists, and Pediatric Urologist

Criteria for new members entering Kaiser Permanente and current members already taking the medication who have not been reviewed previously: Non-formulary **lumasiran (Oxlumo)** will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Diagnosis of primary hyperoxaluria type 1 (PH1) with documented genetic testing confirming *AGXT* mutation. Consultation with genetics is recommended
- Metabolic testing demonstrating:
 - Elevated 24-hour urine oxalate level consistent with diagnosis of PH1 **-OR-**
 - Elevated spot urine oxalate:creatinine ratio consistent with diagnosis of PH1
- Maintaining appropriate fluid intake as advised by treating physician
- Member has a pretreatment estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m²
- No history of liver or kidney transplant
- No diagnosis of primary hyperoxaluria type 2 (PH2) or type 3 (PH3)
- No clinical evidence of systemic oxalosis

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Revised: 07/14/22
Effective: 09/15/22

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Kaiser Foundation Health Plan of the Northwest

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Continued use criteria (6 months after initiation): Non-formulary **lumasiran (Oxlumo)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Documented reduction in either urinary oxalate excretion or urinary oxalate excretion/creatinine ratio
 - Patient is not post liver transplant or in consultation with transplant team
 - Either of the following:
 - Adherence to medication, recommended diet and lifestyle measures, or follow-up labs and assessments
- OR-**
- Documentation of improved or stabilized clinical symptoms (e.g., nephrocalcinosis, formation of renal stones, renal impairment)

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