Field Name	Field Description
Prior Authorization Group Description	**Primary Hyperoxaluria Agents**
Drugs	Oxlumo (lumasiran) Rivfloza (nedosiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a nephrologist, urologist, hepatologist, endocrinologist or consultation with one of these specialists
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.

Other Criteria	**Initial Authorization**
	• Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by one of the following:
	  o Genetic testing confirming at least one mutation at the AGXT gene
	  o Liver biopsy demonstrating absent or significantly reduced AGT activity
	• Metabolic testing demonstrating one of the following:
	  o Oxlumo or Rivfloza
	  ▪ Increased urinary oxalate excretion (≥ 0.5 mmol/1.73 m^2per day[45 mg/1.73 m^2per day])
	  ▪ Increased urinary oxalate:creatinine ratio relative to normative values for age
	  o Oxlumo only: Increased plasma oxalate level (≥ 20 µmol/L)
	• For Rivfloza: member has relatively preserved kidney function (e.g., EGFR ≥ 30 mL/min/1.73 m2)
	• Member is concurrently using pyridoxine or has tried and failed previous pyridoxine therapy for at least 3 months, or has a medical reason for not using pyridoxine
	• Member has no history of liver transplant
	• Medication is prescribed at an FDA approved dose

Revision/Review Date 2/2025	• Patient is not using Oxlumo and Rivfloza concurrently **<u>Reauthorization</u>** • Members previously using pyridoxine will continue to use pyridoxine, or have a medical reason for not using pyridoxine • Documentation has been provided that demonstrates a clinical benefit (e.g. symptomatic improvement, reduction in urinary or plasma oxalate levels from baseline) • Medication is prescribed at an FDA approved dose • Patient is not using Oxlumo and Rivfloza concurrently **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**