Oxlumo *(lumasiran)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Oxlumo is a HAO1-directed small interfering ribonucleic acid (siRNA) indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients.
Exclusion Criteria	Coverage will not be provided in the following situations: (1) Patient has a history of kidney or liver transplant; AND (2) Patient will be using in combination with Rivfloza.
Required Medical Information	1. Medical records supporting the request must be provided; 2. Must have a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by genetic testing of the AGXT mutation or by liver enzyme analysis; 3. For reauthorization requests, must have documented clinical benefit with Oxlumo compared to baseline.
Age Restriction	None.
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or urologist.
Coverage Duration	Initial: one year. Reauthorization: two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.

HCPCS	Description	Billing Units/How Supplied
J0224	Oxlumo (lumasiran)	**Billing unit: 0.5 mg** 94.5 mg/0.5 mL SDV

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	8/21/2025	Pharmacy & Therapeutics (P&T) Committee	8/21/2025