CareSource

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	**Oxlumo (lumasiran)**
BILLING CODE	**J3490**
BENEFIT TYPE	**Medical**
SITE OF SERVICE ALLOWED	**Office/Outpatient**
COVERAGE REQUIREMENTS	**Prior Authorization Required (Non-Preferred Product)** **QUANTITY LIMIT— see Dosage Allowed**
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	**Click Here**

Oxlumo (lumasiran) is a non-preferred product and will only be considered for coverage under the medical benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

Primary Hyperoxaluria Type 1 (PH1)

For initial authorization:

1. **Member has a diagnosis of primary hyperoxaluria type 1 as evidenced by one of the following:**
   a) **Genetic testing shows a mutation in the AGXT gene; OR**
   b) **Lowered AGT catalytic and immunoreactivity in a liver biopsy specimen indicating PH1; AND**
2. **Member has documentation of elevated oxalate levels; AND**
3. **Medication must be prescribed by or in consultation with a urologist or nephrologist; AND**
4. **Member had an inadequate response, intolerance, or contraindication to documented prior therapy with BOTH of the following treatments:**
   a) **At least a 90-day trial of Vitamin B6 (pyridoxine);**
   b) **At least a 30-day trial of a calcium oxalate crystallization inhibitor (i.e., potassium citrate, sodium citrate, organophosphates, magnesium oxide); AND**
5. **Member does not have ESRD (eGFR <30) and is not on dialysis; AND**
6. **Member has not received a liver transplant.**
7. **Dosage allowed:**

Body Weight*	Loading Dose	Maintenance Dose (begin 1 month after the last loading dose)
Less than 10 kg	6 mg/kg once monthly for 3 doses	3 mg/kg once monthly
10 kg to less than 20 kg	6 mg/kg once monthly for 3 doses	6 mg/kg once every 3 months (quarterly)
20 kg and above	3 mg/kg once monthly for 3 doses	3 mg/kg once every 3 months (quarterly)

***Based on actual body weight**

If member meets all the requirements listed above, the medication will be approved for 12 months.

For reauthorization:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been submitted that show the member has:
   a) Decreased excretion of urine oxalate from baseline; OR
   b) Stable or improved kidney function (e.g., improved eGFR or decreased formation of renal stones); AND
3. Member has not received a liver transplant.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Oxlumo (lumasiran) not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
12/08/2020	New policy for Oxlumo created.

References:

1. Oxlumo (lumasiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals Inc; November 2020.
2. Oxlumo (lumasiran) [billing and coding guide]. Cambridge, MA: Alnylam Pharmaceuticals Inc; November 2020.
3. Cochat P, Hulton S, Acquaviva C, et al: Primary hyperoxaluria Type 1: indications for screening and guidance for diagnosis and treatment. Nephrol Dial Transplant 2012;27:1729-1736 doi: 10.1093/ndt/gfs078.
4. Danpure CJ. Molecular and clinical heterogeneity in primary hyperoxaluria type 1. Am J Kidney Dis. 1991 Apr;17(4):366-9. doi: 10.1016/s0272-6386(12)80624-x. PMID: 2008900.

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