PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Oxlumo (lumasiran)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Oxlumo is an 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.
PH1, which is caused by mutations of the AGXT gene, is a rare autosomal recessive disease that mainly affects the kidneys. It results from buildup of oxalate, which normally is filtered through the kidneys and excreted in the urine. Stone formation (calcium oxalate) in the kidneys and urinary tract occurs, as well as elevated levels of calcium in the kidneys. Eventually, if kidney function declines far enough, oxalate can start to accumulate in other body tissues, leading to a variety of problems (systemic oxalosis).

Oxlumo (lumasiran) will be considered for coverage when the following criteria are met:

Primary Hyperoxaluria Type 1 (PH1)

For **initial** authorization:

1. Medication must be prescribed by or in consultation with a urologist or nephrologist; AND
2. Member has a diagnosis of primary hyperoxaluria type 1 confirmed by genetic testing that shows a mutation in the AGXT gene; AND
3. Member has documentation of elevated urinary or plasma oxalate levels (UOx or POx); AND
4. Member has had an inadequate response to vitamin B6 (pyridoxine), defined as <30% reduction in urine oxalate concentration after at least 3 months on optimal dose; AND
5. Member does not receive peritoneal dialysis (hemodialysis allowed); AND
6. Member has not received a liver transplant; AND
7. Oxlumo will not be used in combination with Rivfloza.
8. **Dosage allowed/Quantity limit:** SubQ as below:

Body Weight*	Loading Dose	Maintenance Dose (begin 1 month after the last loading dose)

For **reauthorization**:

1. Chart notes must show reduced level of urinary or plasma oxalate compared to baseline; AND
2. Member has maintained stable kidney function (i.e., no clinically significant decline of eGFR); AND
3. Member has not received a liver transplant and is not on peritoneal dialysis.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Oxlumo (lumasiran) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
12/08/2020	New policy for Oxlumo created.
05/27/2022	Transferred to new template. Updated billing code. Updated references. Added increased fluid intake. In renewal, changed 'or stable kidney function' to 'and stable kidney function' and revised description.
10/18/2022	Changed initial approval duration from 12 months to 6 months. Updated and added references; updated criteria per expanded product labeling which addresses plasma oxalate and use in severe renal disease and hemodialysis populations; peritoneal dialysis remains excluded.
10/18/2023	

10. Ohio Administrative Code. (2022, July 18). 5160-26-03 Managed care: covered services. Retrieved February 22, 2023 from codes.ohio.gov.
11. Ohio Administrative Code. (2020, January 1). 5160-9-03 Pharmacy services: covered drugs and associated limitations. Retrieved February 22, 2023 from codes.ohio.gov.

Effective date: 07/01/2024
Revised date: 02/13/2024