CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Oxlumo (lumasiran)
BILLING CODE	J0224
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 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
3. Member has documentation of elevated urinary or plasma oxalate levels (UOx or POx); AND
4. Member had an inadequate response, intolerance, or contraindication to documented prior therapy with all of the following:
   a) At least a 90-day trial of Vitamin B6 (pyridoxine)
   b) Adequate trial of a calcium oxalate crystallization inhibitor (i.e., potassium citrate, sodium citrate, organophosphates, magnesium oxide)
   c) Increased fluid intake; AND
5. Member does not receive peritoneal dialysis (hemodialysis allowed); AND
6. Member has not received a liver transplant.
7. **Dosage allowed/Quantity limit:**

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; administered subQ**

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

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	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.

References:

1. Oxlumo (lumasiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals Inc; 2022.
2. 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.
3. Milliner DS, Harris PC, Sas DJ, et al. Primary Hyperoxaluria Type 1. 2002 Jun 19 [Updated 2022 Feb 10]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1283/
4. Gupta A, Somers MJG, Baum MA. Treatment of primary hyperoxaluria type 1. *Clin Kidney J*. 2022;15(Suppl 1):i9-i13. Published 2022 May 17. doi:10.1093/ckj/sfab232
5. Hulton SA, Groothoff JW, Frishberg Y, et al. Randomized Clinical Trial on the Long-Term Efficacy and Safety of Lumasiran in Patients With Primary Hyperoxaluria Type 1. *Kidney Int Rep*. 2021;7(3):494-506. Published 2021 Dec 11. doi:10.1016/j.ekir.2021.12.001
6. Hayes W, Sas DJ, Magen D, et al. Efficacy and safety of lumasiran for infants and young children with primary hyperoxaluria type 1: 12-month analysis of the phase 3 ILLUMINATE-B trial [published online ahead of print, 2022 Aug 1]. *Pediatr Nephrol*. 2022;10.1007/s00467-022-05684-1. doi:10.1007/s00467-022-05684-1
7. Michael M, Groothoff JW, Shasha-Lavsky H, et al. Lumasiran for Advanced Primary Hyperoxaluria Type 1: Phase 3 ILLUMINATE-C Trial [published online ahead of print, 2022 Jul 14]. *Am J Kidney Dis*. 2022;S0272-6386(22)00771-5. doi:10.1053/j.ajkd.2022.05.012

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