HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

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) 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)
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)

If all the above requirements are met, the medication will be approved for 6 months.

HAP CareSource™

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.

HAP 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	Added reference. Removed biopsy option for diagnosis confirmation. Removed urinary alkalinization trial requirement. Defined non-response to vitamin B6. Added no concurrent use with Rivfloza.
02/13/2024	Removed hyperhydration requirement.
06/25/2024	Removed specific level of oxalate reduction from B6 trial.

References:

1. Oxlumo (lumasiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals Inc; 2023.
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
8. Groothoff JW, Metry E, Deesker L, et al. Clinical practice recommendations for primary hyperoxaluria: an expert consensus statement from ERKNet and OxalEurope. *Nat Rev Nephrol*. 2023;19(3):194-211. doi:10.1038/s41581-022-00661-1

Effective date: 01/01/2025
Revised date: 06/25/2024