

Oxlumo® (lumasiran) Injection

When requesting Oxlumo® (lumasiran) injection, the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Oxlumo is indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients.

Coverage Guidelines

Primary Hyperoxaluria Type 1

The individual must meet ALL of the following criteria for initial authorization:

- Has had a genetic test confirming the diagnosis of Primary Hyperoxaluria Type 1 via identification of an alanine:glyoxylate aminotransferase gene (AGXT) mutation;
- Meets one of the following:
 - o Has a urinary oxalate excretion greater than or equal to 0.7 mmol/24 hours/1.73 meters²; OR
 - o Has a urinary oxalate:creatinine ratio above the age-specific upper limit of normal; OR
 - o Has a plasma oxalate level greater than or equal to 20 µmol/L;
- Has not previously received a liver transplant for Primary Hyperoxaluria Type 1;
- Oxlumo is prescribed by or in consultation with a nephrologist or urologist.

The individual must meet the following criteria for re-authorization:

- Is continuing to receive benefit from Oxlumo as determined by the most recent (i.e., within the past 6 months) objective measurement (e.g., reduced urinary oxalate excretion, decreased urinary oxalate:creatinine ratio, reduced plasma oxalate levels from baseline [i.e., prior to Oxlumo therapy], or improved or stabilized clinical signs/symptoms of Primary Hyperoxaluria Type 1 [e.g., nephrocalcinosis, formation of renal stones, renal impairment]).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Recommendation

Oxlumo Weight-Based Dosing Regimen

Body Weight	Loading Dose	Maintenance 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)

*Beginning 1 month after the last loading dose

References

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3. Primary Hyperoxaluria: MedlinePlus Genetics. U.S. National Library of Medicine; National Institutes of Health; Department of Health and Human Services. Available at: <https://medlineplus.gov/genetics/condition/primary-hyperoxaluria/#resources>. Updated November 8, 2021. Accessed on September 14, 2023.
4. Cochat P, Rumsby G. Primary hyperoxaluria. *N Engl J Med*. 2013;369(7):649-658.
5. Garrelfs SF, Frishberg Y, Hulton SA, et al. Lumasiran, an RNAi therapeutic for primary hyperoxaluria Type 1. *N Engl J Med*. 2021;384(13):1216-1226.
6. Sas DJ, Magen D, Hayes W, et al. Phase 3 trial of lumasiran for primary hyperoxaluria type 1: a new RNAi therapeutic in infants and young children. *Genet Med*. 2022;24(3):654-662.
7. Michael M, Groothoff JW, Shasha-Lavsky H, et al. Lumasiran for advanced primary hyperoxaluria type 1: phase 3 ILLUMINATE-C. *Am J Kidney Dis*. 2022 July 14. [Epub ahead of print].

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