Louisiana Medicaid
Lumasiran (Oxlumo®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for lumasiran (Oxlumo®).

Additional Point-of-Sale edits may apply.

*This agent may have **Black Box Warnings**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- The recipient has a diagnosis of primary hyperoxaluria type 1 (PH1); **AND**
- The diagnosis has been confirmed by **ONE** of the following: (must be **stated on the request**)
    - Genetic testing demonstrating mutation in the alanine:glyoxylate aminotransferase (AGXT) gene; **OR**
    - Liver biopsy demonstrating significantly decreased or absent alanine:glyoxylate aminotransferase (AGT) enzyme activity; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a nephrologist, urologist, or geneticist; **AND**
- The recipient has not received a liver transplant (must be **stated on the request**); **AND**
- If request is for a non-preferred agent **– ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet initial criteria; **AND**
- The recipient has not received a liver transplant (must be **stated on the request**); **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

References

Cochat P, Hulton SA, Acquaviva C, et. al. Primary hyperoxaluria Type 1: indications for screening and guidance for diagnosis and treatment. Nephrol Dial Transplant. 2012 May;27(5):1729-36.

Oxlumo (lumasiran) [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; October 2022. https://www.alnylam.com/sites/default/files/pdfs/OXLUMO-Prescribing-Information.pdf

UpToDate: Primary hyperoxaluria. Current through September 2022. www.uptodate.com

Revision / Date	Implementation Date
Policy Created / October 2022	April 2023