

Clinical Policy Title:	lumasiran
Policy Number:	RxA.676
Drug(s) Applied:	Oxlumo™
Original Policy Date:	02/23/2021
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Primary hyperoxaluria type 1 (PH1) (must meet all):

- Diagnosis of PH1 with one of the following (a or b):
 - Confirmed AGXT mutation;
 - Liver biopsy demonstrating absent or significantly reduced AGT activity;
- Documentation of one of the following (a or b):
 - Urinary oxalate excretion > 0.70 mmol/1.73 m² /24 h, confirmed on repeat testing;
 - Spot urinary oxalate-to-creatinine molar ratio greater than normal for age, confirmed on repeat testing;
- Estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m²;
- Member does not have a history of kidney or liver transplant;
- Member does not have systemic oxalosis;
- Member has made efforts to increase fluid intake to at least 3 L/day per 1.73 m² BSA;
- Concurrent use of pyridoxine or previous trial of at least 3 months of pyridoxine with no significant improvement observed.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Primary hyperoxaluria type 1 (must meet all):

- Member is currently receiving or has been treated with this medication within the past 120 days, excluding manufacturer samples;
- Improvement in urinary and plasma oxalate excretion from baseline;
- Member has no history of liver or kidney transplant.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

- Genetic and Rare Diseases Information Center. Primary hyperoxaluria type 1. Updated August 2024. Available at: <https://rarediseases.info.nih.gov/diseases/2835/primary-hyperoxaluria-type-1>. Accessed August 28, 2024.
- Milliner DS, Harris PC, Cogal AG, et al. Primary hyperoxaluria type 1. 2002 Jun 19 [Updated 2017 Nov 30]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2020. Available at: https://www.ncbi.nlm.nih.gov/books/NBK1283/pdf/Bookshelf_NBK1283.pdf.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/20/2021	03/09/2021
Policy was reviewed: 1. References were reviewed and updated.	12/10/2021	1/17/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.2: Updated to prescriber criteria to Endocrinologist and Hepatologist. 2. Continued Therapy Approval Criteria, II.A.3: Updated to include documented improvement of plasma oxalate levels. 3. References were reviewed and updated.	10/26/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed prescriber restrictions. 2. Removed dose restrictions. 3. Updated Continued therapy approval with the new verbiage containing 120 days lookback period. 4. Removed reauthorization requirement for toleration of therapy. 5. Updated approval duration verbiage. 6. References were reviewed and updated.	08/28/2024	9/13/2024
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025