Lumasiran (Oxlumo®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

Initial Requests:

- Molecular genetic test results demonstrating a pathogenic variant in the alanine:glyoxylate aminotransferase (AGXT) gene or liver enzyme analysis results demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity.
- Baseline urinary oxalate, urinary oxalate:creatinine ratio, or plasma oxalate testing results.

Continuation Requests:

- Chart notes or medical records demonstrating a positive response to therapy.

PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a geneticist, nephrologist, or urologist.

COVERAGE CRITERIA

Primary Hyperoxaluria Type 1 (PH1)

Authorization of 12 months may be granted for the treatment of primary hyperoxaluria type 1 (PH1) when all of the following criteria are met:

- Member has a diagnosis of PH1 confirmed by either of the following:
  - Molecular genetic test results demonstrating a pathogenic variant in the alanine:glyoxylate aminotransferase (AGXT) gene.

  - Liver enzyme analysis results demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity.
- Member has elevated urinary oxalate, urinary oxalate:creatinine ratio, or plasma oxalate levels prior to initiating therapy with the requested medication, per laboratory performing the test.
- Member has not previously received a liver transplant.
- The requested medication will not be used in combination with Rivfloza (nedosiran).

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members who meet all requirements in the coverage criteria section and demonstrate a positive response to therapy (e.g., decrease or normalization in urinary and/or plasma oxalate levels, improvement in kidney function).

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Oxlumo [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; April 2025.
2. Niaudet, P. Primary hyperoxaluria: Clinical features, diagnosis, and management. Waltham, MA. UpToDate. Last Modified September 30, 2025. https://www.uptodate.com/contents/primary-hyperoxaluria-clinical-features-diagnosis-and-management. Accessed October 20, 2025.
3. Milliner DS. The primary hyperoxalurias: an algorithm for diagnosis. Am J Nephrol 2005; 25:154.
4. Milliner DS, Harris PC, Sas DJ, et al. Primary Hyperoxaluria Type 1. 2002 Jun 19 [Updated 2024 Aug 15]. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1283/

EFFECTIVE DATE 7/31/2026

ID_CHS_2025