Reference number(s)
4395-A

Specialty Guideline Management
Oxlumo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Oxlumo	lumasiran

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[1]

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)[1-4]

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).

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/