CVS Caremark®

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| 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 Indications1

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 mutation in the alanine:glyoxylate aminotransferase (AGXT) gene or liver enzyme analysis results demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity.

#### Continuation requests:

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

## Coverage Criteria

### Primary Hyperoxaluria Type 1 (PH1)1-3

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 mutation in the alanine:glyoxylate aminotransferase (AGXT) gene.
  + Liver enzyme analysis results demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity.
* The requested medication will not be used in combination with 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; September 2023.
2. Niaudet, P. Primary hyperoxaluria. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2024.
3. Milliner DS. The primary hyperoxalurias: an algorithm for diagnosis. Am J Nephrol 2005; 25:154.