

Reference number(s)
4395-A

SPECIALTY GUIDELINE MANAGEMENT

OXLUMO (lumasiran)

POLICY

I. 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 Indication

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.

II. DOCUMENTATION

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

- A. 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.
- B. Chart notes or medical records demonstrating a positive response to therapy (for continuation requests).

III. CRITERIA FOR INITIAL APPROVAL

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:

- A. Member has a diagnosis of PH1 confirmed by either of the following:
 - 1. Molecular genetic test results demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene.
 - 2. Liver enzyme analysis results demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity.
- B. The requested medication will not be used in combination with nedosiran.

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

Reference number(s)
4395-A

1. Oxlumo [package insert]. Cambridge, MA: Anylam Pharmaceuticals, Inc; September 2023.
2. Niaudet, P. Primary hyperoxaluria. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2022.
3. Milliner DS. The primary hyperoxalurias: an algorithm for diagnosis. Am J Nephrol 2005; 25:154.