| 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: Molecular genetic tests showing a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene or liver enzyme analysis demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity.

### III. CRITERIA FOR INITIAL APPROVAL

**Primary hyperoxaluria type 1 (PH1)**
Authorization of 12 months may be granted for treatment of primary hyperoxaluria type 1 (PH1) when the member has a documented diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by either:
A. Molecular genetic test showing a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene.
B. Liver enzyme analysis demonstrating absent or significantly reduced alanine:glyoxulate aminotransferase (AGT) activity.

### IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members who meet all initial authorization criteria and the member's urinary and/or plasma oxalate has decreased or normalized since initiation of therapy.

### V. REFERENCES


1. Oxlumo [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; October 2022.
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.