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 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 all of the following criteria are met:

A. Member has a documented diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by a molecular genetic test showing a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene or liver enzyme analysis demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity.
B. Member has a pretreatment estimated glomerular filtration rate (eGFR) of ≥30 mL/min/1.73 m^2.

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

1. Oxlumo [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; December 2020.
2. Niaudet, P. Primary hyperoxaluria. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2020.
3. Milliner DS. The primary hyperoxalurias: an algorithm for diagnosis. Am J Nephrol 2005; 25:154.