AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Oxlumo		Page:	1 of 2
Effective Date:	11/13/2024		Last Review Date:	8/27/2024
Applies to:	☒Illinois ☐Florida Kids	☒New Jersey ☒Pennsylvania Kids	☒Maryland ☒Virginia	☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Oxlumo under the patient's prescription drug benefit.

Description:

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

Applicable Drug List:

Oxlumo

Policy/Guideline:

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).

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 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.

Criteria for 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).

Approval Duration and Quantity Restrictions:

Approval Duration: 12 months

Quantity Level Limit:

Medication	Standard Limit	FDA-recommended dosing
Oxlumo (lumasiran) 94.5 mg/0.5 mL single dose vial	4 vials per 90 days	For patients with body weight < 10 kg: 6 mg/kg once monthly for first 3 doses; 3 mg/kg once monthly for maintenance therapy For patients with body weight 10 to < 20 kg: 6 mg/kg once monthly for first 3 doses; 6 mg/kg once every 3 months for maintenance therapy For patients with body weight ≥ 20 kg: 3 mg/kg once monthly for first 3 doses; 3 mg/kg once every 3 months for maintenance therapy

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, 2022.
3. Milliner DS. The primary hyperoxalurias: an algorithm for diagnosis. Am J Nephrol 2005; 25:154.