

POLICY Document for OXLUMO

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria 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.

Brand Name	Generic Name	Dosage Form
Oxlumo	lumasiran	subcutaneous

Criteria for Approval for Administration in Outpatient Hospital Setting

This policy provides coverage for administration of Oxlumo in an outpatient hospital setting for up to 60 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Oxlumo in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- The member has experienced an adverse reaction that did not respond to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids or other pre-

medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after administration.

- The member is medically unstable (e.g., respiratory, cardiovascular, or renal conditions).
- The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of therapy AND the patient does not have access to a caregiver.
- Alternative administration sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
- The member is less than 14 years of age.

For situations where administration of Oxlumo does not meet the criteria for outpatient hospital administration, coverage for Oxlumo is provided when given in alternative sites such as; physician office, home, or ambulatory care.

Required Documentation

The following information is necessary to initiate the site of care prior authorization review (where applicable):

Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after administration

Medical records supporting the member is medically unstable

Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver

Records supporting alternative administration sites are greater than 30 miles from the member's home

Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

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

SECTION 1

1. Oxlumo [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; September 2023.

SECTION 2

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.