POLICY Document for OXLUMO (lumasiran)

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

CAREFIRST: OXLUMO

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

FDA-Approved Indication

Oxlumo is indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric (≥ 3 months) and adult patients.

All other indications are considered experimental/investigational and not medically necessary.

I. CRITERIA FOR INITIAL APPROVAL

Primary hyperoxaluria type 1 (PH1)
Authorization of 6 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.
C. Patient is not the recipient of a liver transplant
D. The medication was prescribed by or in consultation with a nephrologist, gastroenterologist, geneticist, urologist or physician specializing in the treatment of hyperoxaluria.
E. Dosing is consistent with product labeling (Adult: Loading dose of 3mg/kg/dose once monthly x 3 doses; Maintenance dose of 3mg/kg/dose every 3 months beginning 1 month after last loading dose.
Pediatric dosing:
Weight <10 kg
    a. **Loading dose:** 6 mg/kg/dose SUBQ once monthly for 3 doses.
    b. **Maintenance dosage:** 3 mg/kg/dose SUBQ once monthly; begin 1 month after last loading dose.
Weight 10 to <20 kg
    a. **Loading dose:** 6 mg/kg/dose SUBQ once monthly for 3 doses.
    b. **Maintenance dosage:** 6 mg/kg/dose SUBQ every 3 months; begin 1 month after last loading dose.
Weight ≥20 kg
    a. **Loading dose:** 3 mg/kg/dose SUBQ once monthly for 3 doses.
    b. **Maintenance dosage:** 3 mg/kg/dose SUBQ every 3 months; begin 1 month after last loading dose.

II. 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.

REFERENCES

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