

Oxlumo (lumasiran)
Effective 03/01/2025

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|------------------------------|---|---------------------|---|
| Plan | <input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange | Program Type | <input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| Benefit | <input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit | | |
| Specialty Limitations | N/A | | |
| Contact Information | Medical and Specialty Medications | | |
| | All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 |
| Exceptions | Non-Specialty Medications | | |
| | All Plans | Phone: 800-711-4555 | Fax: 844-403-1029 |

Overview

Oxlumo (lumasiran) is a HAO1-directed small interfering ribonucleic acid (siRNA) indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients.

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted all of the following criteria are met:

1. 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.

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Member meets ONE of the following:
 - a. Member's urinary oxalate excretion has decreased or normalized since initiating therapy
 - b. Member's plasma oxalate excretion has decreased or normalized since initiating therapy

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.
2. The following quantity limits apply:

| Drug Name | Quantity Limit |
|--|---------------------|
| Oxlumo 94.5mg/0.5mL subcutaneous injection | 4 vials per 90 days |

References

1. Milliner DS. The primary hyperoxalurias: an algorithm for diagnosis. *Am J Nephrol* 2005; 25:154.
2. Niaudet, P. Primary hyperoxaluria. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2020.
3. Oxlumo (lumasiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; September 2023.

Review History

05/19/2021 – Created and Reviewed at May P&T. Effective 07/01/2021.

12/11/2024 – Reviewed and updated at December P&T. Updated initial criteria to remove minimum eGFR requirement. Updated reauthorization criteria to allow for approval if the member’s plasma oxalate levels have decreased. Effective 03/01/2025.

