Mass General Brigham
Health Plan

# Oxlumo (lumasiran)
# Effective 07/01/2021

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| **Plan** | ☐ MassHealth UPPL<br>☒Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☒ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☐ Pharmacy Benefit<br>☒ Medical Benefit (NLX) | | |
| **Specialty Limitations** | N/A | | |
| **Contact Information** | **Specialty Medications** | | |
| | All Plans | Phone: 866-814-5506 | Fax: 866-249-6155 |
| | **Non-Specialty Medications** | | |
| | MassHealth | Phone: 877-433-7643 | Fax: 866-255-7569 |
| | Commercial | Phone: 800-294-5979 | Fax: 888-836-0730 |
| | Exchange | Phone: 855-582-2022 | Fax: 855-245-2134 |
| | **Medical Specialty Medications (NLX)** | | |
| | All Plans | Phone: 844-345-2803 | Fax: 844-851-0882 |
| **Exceptions** | N/A | | |

**Overview**
Oxlumo (lumasiran) is an RNA interface agent that decreases levels of glycolate oxidase (GO) enzyme by targeting the hydroxyacid oxidase 1 messenger ribonucleic acid (RNA) in hepatocytes for the treatment of primary hyperoxaluria type 1 (PH1) in pediatric and adult patients.

**Coverage Guidelines**
Authorization may be granted for members new to the plan who are currently receiving treatment with Oxlumo, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
**OR**
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

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.
2. Member has a pretreatment estimated glomerular filtration rate (eGFR) of ≥30 mL/min/1.73 $m^2$.

**Continuation of Therapy**
Reauthorization 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.

**Limitations**

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

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| Oxlumo 94.5mg/0.5mL subcutaneous injection | 4 vials per 90 days |

**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.


**Review History**

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