Mass General Brigham
Health Plan

Hyperoxaluria Agents
Oxlumo (lumasiran)
Effective 11/12/2024

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

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

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization will be granted when all the following criteria has been met, and documentation has been submitted:

1. Diagnosis of primary hyperoxaluria type 1
2. Prescriber is a specialist (e.g., nephrologist) or consult notes from a specialist's office are provided
3. Results from genetic testing showing mutations in the AGXT gene
4. Member's current weight (use to verify correct dosing)
5. Appropriate dosing

New members who are stable on Oxlumo® (lumasiran) can be approved after meeting reauthorization criteria.

Continuation of Therapy
Reauthorization by physician will need to meet the following criteria:

1. Documentation of positive response to therapy
2. Updated member weight (use to verify correct dosing)
3. Appropriate dosing

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

References

1. Lumasiran® [package insert on the internet]. Cambridge (MA): Alnylam, Inc.; 2020 Nov [cited 2021 Dec 20]. Available from: https://www.oxlumo.com/.
2. National Organization for Rare Disorders. Primary hyperoxaluria [webpage on the Internet]. Danbury (CT): National Organization for Rare Disorders; 2020 [cited 2021 Mar 2]. Available from: https://rarediseases.org/rare-diseases/primary-hyperoxaluria.
3. Niaudet P. Primary hyperoxaluria. In: Mattoo TK (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Dec 20]. Available from: http://www.utdol.com/utd/index.do.

Review History

02/08/2023 - Reviewed and created for Feb P&T; matched MH UPPL. Created criteria to be in compliance with Masshealth unified formulary requirements (Effective 4/1/23).
05/10/23 – Reviewed and updated for P&T. Approval duration as been changed to 12 months. Effective 6/5/23.
10/9/24 – Reviewed and updated for P&T. Oxlumo has been combined under Hyperoxaluria Agents class. Formatting updates made to policy. No clinical changes. Effective 11/12/24