

Hyperoxaluria Agents
Oxlumo (lumasiran)
Effective 09/01/2025

Plan	<input checked="" type="checkbox"/> MassHealth <input 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 Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 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:

1. Diagnosis of primary hyperoxaluria type 1 (PH1)
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. Dosing is appropriate per FDA labeling

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. Dosing is appropriate per FDA labeling

Limitations

1. Initial authorizations 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.uttdol.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 has 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

8/13/25 – Reviewed and updated for P&T. Minor formatting updates. Effective 9/1/25

