Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Oxlumo® (lumasiran)

Effective: January 13, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0965

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0965

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration - Approved Indications

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

Clinical Guideline Coverage Criteria

The plan may authorize the coverage of Oxlumo for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of primary hyperoxaluria type 1 confirmed by **one (1)** of the following:
    a. Molecular genetic test showing a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene
    b. Liver enzyme analysis demonstrating absent or significantly reduced alanine: glyoxylate aminotransferase (AGT) activity

AND

2. Prescribed by, or in consultation with, an endocrinologist, nephrologist or a specialist with experience managing primary hyperoxaluria

AND

3. Documentation the patient has not had a liver transplantation

Reauthorization Criteria

1. Documented diagnosis of primary hyperoxaluria type 1 confirmed by **one (1)** of the following:
    a. Molecular genetic test showing a mutation in the alanine: glyoxylate aminotransferase (AGXT) gene
    b. Liver enzyme analysis demonstrating absent or significantly reduced alanine: glyoxylate aminotransferase (AGT) activity.

AND

2. Prescribed by, or in consultation with, an endocrinologist, nephrologist or a specialist with experience managing primary hyperoxaluria

AND

3. Documentation the patient has not had a liver transplantation

AND

4. Documentation of a positive clinical response as evidenced by at least **ONE (1)** of the following:
    a. Decreased or normalized urinary oxalate concentration compared to pre-treatment baseline
    b. Decreased or normalized plasma oxalate concentration compared to pre-treatment baseline

Limitations

- The plan will not cover Oxlumo in patients with primary hyperoxaluria type 2 or type 3.
- Authorizations for Oxlumo will be provided in 12-month intervals.
- Patients new to the plan stable on Oxlumo should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0224	Injection, lumasiran, 0.5mg

References

1. Cochat P, Hulton SA, Acquaviva C et al. Primary hyperoxaluria type 1: indications for screening and guidance for diagnosis and treatment. Nephrol Dial Transplant. 2012; 27(5):1729-36.
2. Garrelfs SF, et al. Lumasiran, an RNAi Therapeutic for Primary Hyperoxaluria Type 1. N Engl J Med. 2021;384:1216-1226.
3. Hoppe B, Beck BB, Milliner DS. The primary hyperoxalurias. Kidney Int 2009; 75:1264.
4. Bhasin B, et al. Primary and secondary hyperoxaluria: understanding the enigma. World J Nephrol. 2015;4(2):235-44.
5. Oxlumo (lumasiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; September 2023.

Approval And Revision History

April 19, 2023: year: Reviewed by the Medical Policy Approval Committee (MPAC)

May 9, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023
- Administrative update: April 2023 added Medical Benefit Drugs to title and updated MATogether and RITogether fax numbers to 617-673-0939
- May 17, 2023: Annual review added “and plasma oxalate levels in” to FDA approved indications in overview effective July 1, 2023
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- February 13, 2024: Removed the requirement of a pretreatment estimated glomerular filtration rate (eGFR) of ≥ 30 mL/min/1.73 m2. Expanded response to therapy to be a decreased or normalized urinary or plasma oxalate concentrations compared to pre-treatment baseline. Minor wording updates. Clarified duration of approval and how patients new to the plan stable on Oxlumo should be reviewed (effective March 1, 2024).
- January 14, 2025: No changes (eff 1/14/25)
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- January 13, 2026: No changes
- February 2026: Administrative update to remove Carelink from template.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update

Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.