Corporate Medical Policy

Lumasiran (Oxlumo™)

File Name:	lumasiran_oxlumo
Origination:	2/2021
Last CAP Review:	n/a
Next CAP Review:	1/2022
Last Review:	2/2021

Description of Procedure or Service

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

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for lumasiran (Oxlumo) when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Lumasiran (Oxlumo) is covered

Initial Therapy

Lumasiran (Oxlumo) is considered medically necessary for the treatment of primary hyperoxaluria type 1 (PH1) in pediatric and adult patients when the following criteria are met:

1. The patient's diagnosis of PH1 is confirmed by ONE of the following:
    a. Molecular genetic testing demonstrating *AGXT* gene mutation; **OR**
    b. Liver biopsy demonstrating AGT deficiency; **AND**
2. The patient has had metabolic testing demonstrating ONE of the following:
    a. Elevated urinary oxalate excretion as measured by body surface area-normalized daily urinary oxalate output (e.g., greater than 1 mmol/1.73 m^2 per day [90 mg/1.73 m^2 per day] or greater than the upper limit of normal); **OR**
    b. Elevated urinary oxalate excretion as measured by urinary oxalate:creatinine ratio (e.g., above the age-specific upper limit of normal); **OR**

   c. Elevated plasma oxalate concentration (e.g., greater than the upper limit of normal); **AND**
3. The patient does not have secondary causes of hyperoxaluria (e.g., excessive dietary intake of oxalate, gastric bypass surgery, IBD, other intestinal disorders, other unknown causes); **AND**
4. The patient has an eGFR greater than or equal to 30 mL/minute/1.73m^2; **AND**
5. The patient has not had a previous kidney and/or liver transplant; **AND**
6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist, urologist, geneticist) or has consulted with a specialist in the area of the patient's diagnosis.

Initial authorization: 180 days (6 months)

Continuation Therapy

Continuation of treatment with lumasiran (Oxlumo) beyond 6 months after initiation of therapy, and every 12 months thereafter, is considered medically necessary for the treatment of primary hyperoxaluria type 1 (PH1) when the following criteria are met:

1. The patient has been previously approved for lumasiran (Oxlumo) through Blue Cross NC initial criteria for approval; **OR**
2. The patient would have met initial criteria for approval at the time therapy was initiated; **AND**
3. The patient has demonstrated a positive clinical response to lumasiran (Oxlumo) therapy as demonstrated by ONE of the following:
   a. Reduction from baseline in one or more of the following laboratory parameters:
      i. 24-hour urinary oxalate excretion, **or**
      ii. Spot urinary oxalate:creatinine ratio, **or**
      iii. Plasma oxalate concentration; **OR**
   b. Improvement, stabilization, or slowed worsening of one or more clinical manifestations of PH1 (e.g., eGFR, nephrocalcinosis, renal stone events, systemic oxalosis, renal impairment); **AND**
4. The patient has not had a previous kidney and/or liver transplant; **AND**
5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist, urologist, geneticist) or has consulted with a specialist in the area of the patient's diagnosis.

When Lumasiran (Oxlumo) is not covered

Lumasiran (Oxlumo) is considered **investigational** and therefore not covered when the above criteria are not met, and for all other indications not listed above.

Policy Guidelines

The recommended dosing for Oxlumo is based on actual body weight and consists of loading doses followed by maintenance doses, administered subcutaneously by a healthcare professional. Maintenance dosing is initiated 1 month after the last loading dose. See Table 1 below for Oxlumo dosing recommendations based on body weight.

Table 1.

Body Weight	Loading Dose	Maintenance Dose
< 10 kg	6 mg/kg once monthly for 3 doses	3 mg/kg once monthly
10 kg to < 20 kg	6 mg/kg once monthly for 3 doses	6 mg/kg once every 3 months (quarterly)
≥ 20 kg	3 mg/kg once monthly for 3 doses	3 mg/kg once every 3 months (quarterly)

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *C9074, C9399, J3490, J3590*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Alnylam Pharmaceuticals, Inc. Lumasiran (Oxlumo) injection for subcutaneous use. Highlights of prescribing information. November 2020. Available at: https://www.alnylam.com/wp-content/uploads/pdfs/OXLUMO-Prescribing-Information.pdf. Last accessed February 2021.

U.S. Food and Drug Administration. FDA approves first drug to treat rare metabolic disorder. November 23, 2020. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-treat-rare-metabolic-disorder#:~:text=Approval%20is%20for%20primary%20hyperoxaluria,and%20loss%20of%20kidney%20function&text=Today%2C%20the%20U.S.%20Food%20and,)%2C%20a%20rare%20genetic%20disorder. Last accessed February 2021.

Cochat P. Primary hyperoxaluria type 1. Kidney Int. 1999 Jun;55(6):2533-47. (PMID: 10354306)

Medical Director review 2/2021

Policy Implementation/Update Information

2/23/21 New policy developed. Oxlumo is considered medically necessary for the treatment of primary hyperoxaluria type 1 (PH1) in pediatric and adult patients when specific medical criteria and guidelines are met. Added HCPCS codes C9399, J3490, and J3590 to Billing/Coding section. References added. Medical Director review 2/2021. (krc)

3/31/21 Added HCPCS code C9074 to Billing/Coding section effective 4/1/2021. (krc)