RX.PA. 042.MPC *Oxlumo® (lumasiran)*

PURPOSE

Oxlumo® is a 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. Maryland Physicians Care requires Prior Authorization for its use.

Primary Hyperoxaluria Type 1 (PH1) - Approve Oxlumo if the member meets **all** the following conditions:

A. Initial Therapy

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

b. Diagnosis of primary hyperoxaluria type 1 and clinical documentation to confirm diagnosis based on the following:
   i. Molecular genetic test showing mutation in the alanine:glyoxylate aminotransferase (AGXT) gene
   OR
   ii. Liver biopsy showing significantly reduced or absent alanine:glyoxylate aminotransferase (AGT) enzyme activity

AND

c. Documentation of the following:
   i. Elevated plasma oxalate concentration
   AND
   ii. Elevated urinary oxalate excretion

AND

d. Member has pretreatment glomerular filtration rate (GFR) of ≥ 30 mL/min/1.73m^2
AND

e. Member has no documented history of liver transplant

f. Member must be referred to the Maryland Department of Health Rare and Expensive Case Management (REM) program

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Oxlumo will be considered investigational or experimental for any other use and will not be covered.

D. Member Currently Treated with Oxlumo (continuation of therapy):

MPC Renewal:

a. Member has a documented positive clinical response to therapy as determined by the prescriber.
b. Member must have documentation of decreased urinary oxalate excretion compared to baseline
c. Member must have documentation of decreased plasma oxalate concentration compared to baseline
d. Must have documentation that member has not received a liver transplant
e. Prescribed by, or in consultation with a nephrologist, endocrinologist or a specialist with experience in managing primary hyperoxaluria

Non-MPC Renewal:

a. Members who have previously been taking Oxlumo and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria)
b. Member has not been receiving medication samples for Oxlumo; AND
c. Provider has a documented clinical response of the member's condition which has stabilized or improved compared to baseline.

Approval Duration:

A. Initial Therapy: Approve for 6 months
B. Continuation of Therapy: Approve for 1 year

CPT Code	Description
J0224	Injection, lumasiran, 0.5mg

References:

1. Oxlumo® injection [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals Inc; November 2020.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Selected Revision *Addition of MPC vs Non-MPC Renewal Criteria*	*09/2022*
Annual Review and J-code update	*02/2022*
Addition of dosing requirements and off-label restrictions	
P&T Review	*08/2021*