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 hyperoxaluaria
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 alanaine:glycoxylate aminotransfersase (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

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):

a. Documented positive treatment response to therapy:
   i. Decreased urinary oxalate excreation

ii. Decreased plasma oxalate concentration

And

b. Documentation member has not received a liver transplant

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
Annual Review and J-code update	*02/2022*
Addition of dosing requirements and off-label restrictions	
P&T Review	*08/2021*