PART B PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation
Oxlumo (lumasiran) will be approved when ALL of the following are met:

1. The patient has a diagnosis of primary hyperoxaluria type 1 (PH1) [medical record documentation required];
   AND
2. The diagnosis has been confirmed by at least one of the following [medical record documentation required]:
   a. Molecular genetic testing demonstrating AGXT gene mutation
      OR
   b. Liver biopsy demonstrating alanine-glyoxylate aminotransferase (AGT) deficiency
   AND
3. The requested medication will be used to lower urinary oxalate levels
   AND
4. The patient has an eGFR greater than or equal to 30 mL/minute/1.73 m2 [medical record documentation required]
   AND
5. The patient has NOT had a previous liver transplant
   AND
6. The patient does NOT have any FDA labeled contraindications to the requested medication
   AND
7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist, gastroenterologist, urologist, geneticist) or has consulted with a specialist in the area of the patient's diagnosis

Length of approval: 12 months

Renewal Evaluation
Oxlumo (lumasiran) will be approved when ALL of the following are met:

1. ONE of the following:
   a. The patient was approved through Blue Cross NC initial criteria for approval
      OR
   b. The patient would have met initial criteria for approval at the time they started therapy
   AND
2. The patient has demonstrated a positive clinical response while using the medication, as demonstrated by improvement, stabilization, or slowed worsening of disease [e.g., reduction from baseline in laboratory parameters (e.g., 24-hour urinary oxalate excretion, spot urinary oxalate:creatinine ratio, plasma oxalate concentration), improvement/stabilization/slowed worsening of clinical manifestations (e.g., eGFR, nephrocalcinosis, renal stone events, systemic oxalosis, renal impairment)] [medical record documentation required]
   AND
3. The patient has NOT had a previous liver transplant
   AND
4. The patient does NOT have any FDA labeled contraindications to the requested medication
   AND

5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist, gastroenterologist, urologist, geneticist) or has consulted with a specialist in the area of the patient's diagnosis

Length of approval: 12 months

NOTES:

- Length of approval may be shorter due to provider network participation status.
- Coverage of one Medicare Part B Prior Authorization medication could equate to multiple medication authorizations when they share the same Medicare Part B Prior Authorization criteria.

Revision History

June 2024 policy creation for September 12, 2024 implementation.