AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Oxlumo® (lumasiran) **(Pharmacy)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code:** _____

Weight: _____ **Date:** _____

Recommended Dosage:

- Loading dose: 3 mg/kg/dose once monthly for 3 doses. Maintenance dose: 3 mg/kg/dose every 3 months, beginning 1 month after last loading dose
- Oxlumo 94.5 mg/0.5 mL single-dose vial for injection: 4 vials every month for 3 doses then every 3 months thereafter

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Must be prescribed by a Geneticist, Nephrologist or Urologist with expertise in the diagnosis and treatment of primary hyperoxaluria type 1 (PH1)

(Continued on next page)

- ❑ Member has a definitive diagnosis of PH1 confirmed by **ONE** of the following **(must submit documentation)**:
  - ❑ Member has a biallelic pathogenic mutation in the alanine:glyoxylate aminotransferase (AGXT) gene as identified on molecular genetic testing
  - ❑ Identification of alanine:glyoxylate aminotransferase (AGT) enzyme deficiency on liver biopsy
- ❑ Member has signs and symptoms of PH1 (e.g., recurrent kidney stones, urolithiasis, infantile oxalosis, failure to thrive and renal failure, nephrocalcinosis associated with decreased GFR, oxalate crystals in any biological fluid or tissue, increased serum creatinine with calcium oxylate (CaOx) stones, CaOx tissue deposits, renal failure of unknown causes)
- ❑ Member has **ONE** of the following **(must submit lab documentation)**:
  - ❑ Increased urinary oxalate excretion (i.e., greater than 0.7 mmol/1.73 m^2 per day [90 mg/1.73 m^2 per day])
  - ❑ Increased urinary oxalate:creatinine ratio relative to normative values for age
- ❑ Member does **NOT** have severe kidney damage (eGFR <30 mL/min/1.73 m^2), is **NOT** receiving hemodialysis and has **NOT** previously received a liver or kidney transplant
- ❑ Provider has submitted labs documenting member's current 24-hour urinary oxalate excretion (corrected for BSA) _____
- ❑ Provider has submitted member's baseline plasma oxylate levels _____
- ❑ Member does **NOT** have secondary causes of hyperoxaluria (e.g., diet with excessive intake of oxylate, gastric bypass surgery, Irritible Bowel Disease, other intestinal disorders)
- ❑ Requested dosing is in accordance with the United States Food and Drug Administration approved labeling

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Provider has submitted medical records (i.e., chart notes, laboratory values) documenting a positive clinical response to therapy from pre-treatment baseline (i.e., decreased urinary oxalate concentrations, decreased urinary oxalate:creatinine ratio, decreased plasma oxalate concentrations)
- ❑ Member does **NOT** have severe kidney damage (eGFR <30 mL/min/1.73 m^2), is **NOT** receiving hemodialysis and has **NOT** received a liver or kidney transplant

Medication being provided by Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan
If a drug is non-formulary on a Plan, documentation of medical necessity will be required.
*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****
****Previous therapies will be verified through pha rmacy paid claims or submitted chart notes.****