

SENTARA COMMUNITY PLAN (MEDICAID)

MEDICAL 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 1-844-305-2331. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If information provided is not complete, correct, or legible, authorization can be delayed.

Drug Requested: Oxlumo® (lumasiran) (J0224) (Medical)

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

Member Name: _____

Member Sentara #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

- ☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage:

Oxlumo		
Body Weight	Loading Dose	Maintenance Dose
Less than 10 kg	6 mg/kg once monthly for 3 doses	3 mg/kg once monthly, beginning 1 month after the last loading dose
10 kg to less than 20 kg	6 mg/kg once monthly for 3 doses	6 mg/kg once every 3 months (quarterly), beginning 1 month after the last loading dose
20 kg and above	3 mg/kg once monthly for 3 doses	3 mg/kg once every 3 months (quarterly), beginning 1 month after the last loading dose

Max Units (per dose and over time) [HCPS Unit]:

- **Oxlumo:** 345 mg every month for 3 doses then every 3 months thereafter; 1 vial (94.5 mg/0.5 mL) = 189 billable units

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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 or in consultation with a geneticist, nephrologist, or urologist
- ☐ Member has not had a liver transplant
- ☐ Medication will not be used in combination with other oxalate reducing agents
- ☐ Member has a definitive diagnosis of primary hyperoxaluria type 1 (PH1) as 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 a baseline for one or more of the following **(must submit lab documentation)**:
 - ☐ Urinary oxalate excretion level (corrected for BSA)
 - ☐ Spot urinary oxalate: creatinine ratio
 - ☐ Estimated glomerular filtration rate (eGFR)
 - ☐ Plasma oxalate level

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.

- ☐ Member continues to meet the relevant criteria identified in the initial criteria
- ☐ Member has an absence of unacceptable toxicity from the drug
- ☐ Member is being continuously monitored for a beneficial response to therapy

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Medication being provided by (check applicable box(es) below):

☐ Physician's office OR ☐ Specialty Pharmacy – PropriumRx

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****