

# SENTARA HEALTH PLANS

## 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 1-800-750-9692.** 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:** (Select drug below)

**Oxlumo**<sup>®</sup> (lumasiran)

**Rivfloza**<sup>™</sup> (nedosiran)

**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: \_\_\_\_\_

DEA OR NPI #: \_\_\_\_\_

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

Drug Name/Form/Strength: \_\_\_\_\_

Dosing Schedule: \_\_\_\_\_ Length of Therapy: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ ICD Code, if applicable: \_\_\_\_\_

Weight: \_\_\_\_\_ Date: \_\_\_\_\_

### **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

(Continued on next page)

Rivfloza		
Age	Body Weight	Dosing Regimen
Adults and adolescents 12 years and older	Greater than or equal to 50 kg	160 mg once monthly (prefilled syringe, 1 mL)
	Less than 50 kg	128 mg once monthly (prefilled syringe, 0.8 mL)
Children 9 to 11 years	Greater than or equal to 50 kg	160 mg once monthly (prefilled syringe, 1 mL)
	Less than 50 kg	3.3 mg/kg once monthly, not to exceed 128 mg (vial, dose volume rounded to nearest 0.1 mL)

**Quantity Limits:**

- Oxlumo: N/A
- Rivfloza 80 mg vial: 2 vials per month
- Rivfloza 128 mg prefilled syringe: 1 syringe per month
- Rivfloza 160 mg prefilled syringe: 1 syringe per month

**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)
- Member has a definitive diagnosis of PH1 confirmed by biallelic pathogenic mutation in the alanine:glyoxalate aminotransferase (AGXT) gene as identified on molecular genetic testing (**must submit documentation**)
- Member has signs and symptoms attributed to PH1 such as recurrent calcium oxalate (CaOx) kidney stones, urolithiasis, infantile oxalosis, failure to thrive and renal failure in an infant <12 months, nephrocalcinosis associated with decreased GFR, oxalate crystals in any biological fluid or tissue, increased serum creatinine with calcium oxalate (CaOx) stones, CaOx tissue deposits, renal failure of unknown causes (**must submit test results or medical chart notes confirming symptoms**)
- Provider must submit documentation to confirm member meets **ONE** of the following (**must submit lab documentation**):
  - Member had failure to achieve normalization of urinary oxalate (UOx) excretion levels after  $\geq 3$  months of therapy with pyridoxine (vitamin B6) dosed at 5 mg/kg/day, alkalinizing agents (potassium citrate, sodium citrate, neutral phosphate; etc.) and hyperhydration and will continue those therapies while taking the requested medication
  - Member's genetic assessment reveals a mutation consistent with pyridoxine (vitamin B6) non-responsive PH1

(Continued on next page)

- Member has **ONE** of the following (**must submit lab documentation**):
  - Increased urinary oxalate excretion (i.e. greater than 0.7 mmol/1.73 m<sup>2</sup> per day [90 mg/1.73 m<sup>2</sup> 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<sup>2</sup>), is **NOT** receiving hemodialysis and has **NOT** previously received a liver or kidney transplant
- Provider has submitted lab test results documenting member's current 24-hour urinary oxalate excretion (corrected for BSA): \_\_\_\_\_
- Provider has submitted lab test results documenting member's baseline plasma oxalate levels: \_\_\_\_\_
- Member does **NOT** have secondary causes of hyperoxaluria (e.g., diet with excessive intake of oxalate, gastric bypass surgery, Irritable Bowel Disease, other intestinal disorders)
- Medication will **NOT** be used in combination with other urinary oxalate reducing agents (i.e., lumasiran, nedosiran)
- 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.

- Member continues to meet all initial authorization criteria
- Provider has submitted current medical chart notes and laboratory values documenting a positive clinical response to therapy (i.e., improvement in nephrocalcinosis, decreased formation of renal stones) as well as a clinically significant reduction from pre-treatment baseline of urinary oxalate concentration (corrected for BSA), urinary oxalate:creatinine ratio, or plasma oxalate concentrations

**Medication being provided by Specialty Pharmacy – Proprium Rx**

***\*\*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.\****