SENTARA COMMUNITY PLAN
(MEDICAID)

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®** (lumasiran)	❑ **Rivfloza™** (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

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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 ≥ 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

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- ❑ 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 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.