SENTARA HEALTH PLANS

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 1-844-668-1550**. 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**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: (Select drug below)

❑ **Oxlumo®** (lumasiran) **J0224**	❑ **Rivfloza™** (nedosiran) **J3490**

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 Form/Strength: _____

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

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

❑ 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.

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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
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)

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
- **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)**

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- ❑ 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
- ❑ 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

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Medication being provided by: Please check applicable box below.

- ❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan'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***