Generic Name: nedosiran

Therapeutic Class or Brand Name: Rivfloza™

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

VSI Excluded Drugs: Rivfloza™ (nedosiran)

Date of Origin: 7/22/2024

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of primary hyperoxaluria type 1 (PH1) AND must meet all criteria listed:
   A. Diagnosis of PH1 confirmed by genetic testing.
   B. Documentation of eGFR ≥ 30 mL/min/1.73 m^2.
   C. Age 9 years or older.
   D. Documentation of at least two urine oxalate excretion assessments >1.5 times the upper limit of normal (i.e. >1.5 mmol/1.73m^2/day).
   E. Documented treatment failure of or contraindication to ALL of the following for at least 6 months each:
      i. Hyperhydration (3.5-4 liters per day for adults, or 2-3 liters/m^2 BSA for children)
      ii. Pyridoxine (vitamin B6) at a titrated dose (maximum recommended dose of 5 mg/kg)
      iii. Oral potassium citrate at a dosage of 0.1-0.15 g/kg
   F. Documentation of clinically significant phenotype burden consistent with PH1, characterized by active stone disease and/or nephrocalcinosis and/or renal impairment.

II. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

III. Drug is prescribed by or in consultation with a hepatologist, gastroenterologist, or urologist.

IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Prior kidney or liver transplant
- Kidney or liver transplant planned in next 6 months

- Current or planned dialysis

OTHER CRITERIA

- **Table 1: RIVFLOZA™ Dose Regimen in Adults and Pediatric Patients (9 years of age and older)**

Age	Body Weight	Dosing Regimen
Adults and adolescents 12 years and older	Greater than or equal to 50 kg	160 mg once monthly (Pre-filled Syringe, 1 mL)
	Less than 50 kg	128 mg once monthly (Pre-filled Syringe, 0.8 mL)
Children 9 to 11 years	Greater than or equal to 50 kg	160 mg once monthly (Pre-filled 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 / DAYS SUPPLY RESTRICTIONS

- 1 prefilled syringe per 30 days.
    - Nedosiran is available in 80 mg (0.5 mL), 128 mg (0.8 mL), and 160 mg (1 mL) single-dose prefilled syringes.

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months, with an updated letter of medical necessity or progress notes showing improvement or maintenance with the medication. Cessation recommended if urine oxalate remains above 1.5x ULN, if there is less than a 30% reduction of urine oxalate, if there is deterioration of clinical condition, if there is evidence of serious adverse event, or if eGFR falls below 30 mL/min/1.73 m^2.

APPENDIX

N/A

REFERENCES

1. Rivfloza™. Prescribing Information. Novo Nordisk; September 2023. Accessed July 13, 2024. https://www.novo-pi.com/rivfloza.pdf
2. National Kidney Foundation. Primary hyperoxaluria type 1. Kidney.org. Accessed July 13, 2024. https://www.kidney.org/atoz/content/primary-hyperoxaluria-type-1.
3. Baum, MA, et. al., PHYOX2: a pivotal randomized study of nedosiran in primary hyperoxaluria type 1 or 2. *Kidney International*. 2023;103,207-217. doi: https://doi.org/10.1016/j.kint.2022.07.025.

4. Groothoff, J, et. al., Nedosiran Safety and Efficacy in PH1: Interim Analysis of PHYOX3. *Kidney International Reports*. 2024;9(5):1387-1396. doi: https://doi.org/10.1016/j.ekir.2024.02.1439.
5. Groothoff, J.W., et al. Clinical practice recommendations for primary hyperoxaluria: an expert consensus statement from ERKNet and OxalEurope. *Nat Rev Nephrol* 2023;19,194–211. https://doi.org/10.1038/s41581-022-00661-1.