

Applicable Drugs: Rivfloza (nedosiran)

Preferred: N/A

Non-preferred: N/A

VSI Excluded Drugs: Rivfloza (nedosiran)

Date of Origin: 7/22/2024

Date Last Reviewed / Revised: 12/30/2025

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 $\text{eGFR} \geq 30 \text{ mL/min/1.73 m}^2$.
 - C. Age 2 years or older.
 - D. Documentation of at least two urine oxalate excretion assessments >1.5 times the upper limit of normal (i.e. $>1.5 \text{ mmol/1.73m}^2/\text{day}$).
 - 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. Drug is prescribed by or in consultation with a gastroenterologist, geneticist, or urologist.
- III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- 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 (2 years of age and older)

	Body weight		
	Less than 39 kg	39 kg to less than 50 kg	50 kg and above
Age 2 to less than 12 years	3.3 mg/kg	128 mg	160 mg
Age 12 years and older	128 mg		160 mg

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 m².

APPENDIX

N/A

REFERENCES

- Rivfloza™. Prescribing Information. Novo Nordisk; March 2025. Accessed December 30, 2025. <https://www.novo-pi.com/rivfloza.pdf>
- National Kidney Foundation. Primary hyperoxaluria type 1. Kidney.org. Accessed December 30, 2025. <https://www.kidney.org/atoz/content/primary-hyperoxaluria-type-1>.
- 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>.
- 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>.

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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>.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.