CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Rivfloza (nedosiran)
BENEFIT TYPE	Medical or Pharmacy
STATUS	Prior Authorization Required

Rivfloza, approved by the FDA in 2023, is an LDHA-directed small interfering RNA indicated to lower urinary oxalate levels in children 2 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ≥ 30 mL/min/1.73 m^2.
PH1, which is caused by mutations of the AGXT gene, is a rare autosomal recessive disease that mainly affects the kidneys. It results from buildup of oxalate, which normally is filtered through the kidneys and excreted in the urine. Stone formation (calcium oxalate) in the kidneys and urinary tract occurs, as well as elevated levels of calcium in the kidneys. Eventually, if kidney function declines far enough, oxalate can start to accumulate in other body tissues, leading to a variety of problems (systemic oxalosis).

Rivfloza (nedosiran) will be considered for coverage when the following criteria are met:

Primary Hyperoxaluria Type 1 (PH1)

For **initial** authorization:

1. Member is at least 2 years of age; AND
2. Medication must be prescribed by or in consultation with a urologist or nephrologist; AND
3. Member has a diagnosis of primary hyperoxaluria type 1 confirmed by genetic testing that shows a mutation in the AGXT gene; AND
4. Member has documentation of elevated urinary oxalate levels (24-hour Uox excretion ≥0.7 mmol (per 1.73 m2 body surface area [BSA] in age <18 years)) based on at least 2 assessments; AND
5. Member has an eGFR ≥ 30 mL/min/1.73 m^2; AND
6. Member has had an inadequate response to vitamin B6 (pyridoxine) after at least 3 months on optimal dose; AND
7. Member has not received a liver transplant; AND
8. Rivfloza will not be used in combination with Oxlumo.
9. **Dosage allowed/Quantity limit:** Administer subQ once per month as below:

	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

QL: 1 syringe/vial per 28 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show reduced level of urinary oxalate (Uox) excretion compared to baseline; AND
2. Member's eGFR remains ≥ 30 mL/min/1.73 m^2; AND
3. Member has not received a liver transplant.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Rivfloza (nedosiran) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/03/2023	New policy for Rivfloza created.
02/13/2024	Removed hyperhydration requirement.
06/25/2024	Removed specific level of oxalate reduction from B6 trial.
06/09/2025	Updated age limit and dosing per label expansion.

References:

1. Rivfloza [prescribing information]. Pyramid Laboratories; 2025.
2. Baum MA, Langman C, Cochat P, et al. PHYOX2: a pivotal randomized study of nedosiran in primary hyperoxaluria type 1 or 2. *Kidney Int*. 2023;103(1):207-217. doi:10.1016/j.kint.2022.07.025
3. Groothoff JW, Metry E, Deesker L, et al. Clinical practice recommendations for primary hyperoxaluria: an expert consensus statement from ERKNet and OxalEurope. *Nat Rev Nephrol*. 2023;19(3):194-211. doi:10.1038/s41581-022-00661-1

Effective date: 01/01/2026
Revised date: 06/09/2025