

PHARMACY POLICY STATEMENT

Mississippi Medicaid

| | |
|---------------------|------------------------------|
| DRUG NAME | Rivfloza (nedosiran) |
| BENEFIT TYPE | Medical |
| 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 \geq 30 mL/min/1.73 m².

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 \geq 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 \geq 30 mL/min/1.73 m²; 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 m²; 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.

TrueCare 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. |
| 06/25/2024 | Removed specific level of oxalate reduction from B6 trial. |
| 06/09/2025 | Updated age limit and dosing per label expansion. |
| 11/03/2025 | Removed hyperhydration requirement. |

References:

1. Rivfloza [prescribing information]. Pyramid Laboratories; 2023.
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: 04/01/2026

Revised date: 11/03/2025