

Effective Date: 8/1/2024
Reviewed: 5/24, 7/25, 7/26
Scope: Medicaid

Rivfloza (nedosiran)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Rivfloza is 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 of greater than or equal to 30 mL/min/1.73 m².

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Primary hyperoxaluria type 1 (PH1)

Authorization of 6 months may be granted for the treatment of primary hyperoxaluria type 1 (PH1) when all of the following criteria are met:

- A. The medication must be prescribed by, or in consultation with, a specialist in genetics, nephrology or urology.
- B. Member is 2 years of age or older.
- C. Documentation that the member has a diagnosis of PH1 confirmed by either of the following:
 1. Molecular genetic test results demonstrating a mutation in the alanine: glyoxylate aminotransferase (AGXT) gene.
 2. Liver enzyme analysis results demonstrating absent or significantly reduced alanine: glyoxylate aminotransferase (AGT) activity.
- D. Documentation that the member has not had a kidney or liver transplant.
- E. Documentation that the concurrent use of pyridoxine OR previous trial of at least 3 months of pyridoxine with no significant improvement observed (e.g. <30% reduction in urine oxalate concentration after at least 3 months of therapy)
- F. Documentation that the member has a baseline for one or more of the following:
 1. Urinary oxalate excretion level (corrected for BSA)
 2. Spot urinary oxalate: creatinine ratio
 3. Estimated glomerular filtration rate (eGFR)
 4. Plasma oxalate level
- G. Documentation that the member has 24-hour urinary oxalate excretion ≥ 0.7 mmol normalized to 1.73 m² BSA
- H. Documentation that the member has relatively preserved kidney function (e.g., eGFR of greater than or equal to 30 mL/min/1.73 m²).
- I. The requested medication will not be used in combination with Oxlumio (lumasiran).

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III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for members with documentation showing they meet all initial authorization criteria and chart notes or medical records demonstrate a positive response to therapy (e.g., decrease or normalization in urinary and/or plasma oxalate levels, improvement in kidney function).

IV. QUANTITY LIMIT

- A. 80mg/0.5ml vial: two vials per month (daily dose of 0.04 ml)
- B. 128mg/0.8ml prefilled syringe: one prefilled syringe per month (daily dose of 0.03 ml)
- C. 160mg/ml prefilled syringe: one prefilled syringe per month (daily dose of 0.04 ml)

V. REFERENCES

1. Rivfloza [package insert]. Lexington, MA: Dicerna Pharmaceuticals, Inc.; March 2025.