Effective Date: 8/1/2024
Reviewed: 5/24 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 9 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 m^2.

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Molecular genetic test results demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene or liver enzyme analysis results demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity.
B. Chart notes or medical records demonstrating a positive response to therapy (for continuation requests).

III. 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 9 years of age or older.
C. 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. Member has not had a kidney or liver transplant.
E. 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. 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. Member has 24-hour urinary oxalate excretion ≥ 0.7 mmol normalized to 1.73 m^2 BSA
H. Member has relatively preserved kidney function (e.g., eGFR of greater than or equal to 30 mL/min/1.73 m^2).
I. The requested medication will not be used in combination with Oxlumo (lumasiran).

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for members who 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).

V. 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)

VI. REFERENCES

1. Rivfloza [package insert]. Lexington, MA: Dicerna Pharmaceuticals, Inc.; October 2023.