

RIVFLOZA (nedosiran)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 2 years of age or older

Diagnosis

Patient must have the following:

Primary hyperoxaluria type 1 (PH1)

AND ALL of the following:

- a. Diagnosis confirmed by identification of biallelic pathogenic variants in alanine:glyoxylate aminotransferase (*AGT* or *AGXT*) gene **OR** liver biopsy demonstrating AGT deficiency
- b. Presence of 1 of the following clinical signs or symptoms of PH1:
 - i. Elevated urine oxalate excretion (body surface area-normalized daily urine oxalate excretion output $\ge 0.7 \text{ mmol}/1.73 \text{ m}^2$)
 - ii. Elevated plasma oxalate concentration > 20 µmol/L or > 1.76 mg/L
 - iii. Urine oxalate excretion:creatinine ratio above age-specific upper limit of normal
- c. Prescribed by or in consultation with a nephrologist, urologist, geneticist, or any healthcare provider with expertise in treating primary hyperoxaluria type 1
- d. Prescriber agrees to monitor urinary oxalate levels
- e. Patient has not received a liver transplant
- f. Estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73m²
 Patient will be dosed based on actual body weight

Prior - Approval Limits

Duration 12 months

Prior – Approval Renewal Requirements

Age 2 years of age or older

Diagnosis

Patient must have the following:



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Primary hyperoxaluria type 1 (PH1)

- AND ALL of the following:
 - a. Patient has had a clinically meaningful response to therapy from pretreatment baseline (e.g., decreased urinary oxalate concentrations, decreased urinary oxalate:creatinine ratio, decreased plasma oxalate concentrations, improvement, stabilization or slowed worsening of nephrocalcinosis, renal stone events, renal impairment, or systemic calcinosis)
 - b. Patient has not received a liver transplant
 - c. Estimated glomerular filtration rate (eGFR) \ge 30 mL/min/1.73m²
 - d. Patient will be dosed based on actual body weight

Prior - Approval Renewal Limits

Same as above