UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2336-3
Program	Prior Authorization/Medical Necessity
Medication	Rivfloza™ (nedosiran)
P&T Approval Date	3/2024, 4/2024, 5/2024
Effective Date	7/1/2024

1. Background:

Rivfloza™ (nedosiran) is an LDHA-directed small interfering RNA 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 ≥ 30 mL/min/1.73 m2.

Oxlumo® (lumasiran) is an HAO1-directed small interfering ribonucleic acid (siRNA) indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Rivfloza** will be approved based on **one** of the following criteria:

   a. **All** of the following:

      (1) Patient has been established on therapy with Rivfloza under an active UnitedHealthcare medical benefit prior authorization for the treatment of primary hyperoxaluria type 1 (PH1)

      -AND-

      (2) Submission of medical records (e.g., chart notes, laboratory values) documenting a positive clinical response to therapy from pre-treatment baseline (e.g., decreased urinary oxalate concentrations, decreased urinary oxalate: creatinine ratio, decreased plasma oxalate concentrations)

      -AND-

      (3) Patient has not received a liver transplant

      -AND-

      (4) Patient has relatively preserved kidney function (e.g., eGFR ≥ 30 mL/min/1.73 m^2)

      -AND-

      (5) Patient is not receiving Rivfloza in combination with Oxlumo (lumasiran)

-AND-

(6) Prescribed by, or in consultation with, a specialist (e.g., geneticist, nephrologist, urologist) with expertise in the treatment of PH1

-OR-

b. **All** of the following:

(1) Diagnosis of primary hyperoxaluria type 1 (PH1)

-AND-

(2) Confirmation of diagnosis based on **both** of the following:

(a) Metabolic testing demonstrating **one** of the following:

i. Increased urinary oxalate excretion (e.g. greater than 1 mmol/1.73 m2 per day [90 mg/1.73 m2 per day], increased urinary oxalate: creatinine ratio relative to normative values for age)

-OR-

ii. Increased plasma oxalate and glyoxylate concentrations

-AND-

(b) Genetic testing has confirmed a mutation in the alanine: glyoxylate aminotransferase (AGT or AGXT) gene

-AND-

(3) Patient has not received a liver transplant

-AND-

(4) Patient is at least 9 years of age and older

-AND-

(5) Patient has relatively preserved kidney function (e.g., eGFR ≥ 30 mL/min/1.73 m^2)

-AND-

(6) Patient is not receiving Rivfloza in combination with Oxlumo (lumasiran)

-AND-

(7) Prescribed by, or in consultation with, a specialist (e.g., geneticist, nephrologist, urologist) with expertise in the treatment of PH1

Authorization will be issued for 12 months

B. Reauthorization

1. **Rivfloza** will be approved based on **all** of the following criteria:

   a. Submission of medical records (e.g., chart notes, laboratory values) documenting a positive clinical response to therapy from pre-treatment baseline (e.g., decreased urinary oxalate concentrations, decreased urinary oxalate: creatinine ratio, decreased plasma oxalate concentrations)

   -AND-

   b. Patient has not received a liver transplant

   -AND-

   c. Patient has relatively preserved kidney function (e.g., eGFR ≥ 30 mL/min/1.73 m2)

   -AND-

   d. Patient is not receiving Rivfloza in combination with Oxlumo (lumasiran)

   -AND-

   e. Prescribed by, or in consultation with, a specialist (e.g., geneticist, nephrologist, urologist) with expertise in the treatment of PH1

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Rivfloza [package insert]. Plainsboro, NJ: Novo Nordisk, Inc.; September 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. Long term extension study in patients with primary hyperoxaluria (PHYOX3). ClinicalTrials.gov website Study Details | Long Term Extension Study in Patients With Primary Hyperoxaluria | ClinicalTrials.gov Accessed March 6, 2024.
4. Oxlumo [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; September 2023.
5. Cochat P, Hulton SA, Acquaviva C, et al. Primary Hyperoxaluria Type 1: Indications For Screening And Guidance For Diagnosis And Treatment. Nephrol Dial Transplant 2012; 27:1729.
6. Niaudet P. Primary Hyperoxaluria. In: UpToDate, Mattoo TK, Kim MS, (Ed), UpToDate, Waltham, MA, 2024.

Program	Prior Authorization/Medical Necessity - Rivfloza (nedosiran)
Change Control	
3/2024	New program
4/2024	Removed footnote that program applies to PFS formulation only. Specified “medical benefit” for prior UHC PA bypass.
5/2024	Removed step through Oxlumo.