

Program Number	2025 P 1440-4
Program	Prior Authorization/Notification
Medication	Rivfloza™ (nedosiran)
P&T Approval Date	3/2024, 4/2024, 4/2025, 5/2025
Effective Date	8/1/2025

1. Background:

Rivfloza™ (nedosiran) 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).

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) Documentation of positive clinical response to Rivfloza

-AND-

- (3) Patient is not receiving Rivfloza in combination with Oxlumio (lumasiran)

-OR-

b. **All** of the following:

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

-AND-

- (2) Patient is at least 2 years of age and older

-AND-

- (3) Patient has relatively preserved kidney function (e.g., eGFR \geq 30 mL/min/1.73 m²)

-AND-

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

Authorization will be issued for 12 months

B. Reauthorization

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

a. Documentation of positive clinical response to Rivfloza therapy

-AND-

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

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.
- Supply limits, Medical Necessity and/or Step Therapy may be in place.

4. References:

1. Rivfloza [package insert]. Plainsboro, NJ: Novo Nordisk, Inc.; March 2025.

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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.
4/2025	Annual review. No changes to coverage criteria.
5/2025	Updated age limitation based on update to FDA-labeled indication. Updated reference.