nedosiran sodium (Rivfloza)

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: LDHA-directed small interfering RNA
HCPCS:
C9399:Unclassified drugs or biologicals
J3490:Unclassified drugs
How Supplied:
80 mg (0.5 mL) Single-dose vial (NDC 0169-5308-01)

Condition(s) listed in policy *(see coverage criteria for details)*

- Primary Hyperoxaluria Type 1 (PH1)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Rivfloza vials are managed under the Medical Benefit. Please include medical rationale why the patient cannot use the self-administered Rivfloza prefilled syringe in the home. The Rivfloza prefilled syringe can be obtained through the patient's pharmacy benefit. Please refer to the "Self-Administered Drugs" medical benefit drug policy for more information.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Primary Hyperoxaluria Type 1 (PH1)
Meets medical necessity if all the following are met:
1. Age is consistent with the FDA-approved indication (2 years of age or older)

2. Prescribed by or in consultation with a medical geneticist, gastroenterologist, nephrologist, or urologist
3. Relatively preserved kidney function (e.g., eGFR ≥30 mL/min/1.73m^2)
4. Presence of AGXT mutation as confirmed by genetic testing or liver enzyme analysis
5. Not being used in combination with Oxlumo (lumasiran)

Covered Doses:

	Body Weight		
	Less than 39 kg	39 kg to less than 50 kg	50 kg and above
Age 2 to less than 12 years	3.3 mg/kg	128 mg	160 mg

Coverage Period:
Indefinite

ICD-10:
E72.53

References

1. Rivfloza (nedosiran) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; March 2025.

Review History

Date of Last Annual Review: 2Q2025
Changes from previous policy version:

- Updated FDA-approved age from 9 years to 2 years of age or older - ***Rationale:*** on March 2025, Rivfloza's (nedosiran) age indication has been expanded to include children aged 2 years and older with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee