

**nedosiran sodium (Rivfloza)****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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

**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  $\geq 30$  mL/min/1.73m<sup>2</sup>)
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*