

**RIVFLOZA  
(nedosiran)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Rivfloza (nedosiran) is a double-stranded small interfering RNA (siRNA), conjugated to GalNAc aminosugar residues. After subcutaneous administration, the GalNAc-conjugated sugars bind to asialoglycoprotein receptors (ASGPR) to deliver Rivfloza to hepatocytes. Rivfloza reduces levels of hepatic lactate dehydrogenase (LDH) via the degradation of LDHA messenger ribonucleic acid (mRNA) in hepatocytes through RNA interference. The reduction of hepatic LDH by Rivfloza reduces the production of oxalate by the liver, thereby reducing subsequent oxalate burden (1).

**Regulatory Status**

FDA-approved indication: Rivfloza 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/1.73m<sup>2</sup> (1).

The most common adverse reaction is injection site reactions (1).

The safety and effectiveness of Rivfloza in pediatric patients less than 2 years of age have not been established (1).

**Summary**

Rivfloza (nedosiran) reduces LDH which decreases oxalate production. Rivfloza is indicated to lower urinary oxalate levels in children 2 years of age and older and adults with PH1 with relatively preserved renal function. The safety and effectiveness of Rivfloza have not been established in pediatric patients less than 2 years of age (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Rivfloza while maintaining optimal therapeutic outcomes.

**References**

1. Rivfloza [package insert]. Costa Mesa, CA: Pyramid Laboratories; March 2025.