

Reference number(s) 6200-A

# Specialty Guideline Management Rivfloza

# **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rivfloza	nedosiran

## **Indications**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

## FDA-Approved Indications<sup>1</sup>

Rivfloza is 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 of greater than or equal to 30 mL/min/1.73 m<sup>2</sup>.

All other indications are considered experimental/investigational and not medically necessary.

## **Documentation**

Submission of the following information is necessary to initiate the prior authorization review:

#### Initial requests:

 Molecular genetic test results demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene or liver enzyme analysis results demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity.

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#### Continuation requests:

Chart notes or medical records demonstrating a positive response to therapy.

# **Coverage Criteria**

## Primary Hyperoxaluria Type 1 (PH1)<sup>1-3</sup>

Authorization of 12 months may be granted for the treatment of primary hyperoxaluria type 1 (PH1) when all of the following criteria are met:

- Member is 2 years of age or older.
- Member has a diagnosis of PH1 confirmed by either of the following:
  - Molecular genetic test results demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene.
  - Liver enzyme analysis results demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity.
- Member has relatively preserved kidney function (e.g., eGFR of greater than or equal to 30 mL/min/1.73 m²).
- The requested medication will not be used in combination with lumasiran.

# **Continuation of Therapy**

Authorization of 12 months may be granted for members who meet all requirements in the coverage criteria section and demonstrate a positive response to therapy (e.g., decrease or normalization in urinary and/or plasma oxalate levels, improvement in kidney function).

### References

- 1. Rivfloza [package insert]. Lexington, MA: Dicerna Pharmaceuticals, Inc.; March 2025.
- 2. Niaudet, P. Primary hyperoxaluria. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2024.
- 3. Milliner DS. The primary hyperoxalurias: an algorithm for diagnosis. Am J Nephrol 2005; 25:154.