



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: RIVFLOZA (nedosiran) Page: 1 of 2

Effective Date: 2/10/2024 Last Review Date: 12/1/2023

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> New Jersey
	<input checked="" type="checkbox"/> Maryland	<input checked="" type="checkbox"/> Florida Kids	<input checked="" type="checkbox"/> Pennsylvania Kids
	<input type="checkbox"/> Michigan	<input checked="" type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Rivfloza under the patient's prescription drug benefit.

### Description:

#### FDA-Approved Indication

Rivfloza is indicated to lower urinary oxalate levels in children 9 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.

### Applicable Drug List:

Rivfloza

### Policy/Guideline:

#### Documentation

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

- A. 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.
- B. Chart notes or medical records demonstrating a positive response to therapy (for continuation requests).

### Criteria for Initial Approval:

#### Primary hyperoxaluria type 1 (PH1)

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

- A. Member is 9 years of age or older.
- B. Member has a diagnosis of PH1 confirmed by EITHER of the following:
  1. Molecular genetic test results demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene.
  2. Liver enzyme analysis results demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity.



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- C. Member has relatively preserved kidney function (e.g., eGFR of greater than or equal to 30 mL/min/1.73 m<sup>2</sup>).
- D. The requested medication will NOT be used in combination with lumasiran.

### Continuation of Therapy

#### Primary hyperoxaluria type 1 (PH1)

Authorization may be granted for members who meet all initial authorization criteria and demonstrate a positive response to therapy (e.g., decrease or normalization in urinary and/or plasma oxalate levels, improvement in kidney function).

#### Approval Duration and Quantity Restrictions:

**Initial and Renewal:** 12 months

#### Quantity Level Limit:

- 80 mg (0.5 mL) single-dose vial:
  - 2 vials (1 mL) per 28 days
- 128 mg (0.8 mL) single-dose pre-filled syringe:
  - 1 syringe (0.8 mL) per 28 days
- 160 mg (1 mL) single-dose pre-filled syringe:
  - 1 syringe (1 mL) per 28 days

#### References:

1. Rivfloza [package insert]. Lexington, MA: Dicerna Pharmaceuticals, Inc.; October 2023.
2. Niaudet, P. Primary hyperoxaluria. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2022.
3. Milliner DS. The primary hyperoxalurias: an algorithm for diagnosis. Am J Nephrol 2005; 25:154.