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:	☒ Illinois ☒ Maryland ☐ Michigan	☐ Florida ☒ Florida Kids ☒ Virginia	☒ New Jersey ☒ Pennsylvania Kids ☐ 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 m2.

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.

C. Member has relatively preserved kidney function (e.g., eGFR of greater than or equal to 30 mL/min/1.73 m^2).
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.