CVS/caremark™

POLICY Document for RIVFLOZA

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria
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.

Brand Name	Generic Name	Dosage Form
Rivfloza	nedosiran	subcutaneous

Criteria for Approval for Administration in Outpatient Hospital Setting

This policy provides coverage for administration of Rivfloza in an outpatient hospital setting for up to 45 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Rivfloza in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- The member has experienced an adverse reaction that did not respond to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids or other pre-

medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after administration.
- The member is medically unstable (e.g., respiratory, cardiovascular, or renal conditions).
- The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of therapy AND the patient does not have access to a caregiver.
- Alternative administration sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home
- The member is less than 14 years of age.

For situations where administration of Rivfloza does not meet the criteria for outpatient hospital administration, coverage for Rivfloza is provided when given in alternative sites such as; physician office, home, or ambulatory care.

Required Documentation

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after administration
- Medical records supporting the member is medically unstable
- Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- Records supporting alternative administration sites are greater than 30 miles from the member's home
- Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

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[1]

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^2.

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.

Continuation requests:

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

Coverage Criteria

Primary Hyperoxaluria Type 1 (PH1)[1-3]

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 m^2).
- 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

SECTION 1

1. Rivfloza [package insert]. Costa Mesa, CA: Pyramid laboratories.; September 2023.

SECTION 2

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