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Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Genitourinary Agents	**Original Policy Date:**	November 10, 2023
Subject:	Rivfloza	**Page:**	1 of 4

Last Review Date: June 13, 2024

Rivfloza

Description

Rivfloza (nedosiran)

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 Rivflova 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 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ≥ 30 mL/min/1.73m^2 (1).

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

The safety and effectiveness of Rivfloza in pediatric patients less than 9 years of age have not been established (1).

Related policies
Oxlumo

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Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Rivfloza may be considered **medically necessary** if the conditions indicated below are met.

Rivfloza may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 9 years of age or older

Diagnosis

Patient must have the following:

Primary hyperoxaluria type 1 (PH1)

AND ALL of the following:

a. Diagnosis confirmed by identification of biallelic pathogenic variants in alanine:glyoxylate aminotransferase (*AGT* or *AGXT*) gene **OR** liver biopsy demonstrating AGT deficiency
b. Presence of 1 of the following clinical signs or symptoms of PH1:
    i. Elevated urine oxalate excretion (body surface area-normalized daily urine oxalate excretion output ≥ 0.7 mmol/1.73 m^2)
    ii. Elevated plasma oxalate concentration > 20 µmol/L or > 1.76 mg/L
    iii. Urine oxalate excretion:creatinine ratio above age-specific upper limit of normal
c. Prescribed by or in consultation with a nephrologist, urologist, geneticist, or any healthcare provider with expertise in treating primary hyperoxaluria type 1
d. Prescriber agrees to monitor urinary oxalate levels
e. Patient has not received a liver transplant
f. Estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73m^2
g. Patient will be dosed based on actual body weight

Prior – Approval *Renewal* Requirements

Age 9 years of age or older

Diagnosis

Patient must have the following:

Primary hyperoxaluria type 1 (PH1)

AND ALL of the following:

a. Patient has had a clinically meaningful response to therapy from pre-treatment baseline (e.g., decreased urinary oxalate concentrations, decreased urinary oxalate:creatinine ratio, decreased plasma oxalate concentrations, improvement, stabilization or slowed worsening of nephrocalcinosis, renal stone events, renal impairment, or systemic calcinosis)
b. Patient has not received a liver transplant
c. Estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73m^2
d. Patient will be dosed based on actual body weight

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Rivfloza (nedosiran) reduces LDH which decreases oxalate production. Rivfloza is indicated to lower urinary oxalate levels in children 9 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 9 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; September 2023.

Policy History

Date	Action
November 2023	Addition to PA
March 2024	Annual review
June 2024	Annual review. Per SME, added initiation requirement that diagnosis must be confirmed by biallelic pathogenic variants AGT or AGXT gene or liver biopsy and presence of a clinical sign or symptom of PH1. Also added requirement that patient has not had a liver transplant to both initiation and continuation

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.