

Medical Policy:

Rivfloza (nedosiran) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.411	February 20, 2025	May 09, 2024

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

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Definitions

Rivfloza, a lactate dehydrogenase A-directing (LDHA) small interfering RNA, is indicated to lower urinary oxalate levels in adults and children ≥ 9 years of age with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function.

Length of Authorization

Initial coverage will be provided for 6 months and may be renewed for one year.

Dosing Limits [Medical Benefit]

Approve the following dosing regimens.

If weight is ≥ 50 kg, approve for 160mg once monthly.

If weight is < 50 kg, approve 3.3 mg/kg once monthly, not to exceed 128mg.

Guideline

1. **Primary Hyperoxaluria Type 1.** Approve Rivfloza for the duration noted if the patient meets one of the following
 - A. **Initial Therapy.** Approve for 6 months if the patient meets the following (i, ii, iii, iv, v, and vi):
 - i. Patient is ≥ 9 years of age; **AND**
 - ii. Patient has had a genetic test confirming the diagnosis of Primary Hyperoxaluria Type 1 via identification of an alanine:glyoxylate aminotransferase gene (AGXT) mutation **AND**
 - iii. Patient has an estimated glomerular filtration rate (eGFR) ≥ 30 ml/min per 1.73 m^2 ; **AND**
 - iv. Patient meets ONE of the following (a, b, **OR** c):
 - a. Patient has a urinary oxalate excretion ≥ 0.5 mmol/24 hours/ 1.73 m^2 with the absence of secondary sources of oxalate; **OR**
 - b. Patient has a urinary oxalate:creatinine ratio above the age-specific upper limit of normal; **OR**
 - c. Patient has elevated plasma oxalate (POx) concentration (POx concentration $> \text{ULN}$); **AND**
 - v. Patient has not previously received a liver transplant for Primary Hyperoxaluria Type 1; **AND**
 - vi. The medication is prescribed by or in consultation with a nephrologist or urologist.

2. **Renewal: Patient is Currently Receiving Rivfloza.**

- A. Approve for 1 year if, according to the prescriber, the patient is continuing to derive benefit from Rivfloza as determined by the most recent (i.e., within the past 6 months) objective measurement:
Note: Examples of objective measurements of a response to Rivfloza therapy are reduced urinary oxalate excretion, decreased urinary oxalate:creatinine ratio, or reduced plasma oxalate levels from baseline (i.e., prior to Rivfloza therapy) or improved or stabilized clinical signs/symptoms of Primary Hyperoxaluria Type 1 (e.g., nephrocalcinosis, formation of renal stones, renal impairment).
- B. Patient has not previously received a liver transplant for Primary Hyperoxaluria Type 1.

Limitations/Exclusions

1. **Primary Hyperoxaluria Type 2 (PH2).** Rivfloza may have benefit in PH2; however, the efficacy and safety of Rivfloza in patients with PH2 have not been established. Clinical trials are ongoing.
2. **Primary Hyperoxaluria Type 3 (PH3).** Rivfloza may have benefit in PH3; however, the efficacy and safety of Rivfloza in patients with PH3 have not been established. Clinical trials are ongoing.
3. **Primary Hyperoxaluria with end stage renal disease (ESRD).** Rivfloza may have benefit in patients with PH1 or PH2 and ESRD; however, the efficacy and safety of Rivfloza in this patient population have not been established. Clinical trials are ongoing.
4. **Concurrent use of Rivfloza with Oxlummo (lumasiran subcutaneous injection).** Oxlummo is another small interfering RNA agent and should not be used with Rivfloza.

Applicable Procedure Codes

Code	Description
J3490	Unclassified drugs
C9399	Unclassified drugs or biologics

Applicable NDCs

Code	Description
00169-5306-10	Rivfloza SC injection , single-dose prefilled pen, 80mg/0.5ml – (1ml)
00169-5308-01	Rivfloza SC injection , single-dose prefilled pen, 80mg/0.5ml – (0.5ml)
00169-5307-08	Rivfloza SC injection , single-dose prefilled pen, 80mg/0.5ml – (0.8ml)

ICD-10 Diagnoses

Code	Description
E72.53	Primary hyperoxaluria

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/20/2025	Annual Review: Updated Length of authorization. Initial Criteria: <u>Primary Hyperoxaluria Type 1.</u> : removed: "Patient has a urinary oxalate excretion \geq 0.7 mmol/24 hours/1.73 meters ² ; OR" and replaced with: " Patient has a urinary oxalate excretion \geq 0.5 mmol/24 hours/1.73 m ² with the absence of secondary sources of oxalate" Renewal Criteria: Added: "Patient has not previously received a liver transplant for Primary Hyperoxaluria Type 1."
EmblemHealth & ConnectiCare	05/09/2024	New Policy

References

1. Rivfloza subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; September 2023.