Medical Policy:

Rivfloza (nedosiran) subcutaneous injection

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

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

Dosing of Rivfloza is a weight-based monthly subcutaneous injection.

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 ≥ 0.7 mmol/24 hours/1.73 $meters^2$ **; 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 > 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).

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 Oxlumo (lumasiran subcutaneous injection).** Oxlumo 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	05/09/2024	New Policy

References

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