Commercial PA Criteria

Effective: May 9th, 2024

Prior Authorization: Rivfloza

Products Affected: Rivfloza (nedosiran) subcutaneous injection

Medication Description: Rivfloza targets LDHA messenger RNA in hepatocytes through RNA interference, which subsequently reduces lactate dehydrogenase. This results in decreased production of oxalate by the liver and reduces the oxalate burden.

Covered Uses: 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.

Exclusion Criteria:

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.

Required Medical Information:

1. Diagnosis

Prescriber Restriction: prescribed by, or in consultation with, a nephrologist or urologist

Age Restriction: 9 years of age and older

Coverage Duration:

Initial: 6 months

Continuation: 12 months

Other Criteria:

Initial Approval Criteria

1. **<u>Primary Hyperoxaluria Type 1.</u>**
   Approve Rivfloza for the duration noted if the patient meets the following;
   <u>Initial Therapy</u>. Approve if the patient meets the following (A, B, C **AND** D):
   A. 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**
   B. Patient has an estimated glomerular filtration rate (eGFR) ≥ 30 ml/min per 1.73 m^2 ; **AND**
   C. Patient meets ONE of the following (i, ii, **<u>OR</u>** iii):
      i. Patient has a urinary oxalate excretion ≥ 0.7 mmol/24 hours/1.73 $meters^2$ **OR**
      ii. Patient has a urinary oxalate: creatinine ratio above the age-specific upper limit of normal **OR**
      iii. Patient has a plasma oxalate level ≥ 20 µmol/L **AND**
   D. Patient has <u>not</u> previously received a liver transplant for Primary Hyperoxaluria Type 1

Renewal Criteria

1. Approve 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
   <u>Note</u>: 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).

<u>References:</u>

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

<u>Policy Revision history</u>

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	05/09/2024