MEDICAL MUTUAL®

Drug Policy

Policy:	**240101**	**Initial Effective Date: 01/18/2024**
Code(s):	**HCPCS J3490, J3590, C9399**	**Annual Review Date 01/18/2024**
SUBJECT:	**Rivfloza™ (nedosiran subcutaneous)**	**Last Revised Date: 01/18/2024**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

I. Length of Authorization

Coverage will be provided for 6 months initially and may be renewed annually thereafter.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Rivfloza 80 mg in a single-dose vial for injection: 2 vials every month
- Rivfloza 128 mg in a single-dose prefilled syringe: 1 syringe every month
- Rivfloza 160 mg in a single-dose prefilled syringe: 1 syringe every month

B. Max Units (per dose and over time) [HCPS Unit]:

- 160 mg every month

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is 9 years or older; **AND**

Universal Criteria [1-5]

- Patient has not had a liver transplant; **AND**
- Must be prescribed by, or in consultation with, a specialist in genetics, nephrology or urology; **AND**
- Patient does not have renal impairment defined as an eGFR <30 mL/min/1.73 m^2; **AND**
- Will not be used in combination with other urinary oxalate reducing agents (i.e., lumasiran, etc.); **AND**

Primary Hyperoxaluria type 1 (PH1) † Φ [1-5]

- Patient has a definitive diagnosis of primary hyperoxaluria type 1 as evidenced by one of the following:
    - Patient has a biallelic pathogenic mutation in the alanine: glyoxylate aminotransferase (*AGXT)* gene as identified on molecular genetic testing; **OR**
    - Identification of alanine: glyoxylate aminotransferase (AGT) enzyme deficiency on liver biopsy; **AND**
- Patient has a baseline for one or more of the following:
    - Urinary oxalate excretion level (corrected for BSA)
    - Spot urinary oxalate: creatinine ratio
    - Estimated glomerular filtration rate (eGFR)
    - Plasma oxalate level

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe injection site reactions, etc.; **AND**
- Disease response as evidenced by a decrease in urinary oxalate excretion from baseline, a reduction in spot urinary oxalate: creatinine ratio from baseline, stabilization of glomerular filtration rate and/or a decrease in plasma oxalate level from baseline

V. Dosage/Administration [1]

Indication	Dose
Primary Hyperoxaluria Type 1 (PH1)	**For administration by a healthcare professional, caregiver or patient as a subcutaneous injection.** Children 9 to 11 years - ≥ 50 kg: 160 mg p/f syringe once monthly - <50 kg: 3.3 mg/kg once monthly, not to exceed 128 mg (vial, dose volume rounded to the nearest 0.1 mL) Adults and adolescents 12 years and older - ≥ 50 kg: 160 mg p/f syringe once monthly - <50 kg: 128 mg p/f syringe once monthly

VI. Billing Code/Availability Information

HCPCS:

- J3490 – Unclassified drugs

NDC:

- Rivfloza 80 mg/0.5 mL in a single-dose vial solution for injection: 00169-5308-xx
- Rivfloza 128 mg/0.8 mL in a single-dose pre-filled syringe for injection: 00169-5307-xx
- Rivfloza 160 mg/1 mL in a single-dose pre-filled syringe for injection: 00169-5306-xx

VII. References

1. Rivfloza [package insert]. Plainsboro, NJ; Novo Nordisk, Inc., October 2023. Accessed October 2023.
2. Milliner DS, Harris PC, Sas DJ, et al. Primary Hyperoxaluria Type 1. 2002 June 19 [Updated 2022 Feb 10]. In: Adam MP, Everman DB, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1283/.
3. Baum MA, Langman C, Cochat P, et al. PHYOX2: a pivotal randomized study of nedosiran in primary hyperoxaluria type 1 or 2. Kidney International, Volume 103, Issue 1, 2023, Pages 207-217, ISSN 0085-2538, https://doi.org/10.1016/j.kint.2022.07.025.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E72.53	Primary hyperoxaluria

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for HCPCS Codes J3490 and C9399

†When *unclassified drugs* (J3490) or *unclassified biologics* (J3590) or *unclassified drugs or biologics [hospital outpatient use]* (C9399) is determined to be Rivfloza