MEDICAL MUTUAL®

Drug Policy

Policy:	**240101**	**Initial Effective Date: 01/18/2024**
Code(s):	**HCPCS J3490, J3590, C9399**	**Annual Review Date 02/20/2025**
SUBJECT:	**Rivfloza™ (nedosiran subcutaneous)**	**Last Revised Date: 02/20/2025**

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

Max Units (per dose and over time) [HCPCS Unit]:

- 160 mg every month

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 9 years of age; **AND**

Universal Criteria [1-4]

- 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 severe 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 [1-4]

- 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 [1-4]

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 at least one of the following:
  - Decrease in urinary oxalate excretion level (corrected for BSA) from baseline
  - Reduction in spot urinary oxalate: creatinine ratio from baseline
  - Stabilization of estimated glomerular filtration rate (eGFR)
  - 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 of age - ≥ 50 kg: 160 mg pre-filled 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 of age and older - ≥ 50 kg: 160 mg pre-filled syringe once monthly - < 50 kg: 128 mg pre-filled syringe once monthly

VI. Billing Code/Availability Information

HCPCS:

- J3490 – Unclassified drugs

- C9399 – Unclassified drugs or biologicals (*Hospital outpatient use ONLY*)

NDC:

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

VII. References

1. Rivfloza [package insert]. Plainsboro, NJ; Novo Nordisk, Inc., September 2023. Accessed December 2024.
2. Milliner DS, Harris PC, Sas DJ, et al. Primary Hyperoxaluria Type 1. Initial Posting: June 19, 2002; Last Update: August 15, 2024. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2024. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1283/. Accessed January 8, 2025.
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.
4. Groothoff J, Sellier-Leclerc AL, Deesker L, et al. Nedosiran Safety and Efficacy in PH1: Interim Analysis of PHYOX3. Kidney Int Rep. 2024 Mar 4;9(5):1387-1396. doi: 10.1016/j.ekir.2024.02.1439. PMID: 38707801; PMCID: PMC11068990.

Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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,	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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria	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

Edits and Denials:

Prior approval: Prior approval is required for Rifloza **(HCPCS Codes J3490 , J3590, C9399)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

HCPCS Code(s):	
J3490	Unclassified drugs
J3590	Unclassified biologics
C9399	unclassified drugs or biologics [hospital outpatient use]