Rivfloza® (nedosiran)
(Subcutaneous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity 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]

Prior authorization validity is provided in the following conditions:

- Patient is at least 2 years of age; **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 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 [1-5]

- 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 [1-5]

Prior authorization validity 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)	Pediatric patients 2 to <12 years of age: - Weight <39 kg: Administer 3.3 mg/kg subcutaneously once monthly - Weight 39 to <50 kg: Administer 128 mg subcutaneously once monthly - Weight ≥50 kg: 160 mg once monthly Adults and pediatric patients ≥12 years of age: - Weight <50 kg: Administer 128 mg subcutaneously once monthly - Weight ≥50 kg: Administer 160 mg subcutaneously once monthly ***NOTE:*** • *Pre-filled syringe: A healthcare provider, caregiver, or patient 12 years of age and older may inject Rivfloza using the pre-filled syringe.*

	• *Vials: Rivfloza vials are intended for use under the guidance and supervision of a healthcare provider. Adult patients or caregivers may administer Rivfloza after proper training.*

VI. Billing Code/Availability Information

HCPCS Code(s):

- J3490 – Unclassified drugs
- C9399 – Unclassified drugs or biologicals (*Hospital outpatient use ONLY*)

NDC(s):

- 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., March 2025. Accessed April 2025.
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.
5. Sas DJ, Bakkaloglu SA, Belostotsky V, et al. Nedosiran in pediatric patients with PH1 and relatively preserved kidney function, a phase 2 study (PHYOX8). Pediatr Nephrol. 2025 Jan 28. doi: 10.1007/s00467-025-06675-8. Epub ahead of print. PMID: 39875734

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

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

Appendix 2 – 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, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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 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