Mass General Brigham
Health Plan

Rivfloza (nedosiran)
Effective 01/01/2026

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	Rivfloza prefilled syringe is available through both the pharmacy and medical benefits Rivfloza vial is restricted to the medical benefit		

Overview

Rivfloza (nedosiran) injection is an LDHA-directed small interfering RNA indicated to lower urinary oxalate levels in children 2 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function (e.g., eGFR ≥ 30 mL/minute/1.73m^2).

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when the following criteria are met:

1. Member has a documented diagnosis of primary hyperoxaluria type 1 (PH1), confirmed by submission of medical records showing one of the following:
    a. Mutation of alanine:glyoxylate aminotransferase (AGXT) gene
    b. Liver enzyme analysis demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity
2. Member is 2 years of age or older
3. Member has a pretreatment estimated glomerular filtration rate (eGFR) ≥ 30 mL/minute/1.73m^2
4. Member has a 24-hour urinary oxalate excretion ≥ 0.7 mmol normalized to 1.73 m^2 body surface area (BSA)
5. Member does not have a history of renal or liver transplantation
6. Member will not take the requested medication concurrently with lumasiran

<u>Continuation of Therapy</u>

Requests for reauthorization will be approved when the following criteria are met:

1. Member has not had a renal or liver transplant
2. Member has an estimated glomerular filtration rate (eGFR) ≥ 30 mL/minute/1.73m^2
3. Submission of medical records (e.g., chart notes, laboratory values) demonstrating a positive response to therapy from baseline. Examples include decreased urinary oxalate concentration, plasma oxalate concentration, or spot urinary oxalate:creatinine ratio

Limitations

1. Initial and reauthorization approvals will be granted for 12 months.

References

1. Baum MA, Langman C, Cochat P, et al. PHYOX2: a pivotal randomized study of nedosiran in primary hyperoxaluria type 1 or 2. *Kidney Int*. 2023;103(1):207-217.
2. Cochat P, Hulton SA, Acquaviva C, et al. Primary hyperoxaluria type 1: Indications for screening and guidance for diagnosis and treatment. *Nephrol Dial Transplant*. 2012 May;27(5):1729-36. doi: 10.1093/ndt/gfs078.
3. Garrelfs SF, Frishberg Y, Hulton SA, et al. Lumasiran, an RNAi therapeutic for primary hyperoxaluria type 1. *New Engl J Med*. 2021; 384:1216-1226.
4. Groothoff JW, Metry E, Deesker L, et al. Clinical practice recommendations for primary hyperoxaluria: an expert consensus statement from ERKNet and OxalEurope. *Nat Rev Nephrol*. 2023;19(3):194-211.
5. Hayes W, Sas DJ, Magen D, et al. Efficacy and safety of lumasiran for infants and young children with primary hyperoxaluria type 1: 12-month analysis of the phase 3 ILLUMINATE-B trial. *Pediatr Nephrol*. 2023;38(4):1075-1086.
6. Hoppe B, Beck BB, Milliner DS. The primary hyperoxalurias. *Kidney Int*. 2009;75(12):1264-1271. doi: 10.1038/ki.2009.32.
7. Hulton SA. The primary hyperoxalurias: A practical approach to diagnosis and treatment. *Int J Surg*. 2016;36(Pt D):649-654. doi: 10.1016/j.ijsu.2016.10.039.
8. Michael M, Groothoff JW, Shasha-Lavsky H, et al. Lumasiran for advanced primary hyperoxaluria type 1: Phase 3 ILLUMINATE-C trial. *Am J Kidney Dis*. 81(2):145-155.
9. Rivfloza (nedosiran) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc.; March 2025.
10. Sas D, Magen D, Hayes W, et al. Phase 3 trial of lumasiran for primary hyperoxaluria type 1: A new RNAi therapeutic in infants and young children. *Genet Med*. 2022;24(3):654-662.
11. Zhao F, Bergstralh EJ, Mehta RA, et al. Predictors of incident ESRD among patients with primary hyperoxaluria presenting prior to kidney failure. *Clin J AmSoc Nephrol.* 2016;11:119-126.

Review History

10/09/2024 – Reviewed at October P&T. Effective 01/01/2025.
05/14/2025 – Reviewed and updated at May P&T. Decreased minimum age from 9 years to 2 years to align with update package labeling. Effective 08/01/2025.
10/08/2025 – Reviewed at October P&T. Updated policy to indicate it no longer applies to the medical benefit. Effective 01/01/2026.