Medical Benefit Drug Policy

Oxlumo (lumasiran) and Rivfloza (nedosiran)

Policy Number: MC/PC 098
Effective Date: February 1, 2026

Instructions for Use

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Related Policies

- n/a

Coverage Rationale

Primary Hyperoxaluria type 1

For initial coverage of Oxlumo for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients, the following will be required:

- Diagnosis of primary hyperoxaluria type 1 **and**
- Disease is confirmed by both of the following:
  - Elevated urinary oxalate excretion, elevated plasma oxalate concentration, or spot urinary oxalate to creatinine molar ratio greater than normal for age **and**
  - Presence of mutation in the alanine:glyoxylate aminotransferase (*AGXT*) gene as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) **and**
- Patient has not received a liver transplant **and**
- Prescribed by, or in consultation with a Hepatologist, Nephrologist, Urologist, Geneticist, or a Specialist with expertise in the treatment of PH1 **and**
- Patient is not receiving Oxlumo in combination with Rivfloza (nedosiran)

For reauthorization coverage of Oxlumo, the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., decreased urinary oxalate excretion, decreased plasma oxalate concentration) **and**
- Patient has not received a liver transplant **and**
- Prescribed by, or in consultation with a Hepatologist, Nephrologist, Urologist, Geneticist, or a Specialist with expertise in the treatment of PH1 **and**
- Patient is not receiving Oxlumo in combination with Rivfloza (nedosiran)

For initial coverage of Rivfloza to lower urinary oxalate levels in children 2 years of age and older and adults with primary hyperoxaluria type 1 and relatively preserved kidney function, e.g., eGFR ≥30 mL/min/1.73 m^2, the following will be required:

- Diagnosis of primary hyperoxaluria type 1 **and**

- Diagnosis has been confirmed by both of the following:
    - Elevated urinary oxalate excretion, elevated plasma oxalate cc :o creatinine molar ratio greater than normal for age **and**
    - Presence of mutation in the alanine:glyoxylate aminotransferase (*AGXT*) gene as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) **and**
- Patient is 2 years of age or older **and**
- Patient has preserved kidney function (e.g., eGFR greater than or equal to 30mL/min/1.73m^2) **and**
- Patient has not received a liver transplant **and**
- Prescribed by, or in consultation with a Hepatologist, Nephrologist, Urologist, Geneticist, or a Specialist with expertise in the treatment of PH1 **and**
- Patient is not receiving Rivfloza in combination with Oxlumo (lumasiran)

For reauthorization coverage of Rivfloza, the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., decreased urinary oxalate excretion, decreased plasma oxalate concentration) **and**
- Patient has not received a liver transplant **and**
- Prescribed by, or in consultation with a Hepatologist, Nephrologist, Urologist, Geneticist, or a Specialist with expertise in the treatment of PH1 **and**
- Patient is not receiving Rivfloza in combination with Oxlumo (lumasiran)

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
C9399	Unclassified drugs or biologicals
J0224	Injection, lumasiran, 0.5 mg
J3490	Unclassified drugs

ICD-10 Code	Description
E72.530	Primary hyperoxaluria, type 1

Background

Primary hyperoxaluria (PH) is a family of ultrarare severe genetic inborn errors of hepatic glyoxylate metabolism characterized by overproduction of oxalate by the liver. Three subtypes of PH have been identified (PH1, PH2, and PH3) which are defined by the affected gene (Food and Drug Administration [FDA] Rivfloza integrated review 2023, Rivfloza Clinical Overview 2024). The estimated prevalence of PH is 1 to 3 people out of every 1 million worldwide. The prevalence in the United States (U.S.) is over 8000 based on genetic analysis (Rivfloza Clinical Overview 2024).

Primary Hyperoxaluria type 1 (PH1) is the most common and severe subtype, accounting for approximately 70 to 80% of cases. It is caused by *AGXT* gene mutations leading to AGT enzyme deficiency, which results in glyoxylate accumulation and conversion to oxalate. Excess oxalate leads to calcium oxalate crystal formation, resulting in nephrolithiasis,

nephrocalcinosis, and progressive renal failure. With declining glomerular filtra develops, characterized by crystal deposition in multiple organs. Complications hy, fractures, retinopathy, neuropathy, hypothyroidism, anemia, and, if untreated, early death (Cochat et al 2012; FDA Rivfloza integrated review 2023; Hoppe et al 2009; Milliner et al 2017).

Conservative treatment options for PH1 to slow or delay disease progression include hyperhydration, calcium oxalate crystallization inhibitors (e.g., potassium citrate), and pyridoxine, though many patients progress despite these interventions. Although renal replacement therapy can reduce the amount of oxalate buildup in the body, it cannot completely eliminate the excess oxalate produced by the liver. The only curative treatment for PH1 is combined or sequential liver and kidney transplantation, which is associated with substantial morbidity (Cochat et al 2012; FDA Rivfloza integrated review 2023; Hoppe et al 2009; Milliner et al 2017; Rivfloza Clinical Overview 2024). Oxlumo (lumasiran) was the first agent approved by the FDA for the treatment of PH1 in November 2020 followed by Rivfloza (nedosiran) in September 2023 (FDA Web site).

Oxlumo reduces levels of glycolate oxidase (GO) enzyme by targeting the hydroxyacid oxidase 1 (*HAO1*) messenger ribonucleic acid (mRNA) in hepatocytes through RNA interference. Decreased GO enzyme levels reduce the amount of available glyoxylate, a substrate for oxalate production. As the GO enzyme is upstream of the deficient AGT enzyme that causes PH1, the mechanism of action of Oxlumo is independent of the underlying *AGXT* gene mutation (Oxlumo Prescribing Information 2025).

Rivfloza is a double-stranded siRNA, conjugated to GalNAc aminosugar residues. After subcutaneous administration, the GalNAc-conjugated sugars bind to asialoglycoprotein receptors (ASGPR) to deliver Rivfloza to hepatocytes. Rivfloza reduces levels of hepatic lactate dehydrogenase (LDH) via the degradation of LDHA messenger ribonucleic acid (mRNA) in hepatocytes through RNA interference. The reduction of hepatic LDH by Rivfloza reduces the production of oxalate by the liver, thereby reducing subsequent oxalate burden (Rivfloza Prescribing Information 2025).

Clinical Evidence

Oxlumo (lumasiran)

The approval of Oxlumo was supported by ILLUMINATE-A and ILLUMINATE-B, which are both 6-month, Phase 3, multicenter (MC) international trials with ongoing 54-month open-label extensions (OLEs) (Garrelfs et al 2021, Hayes et al 2023). Both studies enrolled patients with PH1 confirmed by *AGXT* gene mutation with elevated Uox and preserved renal function, i.e., eGFR > 45 mL/min/1.73 m2 body surface area (BSA). The primary outcome was the percent change from baseline in Uox excretion after 6 months of Oxlumo when added to standard therapy (e.g., hyperhydration, crystallization inhibitors, and/or pyridoxine therapy).

ILLUMINATE-A (N = 39) was a double-blind (DB), placebo-controlled (PC), randomized controlled trial (RCT) that enrolled patients ≥ 6 years of age (range, 6 to 60 years). Oxlumo was administered subcutaneously (SC) in 3 monthly loading doses, followed by maintenance doses every 3 months. Concomitant pyridoxine use was reported in 56% of patients. For the primary endpoint, the change in 24-hour Uox excretion from baseline to month 6 was -65.4% in the Oxlumo group vs -11.8% in the placebo group (least squares [LS] mean difference, -53.6%; 95% confidence interval [CI], -62.3 to -44.8; p < 0.0001).
At month 6, a 24-hour Uox level within normal limits was achieved by 13/25 patients (52%) in the Oxlumo group vs 0/13 patients in the placebo group (p = 0.001).

ILLUMINATE-B (N = 18) was a single-arm, baseline-controlled, OL trial that enrolled patients < 6 years of age (range, 3 to 72 months). The median baseline spot Uox to creatinine ratio (Uox:Cr) was 0.469 mmol/mmol. The upper limit of normal (ULN) for Uox:Cr ranges from 0.22 mmol/mmol in patients 1 to 6 months of age to 0.07 mmol/mmol in patients 5 to 6 years of age. Concomitant pyridoxine use was reported in 61% of patients. For the primary endpoint, the mean change (standard error of the mean [SEM]) in spot Uox:Cr from baseline was 72% (3.4%) or 0.49 (0.09) mmol/mmol at month 6

and 72% (3.2%) or 0.49 (0.1) mmol/mmol at month 12. The mean reduction fr[illegible] month 6, which improved to 47% at month 12.

ILLUMINATE-C (N = 21) was a 6-month, Phase 3, single-arm, OL study that evaluated the safety and efficacy of lumasiran in pediatric and adult patients with PH1 and advanced kidney disease; i.e., eGFR ≤ 45 mL/min/1.73 m2 or increased serum creatinine [SCr] level (if age < 12 months) and Pox ≥ 20 μ mol/L at screening (Michael et al 2022). cohort A (n = 6) included patients who were not receiving hemodialysis at study enrollment, while cohort B (n = 15) included patients who were receiving hemodialysis at study enrollment. LS mean reductions in Pox were 33.3% (95% CI, -15.2 to 81.8) in cohort A and 42.4% (95% CI, 34.2 to 50.7) in cohort B.

Rivfloza (nedosiran)
PHYOX2 was a 6-month, Phase 2, multinational, DB, PC, RCT designed to evaluate the efficacy and safety of monthly SC Rivfloza in patients ≥ 6 years of age (N = 35; age range, 9 to 46 years) with PH1 (n = 29) or PH2 (n = 6) and preserved renal function; i.e., eGFR ≥ 30 mL/min per 1.73 m2 (Baum et al 2023). Patients continued their standard care measures. At baseline, 52.5% of patients in the Rivfloza group and 75.0% in the placebo group were receiving pyridoxine. The primary endpoint was the percent change from baseline in 24-hour Uox excretion, as assessed by area under the curve (AUC) from day 90 to day 180. The primary endpoint was met with a statistically significantly greater reduction in Uox, as measured by the AUC from day 90 to day 180 in the Rivfloza arm vs the placebo arm (LS mean [standard error (SE)]), +3507.4 [788.49] vs -1664.4 [1190.0]; LS difference [Rivfloza minus placebo], 5171.7; 95% CI, 2929.3 to 7414.2; p < 0.001). At day 180, patients treated with Rivfloza had a mean (standard deviation [SD]) Uox of 0.68 (0.39) mmol/24 hour (change from baseline, -0.61 [0.54]) compared with 1.70 (1.07) mmol/24 hours (change from baseline, -0.27 [0.58]) in the placebo group. The LS mean difference (Rivfloza minus placebo) in reduction in Uox from baseline was 51% in the Rivfloza arm, when averaged over day 90 to day 180 (p < 0.001). The FDA required the primary endpoint results to be expressed in the prescribing information as the LS mean percent change from baseline in 24-hour Uox excretion (corrected for BSA in patients < 18 years of age) averaged over days 90, 120, 150, and 180, as this may be more easily understood by prescribers (FDA Rivfloza integrated review 2023). The LS mean percent change from baseline in 24-hour Uox excretion averaged over days 90, 120, 150, and 180 was -37% (95% CI, -53 to -21) in the Rivfloza group and 12% (95% CI, -12 to 36) in the placebo group, for a between group difference of 49% (95% CI, 26 to 72). Among patients with PH1, the between group difference was 56% (95% CI, 33%, 80%) (Rivfloza prescribing information 2023). A statistically significantly greater proportion of patients in the Rivfloza arm than the placebo arm (50% vs 0%; p = 0.002) achieved the key secondary endpoint of normal or near-normal 24-hour Uox on ≥ 2 consecutive visits, starting at day 90. The PH1 subgroup maintained a sustained Uox reduction while on Rivfloza, whereas no consistent effect was seen in the PH2 subgroup.

PHYOX8 was a Phase 2, MC, single-arm, OL study assessing safety and efficacy of Rivfloza in 15 patients from 2 to 11 years of age with PH1 and relatively preserved renal function (eGFR ≥ 30 mL/min/1.73 m²) (Schaefer et al 2025). Patients received a monthly weight-based dose of Rivfloza for 6 months. Patients continued their standard care measures. The primary endpoint was to evaluate change from baseline to month 6 in both absolute and percentage change in spot Uox:Ucr ratio values. Treatment with Rivfloza reduced the spot urinary oxalate to creatinine ratio by 64% (95% CI: 44, 84) from baseline, with an absolute risk reduction of 0.25mmol/mmol (95% CI: 0.21, 0.29). There were no deaths or adverse events leading to discontinuation from the study and 13 patients continued on to the PHYOX 3 open label extension (OLE) study.

PHYOX3 is an ongoing, Phase 3, OLE trial evaluating long-term safety and efficacy of Rivfloza in patients with PH1 and eGFR ≥ 30 mL/min/1.73 m^2 who completed a previous Rivfloza study (Lieske et al 2025). Patients receive a fixed monthly weight-based dose of Rivfloza for up to 6 years. The primary endpoint is to evaluate treatment efficacy as measured by eGFR annual rate of decline. Interim data from 40 patients (followed up to 42 months) show that mean eGFR remained stable (71.1–81.5 mL/min/1.73 m²). Urinary oxalate excretion decreased rapidly and was sustained at ≥60% reduction from baseline starting at month 2, with most participants achieving normal (<0.46 mmol/24 h/1.73 m²) or near-normal levels throughout the study. The annualized kidney stone event rate dropped from 0.40 to 0.20 events per person-year. Rivfloza was well tolerated; the most common treatment-related adverse event was injection site reactions (15%). No deaths or discontinuations due to adverse events were reported.

Place in Therapy

Clinical practice recommendations for PH were published in January 2023 in a consensus statement from the European Rare Kidney Disease Reference Network (ERKNet) and OxalEurope (Groothoff et al 2023). The authors recommend that all patients with suspected PH receive prompt initiation of conservative therapy including hyperhydration and administration of potassium citrate in patients with preserved kidney function. Testing for pyridoxine responsiveness in patients with PH1 received a strong recommendation. In patients with renal dysfunction, consideration of renal replacement therapy is suggested before kidney failure has developed in those who are at high risk of systemic oxalosis due to high Pox levels or are already suffering from comorbidities. A personalized dialysis regimen is recommended based on clinical condition and Pox values, aiming to keep Pox in the range of values for patients with kidney failure without PH.

RNA interference (RNAi) therapy is recommended in patients with:

- Unresponsiveness to pyridoxine (biochemically or based on genetic analysis), Uox excretion > 1.5 x the upper reference limit, and clinical phenotype of PH1 characterized by active stone disease and/or nephrocalcinosis and/or renal impairment.
- A mutation consistent with pyridoxine unresponsiveness and eGFR < 30 mL/min/1.73 m2.

RNAi therapy is suggested in patients with:

- Partial pyridoxine responsiveness with Uox excretion > 1.5 x the upper reference limit and demonstration of a clinical phenotype of PH1 characterized by active stone disease and/or nephrocalcinosis and/or renal impairment.
- Unresponsiveness to pyridoxine (biochemically or anticipated based on genetic analysis), Uox excretion > 1.5 x upper reference limit, and no ongoing clinical disease.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Oxlumo is a *HAO1*-directed small interfering ribonucleic acid (siRNA) indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients.

Rivfloza 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/min/1.73 m^2.

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Policy History/Revision Information

Date	Summary of Changes
1/21/2026	Approved by OptumRx P&T Committee

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).