Corporate Medical Policy: Lumasiran (Oxlumo™)

Restricted Product(s):

- lumasiran (Oxlumo™) subcutaneous injection for administration by a healthcare professional

FDA Approved Use:

- For treatment of adult and pediatric patients (birth and older) with primary hyperoxaluria type 1 to lower urinary oxalate levels

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

Initial Criteria for Approval:

1. The patient has a diagnosis of **primary hyperoxaluria type 1 (PH1) [medical record documentation required]**; **AND**
2. The diagnosis has been confirmed by at least one of the following **[medical record documentation required]**:
    a. Molecular genetic testing demonstrating *AGXT* gene mutation; **OR**
    b. Liver biopsy demonstrating alanine-glyoxylate aminotransferase (AGT) deficiency; **AND**
3. The requested agent will be used to lower urinary oxalate levels **[medical record documentation required]**; **AND**
4. The patient has an eGFR greater than or equal to 30 mL/minute/1.73 m^2 **[medical record documentation required]**; **AND**
5. The patient has NOT had a previous liver transplant **[medical record documentation required]**; **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent **[medical record documentation required]**; **AND**
7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist, gastroenterologist, urologist, geneticist) or has consulted with a specialist in the area of the patient's diagnosis **[medical record documentation required]**; **AND**
8. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
9. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

    Duration of Approval: 180 days (6 months)

Continuation Criteria for Approval:

1. The patient was approved through Blue Cross NC initial criteria for approval; **OR**
2. The patient would have met initial criteria for approval at the time they started therapy; **AND**

3. The patient has demonstrated a positive clinical response while using the medication, as demonstrated by improvement, stabilization, or slowed worsening of disease [e.g., reduction from baseline in laboratory parameters (e.g., 24-hour urinary oxalate excretion, spot urinary oxalate:creatinine ratio, plasma oxalate concentration), improvement/stabilization/slowed worsening of clinical manifestations (e.g., eGFR, nephrocalcinosis, renal stone events, systemic oxalosis, renal impairment)] **[medical record documentation required]**; **AND**
4. The patient has NOT had a previous liver transplant **[medical record documentation required]**; **AND**
5. The patient does NOT have any FDA labeled contraindications to the requested agent **[medical record documentation required]**; **AND**
6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist, gastroenterologist, urologist, geneticist) or has consulted with a specialist in the area of the patient's diagnosis **[medical record documentation required]**; **AND**
7. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
8. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval: 365 days (1 year)

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
lumasiran (Oxlumo™) subcutaneous (SC) injection	PH1 in patients age birth or older	SC (loading dose [LD], then maintenance dose starting 1 month after last LD): • < 10 kg: 6 mg/kg once monthly x 3 doses, then 3 mg/kg once monthly • 10 kg to < 20 kg: 6 mg/kg once monthly x 3 doses, then 6 mg/kg once every 3 months (quarterly) • ≥ 20 kg: 3 mg/kg once monthly x 3 doses, then 3 mg/kg once every 3 months (quarterly)	J0224	Initial: 2700 Continuation: 2160

***Maximum units allowed for duration of approval**

***Site of Care Medical Necessity Criteria**

1. For requests for injection or infusion administration in an **inpatient setting**, the injection or infusion may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the injection or infusion; **OR**
2. For requests for injection or infusion administration in an **outpatient hospital setting**, the injection or infusion may be given if the above medical necessity criteria are met AND ONE of the following must be met:
    a. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
    b. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
    c. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**
    d. Re-initiation of therapy, defined as ONE of the following:
        i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; **OR**
        ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**
    e. Requirement of a change in the requested restricted product formulation; **AND**
3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information

November 2021: Criteria change: Removed baseline diagnostic metabolic testing requirements, and no secondary causes of hyperoxaluria; added use to lower urinary oxalate levels and no FDA labeled contraindications to therapy for clarity according to FDA labeling; reformatted continuation criteria to require a positive clinical response while using the medication as demonstrated by improvement, stabilization, or slowed worsening of disease.
October 2021: Criteria change: Added Site of Care medical necessity criteria. **Policy notification given 8/2/2021 for effective date 10/1/2021**.
July 2021: Criteria update: Added HCPCS code J0224 to dosing reference table effective 7/1/2021, deleted C9074 and non-specific codes C9399, J3490, and J3590 termed 6/30/2021.
June 2021: Criteria change: Added maximum units; medical policy formatting change. **Policy notification given 4/16/2021 for effective date 6/16/2021**.

*Further historical criteria changes and updates available upon request from Medical Policy and/or Corporate Pharmacy.

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- If you need these services, contact Customer Service **1-888-206-4697**, TTY and TDD, call **1-800-442-7028**.
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- You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, Civil Rights Coordinator - Privacy, Ethics & Corporate Policy Office 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.*

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ATTENTION: If you speak another language, language assistance services, free of charge, are available to you. Call 1-888-206-4697 (TTY: 1-800-442-7028).

ATENCIÓN: Si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-888-206-4697 (TTY: 1-800-442-7028).

注意：如果您講廣東話或普通話， 您可以免費獲得語言援助服務。請致電 1-888-206-4697
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CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số
1-888-206-4697 (TTY: 1-800-442-7028).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.
1-888-206-4697 (TTY: 1- 800-442-7028)번으로 전화해 주십시오.

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-888-206-4697 (ATS : 1-800-442-7028).

ملحوظة: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم
1-888-206-4697. المبرقة الكاتبة: 1-800-442-7028.

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau
1-888-206-4697 (TTY: 1-800-442-7028).

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-888-206-4697 (телетайп: 1-800-442-7028).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1-888-206-4697 (TTY: 1-800-442-7028).

સુચના: જો તમે ગુજરાતી બોલતા હો, તો નિ:સુલ્કુ ભાષા સહાય સેવાઓ તમારા માટે ઉપલબ્ધ છે. ફોન કરો 1-888-206-4697 (TTY: 1-800-442-7028).

ចំណាំ៖ ប្រសិនបើលោកអ្នកនិយាយជាភាសាខ្មែរ សេវាកម្មជំនួយផ្នែកភាសាមានផ្តល់ជូនសម្រាប់លោកអ្នកដោយមិនគិតថ្លៃ។ សូមទំនាក់ទំនងតាមរយៈលេខ៖ 1-888-206-4697 (TTY: 1-800-442-7028)។

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-888-206-4697 (TTY: 1-800-442-7028).

ध्यान दें: यदि आप हिन्दी बोलते हैं तो आपके लिए मुफ्त में भाषा सहायता सेवाएं उपलब्ध हैं। 1-888-206-4697 (TTY: 1-800-442-7028) पर कॉल करें।

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注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。1-888-206-4697（TTY: 1-800-442-7028）まで、お電話にてご連絡ください。