Clinical Policy Title:	lumasiran
Policy Number:	RxA.676
Drug(s) Applied:	Oxlumo™
Original Policy Date:	02/23/2021
Last Review Date:	01/17/2022
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
lumasiran (Oxlumo™)	Treatment of primary hyperoxaluria type 1	Less than 10 kg: • Loading dosage, 6 mg/kg subcutaneously once monthly for 3 months; • Maintenance dosage, 3 mg/kg subcutaneously once monthly starting 1 month after last loading dose. 10 to less than 20 kg: • Loading dosage, 6 mg/kg subcutaneously once monthly for 3 months; • Maintenance dosage, 6 mg/kg subcutaneously once every 3 months starting 1 month after last loading dose. 20 kg and above: • Loading dosage, 3 mg/kg subcutaneously once monthly for 3 months; • Maintenance dosage, 3 mg/kg subcutaneously once every 3 months starting 1 month after last loading dose.	Refer to Dosing Regimen

Dosage Forms

- Injection: 94.5 mg/0.5 mL in a single-dose vial

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Primary hyperoxaluria type 1 (must meet all):

1. Diagnosis of PH1 with confirmed AGXT mutation or a liver biopsy demonstrating absent or significantly reduced AGT activity;
   Per UTDOL: If no mutation has been found, the diagnosis can be made by a liver biopsy demonstrating absent or significantly reduced AGT activity
2. Prescribed by or in consultation with a nephrologist;
3. eGFR ≥ 30 mL/min/1.73 m^2;
4. Patient does not have a history of kidney or liver transplant;
5. Patient does not have systemic oxalosis;
6. Documentation that the patient has made efforts to increase fluid intake to at least 3 L/day per 1.73 m^2 BSA;
7. Concurrent use of pyridoxine or previous trial of at least 3 months of pyridoxine with no significant improvement observed (for example, < 30% reduction in urine oxalate concentration after at least 3 months of therapy).
8. Requested dose does not exceed the FDA approved dosing recommendation.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Primary hyperoxaluria type 1 (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is tolerating therapy;
3. Documented improvement in urinary oxalate excretion from baseline;
4. Member has no history of liver and kidney transplant;
5. Requested dose does not exceed the FDA approved dosing recommendation for continued therapy.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
SC: subcutaneous
siRNA: small interfering ribonucleic acid
PH1: primary hyperoxaluria type 1

APPENDIX B: Therapeutic Alternatives

Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

None

References

1. Oxlumo Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals Inc; November 2020. Available at: https://www.alnylam.com/wp-content/uploads/pdfs/OXLUMO-Prescribing-Information.pdf. Accessed December 10, 2021.
2. Genetic and Rare Diseases Information Center. Primary hyperoxaluria type 1. Updated August 12, 2016. Available at: https://rarediseases.info.nih.gov/diseases/2835/primary-hyperoxaluria-type-1 Accessed December 10, 2021.
3. IPD Analytics_New Drug Review_Oxlumo_12 2020.pdf. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Oxlumo. Accessed December 10, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/20/2021	03/09/2021
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. References were reviewed and updated.	12/10/2021	1/17/2022