ATRIO HEALTH PLANS

Hyperoxaluria
Oxlumo (lumasiran) J0224
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ **Nexviazyme**

☐ Individual has a diagnosis of non-infantile onset (late-onset) Pompe disease as confirmed by all the following:

- ☐ Documentation is provided that individual has a GAA enzyme assay which shows reduced enzyme activity less than 40% of the lab specific normal mean value; AND
- ☐ Documentation is provided that individual has a second GAA enzyme activity assay in a separate sample (from purified lymphocytes, fibroblasts or muscle) or by GAA sequencing (AANEM 2009); AND
- ☐ Forced vital capacity (FVC) 30 – 85% of predicted value, and documentation is provided; AND
- ☐ Ability to walk 40 meters on a 6- minute walk test (w/o assistive devices), with documentation

Lumizyme on next page >>>

☐ **Lumizyme**

☐ Individual has a diagnosis of infantile-onset Pompe disease as confirmed by all of the following:

- ☐ Documentation is provided that individual has acid alpha-glucosidase deficiency (GAA) activity in skin fibroblasts of less than 1% of the normal mean or by GAA gene sequencing; AND
- ☐ Individual has symptoms (for example respiratory and/or skeletal muscle weakness); AND
- ☐ Confirmed evidence of hypertrophic cardiomyopathy;

☐ Individual has a diagnosis of non-infantile onset (late-onset) Pompe disease as confirmed by::

- ☐ A. Documentation is provided that individual has a GAA enzyme assay which shows reduced enzyme activity less than 40% of the lab specific normal mean value; AND
- ☐ B. Documentation is provided that individual has a second GAA enzyme activity assay in a separate sample (from purified lymphocytes, fibroblasts or muscle) or by GAA sequencing; AND
- ☐ C. Forced vital capacity (FVC) 30 – 79% of predicted value, and documentation is provided; AND
- ☐ D. Ability to walk 40 meters on a 6- minute walk test (assisted devices permitted), and documentation is provided; AND
- ☐ E. Muscle weakness in the lower extremities.

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Nexviazyme**

☐ Individuals with non-infantile onset (late-onset) Pompe disease are responding to therapy (including improvement, stabilization, or slowing of disease progression).

☐ **Lumizyme**

☐ Individuals are using Lumizyme for the treatment of infantile-onset Pompe disease;

OR

☐ Individuals with non-infantile onset (late-onset) Pompe disease are responding to therapy (including improvement, stabilization, or slowing of disease progression).

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Hyperoxaluria Drug PA

Drug Name(s):
OXLUMO **LUMASIRAN**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:
N/A

Prescriber Restrictions:
Urologist or another related specialist

Coverage Duration:
Approval will be for 12 months

FDA Indications:
Oxlumo

- Primary hyperoxaluria, type I

Off-Label Uses:
N/A

Age Restrictions:
N/A

Other Clinical Consideration:
N/A

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/80AFB2/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/D90D13/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=933107&contentSetId=100&title=Lumasiran&servicesTitle=Lumasiran&brandName=Oxlumo&UserMdxSearchTerm=Oxlumo&=null#