LETTER OF MEDICAL NECESSITY TEMPLATE

OXLUMO® (lumasiran) injection for subcutaneous use

for the treatment of Primary Hyperoxaluria Type 1 (PH1)

**To the HCP:** The following is a sample letter of medical necessity template that can be customized based on your patient’s medical history and demographic information using your independent clinical judgment. You are responsible for providing information that completely and accurately represents your patient’s circumstances. Please note that some payers may have specific forms that must be completed in order to request prior authorization or to document medical necessity. Use of this document does not guarantee coverage or reimbursement by any third-party payer.

[Date] RE: [Patient Name]

[Medical Director Name] [Group Number]

[Payer Name] [Policy Number]

[Payer Address Line 1] [Claim Number]

[Payer City, State, ZIP] [Diagnosis, ICD-10]

Dear [Medical Director],

I am writing this letter of medical necessity to request that my patient, [insert patient name], receive OXLUMO® (lumasiran), a product that is approved by the United States Food and Drug Administration (FDA) for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients.1

# Product Description

OXLUMO® is a small interfering ribonucleic acid (siRNA), covalently linked to a ligand containing three N-acetylgalactosamine (GalNAc) residues to enable targeted delivery of the siRNA to hepatocytes, where the PH1 disease process originates. OXLUMO targets the hydroxyacid oxidase 1 (HAO1) messenger ribonucleic acid (mRNA) in hepatocytes through RNA interference, thereby reducing levels of the glycolate oxidase (GO) enzyme encoded by HAO1. Decreased GO enzyme levels reduce the amount of available glyoxylate, a necessary substrate for oxalate production, in the liver. This results in reduction of hepatic oxalate production, the primary driver of the disease process in PH1.1

# Rationale for Treatment

***[Add additional information that is pertinent to your patient]***

Based on the clinical efficacy and safety data of OXLUMO® (lumasiran), it is my medical opinion that initiating OXLUMO® for this patient is appropriate and medically necessary at this time. Coverage of OXLUMO® therapy, including all administration services (described in further detail below), should be reimbursed. The remainder of the letter describes the patient’s medical history, prognosis, and rationale for treatment with OXLUMO®.

## Summary of Patient’s Medical History

***[Please complete based on your patient’s medical history; delete any categories that are not pertinent to your patient]***

□ Date of PH1 diagnosis: [complete]

* Genetic Testing: [If applicable, provide genetic confirmation of AGXT gene mutation]
* Biochemical testing: [If applicable, provide results of your patient’s urine (UOx) and/or plasma (POx) oxalate testing and/or UOx:creatinine ratio with reference ULN]
* Other evaluation(s): [If applicable, describe other means of diagnosis]

□ Family history of PH1:

* [Provide a brief description of relevant family history (e.g., impacted family members, known outcomes)]

□ Relevant Medical History:

* PH1 sign(s) and symptom(s):
	+ Current kidney function: (if applicable) [please describe]
	+ Kidney manifestations (kidney and / or urinary tract stones, chronic kidney disease, acute loss of kidney function, nephrocalcinosis, failure to thrive, etc): (if applicable) [please describe]
	+ Other PH1 related clinical manifestations: (if applicable) [please describe]

□ Previous/current treatments:

* [Describe previous and current treatment strategies; include the dose, start date, end date (if applicable) of each treatment, and reason for discontinuation (if applicable)]

□ Other relevant medical information:

* [Add any additional medical information that would be useful in assessing use of OXLUMO® for the patient.]

# Dosing and Administration1

The recommended dosing regimen of OXLUMO® consists of starting doses followed by ongoing doses as shown in Table 1. OXLUMO® is intended for subcutaneous administration by a healthcare professional. My patient weighs [insert weight in kilograms]. Therefore, [he/she] should receive a starting dose of [insert dose] mg once monthly for three doses then an ongoing dose of [insert dose] mg [once monthly/every 3 months (quarterly)].

### Table 1. OXLUMO® Weight-Based Dosing Regimen

|  |  |  |
| --- | --- | --- |
| **Body Weight** | **Loading Dose** | **Maintenance Dose** |
| Less than 10 kg | 6 mg/kg once monthly for 3 doses | 3 mg/kg once monthly, beginning 1 month after the last loading dose |
| 10 kg to less than 20 kg | 6 mg/kg once monthly for 3 doses | 6 mg/kg once every 3 months (quarterly), beginning 1 month after the last loading dose |
| 20 kg and above | 3 mg/kg once monthly for 3 doses | 3 mg/kg once every 3 months (quarterly), beginning 1 month after the last loading dose |

For Patients on Hemodialysis

Administer OXLUMO after hemodialysis if administered on dialysis days.

Missed Dose

If a dose is delayed or missed, administer OXLUMO® as soon as possible. Resume prescribed monthly or quarterly dosing, from the most recently administered dose.

# Closing Remarks

*[Please provide closing comments relative to this patient’s case (e.g., given the patient’s existing signs and symptoms, the potentially life threatening or debilitating nature of PH1, and the efficacy and safety profile of OXLUMO®, it is medically necessary and appropriate to initiate treatment with OXLUMO® using the FDA-approved dosing regimen.)]*

Please contact my office at [insert phone number] if more information is needed. I look forward to receiving your timely response to this claim.

Sincerely,

[Insert physician name and provider number]

[Attachments: describe]

# References:

1. OXLUMO® (lumasiran) [Package Insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.