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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Genitourinary Agents	**Original Policy Date:**	December 18, 2020
Subject:	Oxlumo	**Page:**	1 of 4

Last Review Date: March 12, 2021

Oxlumo

Description

Oxlumo (lumasiran)

Background
Oxlumo (lumasiran) targets oxalate overproduction in the liver. Primary hyperoxaluria type 1 (PH1) is a progressive genetic disease caused by mutations in the *AGXT* gene that render the liver enzyme alanine:glyoxylate aminotransferase (AGT) dysfunctional. Normally, AGT processes glyoxylate, which is generated by another liver enzyme, glycolate oxidase (GO). In PH1, a defect in AGT means glyoxylate is instead converted to oxalate. Oxalate cannot be metabolized and is typically excreted by the kidneys at normal levels. When overproduced as it is in PH1, oxalate can cause progressive, irreversible damage. Oxalate combines with calcium, creating calcium oxalate crystals leading to kidney stones and crystal deposits throughout the body. Oxlumo is not expected to be effective in primary hyperoxaluria type 2 (PH2) or type 3 (PH3) because its mechanism of action does not affect the metabolic pathways causing PH2 and PH3 (1-2).

Regulatory Status
FDA-approved indication: 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 (1).

Oxlumo is intended for subcutaneous use and should be administered by a healthcare professional. The recommended dosing regimen of Oxlumo consists of loading doses followed

by maintenance doses administered subcutaneously. Dosing is based on actual body weight (1).

The most common adverse reaction is injection site reactions (1).

The safety and effectiveness of Oxlumo have been established in pediatric patients aged birth and older (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Oxlumo may be considered **medically necessary** for the treatment of primary hyperoxaluria type 1 (PH1) and if the conditions indicated below are met.

Oxlumo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

Primary hyperoxaluria type 1 (PH1)

AND ALL of the following:

a. Patient will be dosed based on actual body weight
b. Prescriber agrees to monitor urinary oxalate levels

Prior – Approval *Renewal* Requirements

Diagnosis

Patient must have the following:

Primary hyperoxaluria type 1 (PH1)

AND ALL of the following:

a. Patient will be dosed based on actual body weight
b. Urinary oxalate levels have decreased

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Oxlumo (lumasiran) 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. The safety and effectiveness of Oxlumo have been established in pediatric patients aged birth and older (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Oxlumo while maintaining optimal therapeutic outcomes.

References

1. Oxlumo [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; November 2020.
2. Cochat P, Rumsby G. *N Engl J Med*. 2013;369(7):649-658. Accessed on January 30, 2021.

Policy History

Date	Action
December 2020	Addition to PA
March 2021	Annual editorial review

Revised background and summary sections per SME

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.