CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines
Medical Benefit Drugs
Oxlumo® (lumasiran)

Effective: July 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Approval of Oxlumo was based on the placebo-controlled ILLUMINATE-A and open-label ILLUMINATE-B trials which included a combined 57 patients with PH1. Patients who received Oxlumo saw a reduction in urinary oxalate versus placebo.

Food and Drug Administration (FDA) Approved Indications:

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

Clinical Guideline Coverage Criteria

The Plan may authorize coverage for Oxlumo when **both** of the following clinical criteria are met:

1. Member has a diagnosis of primary hyperoxaluria type 1 (PH1).

AND

2. Prescribed by or in consultation with endocrinologist, nephrologist, or any healthcare provider with experience managing primary hyperoxaluria

Limitations

- Any indications other than those listed are considered experimental or investigational and will not be approved by the Plan
- The Plan will not cover Oxlumo in Members with primary hyperoxaluria type 2 or type 3

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0224	Injection ferric lumasiran, .5mg

References:

1. A Phase 1/2 Trial Of Lumasiran (ALN-GO1), An Investigational RNA Interference (RNAi) Therapeutic, For Primary Hyperoxaluria Type 1. ESPN Annual Meeting. Antalya, Turkey. 4 October 2018.
2. A Study to Evaluate Lumasiran in Children and Adults with Primary Hyperoxaluria Type 1 (ILLUMINATE-A). Clinicaltrials.gov website https://clinicaltrials.gov/ct2/show/NCT03681184?term=lumasiran&draw=2&rank=4. Accessed December 1, 2020.
3. A Study of Lumasiran in Infants and Young Children With Primary Hyperoxaluria Type 1 (ILLUMINATE-B). Clinicaltrials.gov website https://clinicaltrials.gov/ct2/show/NCT03905694?term=lumasiran&draw=2&rank=2. Accessed December 1, 2020.
4. A Study to Evaluate Lumasiran in Patients With Advanced Primary Hyperoxaluria Type 1 (ILLUMINATE-C). Clinicaltrials.gov website https://clinicaltrials.gov/ct2/show/NCT04152200?term=lumasiran&draw=2&rank=1. Accessed December 1, 2020.

5. Cochat P, Hulton SA, Acquaviva C, et al. Primary Hyperoxaluria Type 1: Indications For Screening And Guidance For Diagnosis And Treatment. Nephrol Dial Transplant 2012; 27:1729.
6. Hoppe B, Beck BB, Milliner DS. The primary hyperoxalurias. Kidney Int 2009; 75:1264.
7. Niaudet P. Primary Hyperoxaluria. In: UpToDate, Mattoo TK, Kim MS, (Ed), UpToDate, Waltham, MA, 2020.
8. Oxlumo® (lumasiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; November 2020 accessed May 16, 2022 athttps://www.alnylam.com/sites/default/files/pdfs/OXLUMO-Prescribing-Information.pdf.
9. Bhasin B, Urekli HM, Atta MG. Primary and secondary hyperoxaluria: understanding the enigma. World J Nephrol. 2015;4(2):235-244.

Approval And Revision History

April 19, 2023: year: Reviewed by the Medical Policy Approval Committee (MPAC).

May 9, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023.
- Administrative update: April 2023 added Medical Benefit Drugs to title and CPCT logo update.
- May 17, 2023: Annual review added “and plasma oxalate levels in” to FDA approved indications in overview effective July 1, 2023.
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.