Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 234.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Oxlumo (lumasiran)

I. Policy:
Oxlumo (lumasiran)

II. Purpose/Objective:
To provide a policy of coverage regarding Oxlumo (lumasiran)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Oxlumo (lumasiran) is a hydroxyacid oxidase 1 (HAO1)-directed small interfering ribonucleic acid (siRNA) that reduces the amount of available glyoxylate, a substrate for oxalate production, by targeting hydroxyacid oxidase 1 (HAO1) messenger RNA in hepatocytes through RNA interference, subsequently decreasing glycolate oxidase enzyme levels.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Oxlumo (lumasiran) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Prescription written by or in consultation with an appropriate specialist (including but not limited to a nephrologist, urologist, geneticist, or hepatologist) **AND**
- Medical Record documentation of primary hyperoxaluria type 1 (PH1) as confirmed by ONE of the following:
    - Molecular genetic testing that confirms a mutation of alanin:glyoxylate aminotransferase (AGXT) gene* **OR**
    - A liver biopsy to confirm absent or significantly reduced alanin:glyoxylate aminotransferase (AGT)

AND

- Medical record documentation of metabolic screening that demonstrates ONE of the following:
    - Markedly increased urinary oxalate excretion (i.e. generally greater than 0.7 mmol/1.73 m^2 per day or greater than the upper limit of normal) **OR**
    - Increased urinary oxalate to creatinine ratio (i.e. greater than the age-specific upper limit of normal)

AND

- Medical record documentation of sufficient kidney function as defined by ONE of the following:
    - Medical record documentation patient has an eGFR ≥30 mL/min/1.73m^2 **OR**
    - If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range

AND

- Medical record documentation that the patient does not have a history of liver transplant.

*****Note: AGXT genotypes include but are not limited to: PR/RR, PR/M, PR/N, M/M, M/N, N/N

AUTHORIZATION DURATION: Approval will be given for an **initial duration of six (6) months** or less if the reviewing provider feels it is medically appropriate. After the initial six (6) month approval, subsequent approvals will be for a **duration of twelve (12) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- Sufficient kidney function as defined by ONE of the following:
    - Medical record documentation patient has an eGFR ≥30 mL/min/1.73m^2 **OR**
    - If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range

AND

- Medical record documentation that the patient does not have a history of liver transplant.

Ongoing subsequent approvals will be for a **duration of twelve (12) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- Sufficient kidney function as defined by ONE of the following:
    - Medical record documentation patient has an eGFR ≥30 mL/min/1.73m^2 **OR**
    - If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range

AND

- Medical record documentation that the patient does not have a history of liver transplant.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 5/18/21

Revised: 3/31/23 (LOB carve out, Medicaid business segment)

Reviewed: 5/2/22 (Medicaid PARP statement)