Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 280.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Lunsumio (mosunetuzumab-axgb)

I. Policy:
Lunsumio (mosunetuzumab-axgb)

II. Purpose/Objective:
To provide a policy of coverage regarding Lunsumio (mosunetuzumab-axgb)

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:
Lunsumio (mosunetuzumab-axgb) is a T-cell engaging bispecific humanized monoclonal antibody that binds to the CD3 receptor expressed on the surface of T-cells and CD20 expressed on the surface of lymphoma cells and some healthy B-lineage cells. Mosunetuzumab activates T-cells, releasing proinflammatory cytokines, and inducing B-cell lysis.

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

Lunsumio (mosunetuzumab-axgb) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation that Lunsumio is written by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years of age **AND**
- Medical record documentation of a diagnosis with relapsed or refractory follicular lymphoma **AND**
- Medical record documentation of prior treatment with two or more lines of therapy

AUTHORIZATION DURATION: Approval of Lunsumio will be given for an initial authorization of 6 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be given for 12 months or less if the reviewing provider feels it is medically appropriate, not to exceed the limitations outlined below.

Authorization of Lunsumio for the treatment of relapsed or refractory follicular lymphoma should not exceed the FDA-approved treatment duration of 8 total cycles for patients who are in complete remission following 8 cycles of Lunsumio treatment.

Authorization of Lunsumio for the treatment of relapsed or refractory follicular lymphoma should not exceed the FDA-approved treatment duration of 17 total cycles for patients who are in partial remission or stable disease following 8 cycles of Lunsumio treatment.

For requests exceeding the above limits, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

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.

REFERENCES:

1. Lunsumio [prescribing information]. South San Francisco, CA: Genentech Inc; December 2022.

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

Devised: 5/16/23

Revised: 12/28/23 (references added)

Reviewed: 5/14/24

MA UM Committee approval: 12/31/23