Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 228.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Breyanzi (lisocabtagene maraleucel)

I. Policy:
Breyanzi (lisocabtagene maraleucel)

II. Purpose/Objective:
To provide a policy of coverage regarding Breyanzi (lisocabtagene maraleucel)

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:
Breyanzi (lisocabtagene maraleucel) is a CD19-directed genetically modified autologous T-cell immunotherapy in which a patient's T-cells are reprogrammed with a transgene encoding a chimeric antigen receptor (CAR) to identify and eliminate CD19-expressing cells (malignant and normal). Lisocabtagene maraleucel has a defined composition of CD8-and CD4-positive CAR T-cells. CAR is comprised of an FMC63 monoclonal antibody-derived single chain variable fragment (scFv), IgG4 hinge region, CD28 transmembrane domain, 4-1BB (CD137) costimulatory domain, and CD3 zeta activation domain. CD3 zeta signaling initiates activation and antitumor activity, while 4-1BB (CD137) signaling enhances T-cell expansion. CAR binding to CD19 (expressed on cell surfaces) induces activation and proliferation of CAR T-cells, release of pro-inflammatory cytokines, and results in cytotoxic destruction of target cells. Lisocabtagene maraleucel is prepared from the patient's T-cells, which are obtained via leukapheresis.

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

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

- Medical record documentation that Breyanzi is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy **AND**
- Medical record documentation of one of the following diagnoses:
    - High-grade B-cell lymphoma **OR**
    - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma) **OR**
    - Primary mediastinal large B-cell lymphoma **OR**
    - Follicular lymphoma grade 3B

  AND
- One of the following:
    - Medical record documentation of two or more lines of prior systemic therapy **OR**
    - Medical record documentation of refractory disease to first-line chemoimmunotherapy **OR**
    - Medical record documentation of relapse within 12 months of first-line chemoimmunotherapy **OR**
    - Medical record documentation of relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age

AUTHORIZATION DURATION One-time authorization for one administration of Breyanzi

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: 4/29/21

Revised: 3/29/22 (Medicaid PARP statement), 8/25/22 (Relapsed after first line treatment indication), 8/22/23 (LOB carve out, Medicaid business segment)

Reviewed: