Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 159.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Kymriah (tisagenlecleucel)

I. Policy:
Kymriah (tisagenlecleucel)

II. Purpose/Objective:
To provide a policy of coverage regarding Kymriah (tisagenlecleucel)

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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit 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:
Kymriah (tisagenlecleucel) 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 malignant and normal cells. The CAR is comprised of a murine single-chain antibody fragment which recognizes CD19 and is fused to intracellular signaling domains from 4-1BB (CD137) and CD3 zeta. CD3 zeta is a critical component for initiating T-cell activation and antitumor activity, while 4-1BB enhances expansion and persistence of tisagenlecleucel. After binding to CD19-expressing cells, the CAR transmits a signal to promote T-cell expansion, activation, target cell elimination, and persistence of the tisagenlecleucel cells. Tisagenlecleucel is prepared from the patient's peripheral blood cells obtained via leukapheresis.

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

Kymriah (tisagenlecleucel) will be considered medically necessary when ALL of the following criteria are met:

Acute Lymphoblastic Leukemia (ALL)
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is less than 26 years of age **AND**
- Medical record documentation of a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second (or later) relapse AND
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Note: The indication of Kymriah for Acute Lymphoblastic Leukemia (ALL) is intended to treat patients up to the age of 25 years 364 days. Upon reaching 26 years of age the patient is no longer a candidate for Kymriah treatment. Per Novartis, Kymiah will not be manufactured for any patient who does not meet the specific FDA approved indication, including these age restrictions. (This does not apply to Large B-Cell Lymphoma)

Large B-Cell Lymphoma
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or greater **AND**
- Medical record documentation of one of the following diagnoses:
    - High grade B-cell lymphoma **OR**
    - Diffuse Large B-Cell Lymphoma (DLBCL) arising from follicular lymphoma **OR**
    - Diffuse Large B-cell Lymphoma (DLBCL) not otherwise specified

  AND
- Medical record documentation of relapsed or refractory disease after at least two lines of systemic therapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Limitation of use: Kymriah is not indicated for treatment of patients with primary central nervous system lymphoma.

Follicular Lymphoma, Relapsed or Refractory (r/r FL)
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of relapsed or refractory follicular lymphoma (FL) **AND**
- Medical record documentation of a therapeutic failure on two or more previous lines of therapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

AUTHORIZATION DURATION: (For all indications) Approved requests will be for a One-time authorization for one administration of Kymriah.

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: 11/21/17

Revised: 1/15/19 (Large B-cell lymphoma), 8/25/22 (Follicular Lymphoma, Medicaid PARP statement)

Reviewed: 9/28/18, 11/1/19, 9/30/20, 9/22/21