Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 256.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Carvykti (ciltacabtagene autoleucel)

I. Policy:
Carvykti (ciltacabtagene autoleucel)

II. Purpose/Objective:
To provide a policy of coverage regarding Carvykti (ciltacabtagene autoleucel).

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:
Ciltacabtagene autoleucel is a B cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy in which a patient's T cells are reprogrammed via transduction with a lentiviral vector to express an anti-BCMA chimeric antigen receptor (CAR). The CAR T-cell construct includes an anti-BCMA targeting domain consisting of a CD3-zeta signaling domain and a 4-1BB costimulatory domain. Ciltacabtagene autoleucel is prepared from the patient's peripheral blood mononuclear cells (obtained via leukapheresis), which are enriched for T cells. When infused back into the patient, the anti-BCMA CAR T cells recognize and eliminate BCMA-expressing target cells. In addition to T cells, ciltacabtagene autoleucel may contain natural killer (NK) cells.

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

Carvykti (ciltacabtagene autoleucel) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Medical record documentation that Carvykti is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of relapsed or refractory multiple myeloma **AND**
- Medical record documentation of at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody **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: One-time authorization for one administration of Carvykti.

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: 5/17/22

Revised: 5/11/23 (LOB carve out, Medicaid business segment)

Reviewed: