Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 324.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Amtagvi (lifileucel)

I. Policy:
Amtagvi (lifileucel)

II. Purpose/Objective:
To provide a policy of coverage regarding Amtagvi (lifileucel).

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:
Amtagvi (lifileucel) is a tumor-derived autologous tumor-infiltrating lymphocyte (TIL) therapy, composed primarily of CD4+ and CD8+ T-cells, manufactured using resected tumor tissue from the eligible patient, and then expanded ex-vivo. Resection of the tumor tissue, followed by ex-vivo expansion, allows for reinvigoration of T-cell functionality outside of the immunosuppressive tumor microenvironment. Following lymphodepleting therapy, re-infusion, and in vivo T-cell expansion with high-dose aldesleukin (IL-2), TILs migrate to tumor sites, target tumor-associated antigens, and facilitate immune-mediated tumor cell lysis and overall tumor regression.

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

Amtagvi (lifileucel) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Medical record documentation that Amtagvi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years old **AND**
- Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
- Medical record documentation of previous treatment with an anti-programmed cell death protein 1/programmed cell death ligand 1 (PD-1/PD-L1) inhibitor **AND**
- If BRAF V600 mutation positive: Medical record documentation of previous treatment with a BRAF inhibitor with or without a MEK inhibitor **AND**
- Medical record documentation that the member has not received prior treatment with tumor-derived T cell therapy or other genetically modified T cell therapy.

AUTHORIZATION DURATION: Amtagvi will be approved for a one-time authorization for one administration of Amtagvi.

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. Amtagvi [prescribing information]. Philadelphia, PA. Iovance Biotherapeutics Inc.; February 2024.

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

Devised: 5/21/24

Revised:

Reviewed:

MA UM Committee approval: 8/30/24