# Amtagvi (lifileucel)

Humana

Medicaid Medical Coverage Policy

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**Line of Business:** Medicaid
**State(s):** SC

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## Description

Melanoma is an aggressive malignancy of melanocytes that usually occurs in older adults. Melanoma accounts for 1.7% of global cancer diagnoses and is the fifth most common cancer in the United States. While advanced stages III or IV melanoma that is incurable has an uncertain prognosis, whereas early-stage contained melanoma is often curable. Less than or equal to 10% of those with metastatic melanoma still live after five years, according to the median survival of six to nine months following diagnosis. The stage of melanoma determines the course of treatment. The standard course of treatment for local or regional melanoma involves surgically removing the primary lesion or lesions, removing additional tissue to fully eradicate cancerous cells, and managing lymph nodes as needed. Relapse is common following surgical treatment, particularly in individuals presenting with high-risk characteristics like ulceration, an increased number of mitotic cells, and an elevated primary tumor thickness.[1]

Unresectable or disseminated disease requires systemic therapy that may include immunotherapy, chemotherapy, targeted therapy, or palliative local therapy.[3] Cytotoxic chemotherapy may be used to treat advanced melanoma; however the outcomes are usually poor, with associated substantial toxicities and drug resistance. Because no evidence exists to show a survival benefit of chemotherapy for metastatic disease, it is typically used with palliative rather than curative intent. Newer treatments emphasize targeted therapies or immunotherapy, some of which have shown a survival benefit.[1]

**Amtagvi (lifileucel)** is an autologous tumor-derived T cell immunotherapy indicated for previously treated unresectable or metastatic melanoma who had been treated with a programmed cell death-1 (PD-1)

inhibitor and, if B-Raf proto-oncogene (BRAF) V600 mutation positive, a BRAF inhibitor with or without a methyl ethyl ketone (MEK) inhibitor. Amtagvi is an adoptive cell therapy with tumor-infiltrating lymphocytes (TILs). TILs are immune cells that recognize tumor markers on cancer cells, infiltrate the tumor, and kill the cancer cells. Solid tumors employ multiple methods to suppress immune function, rendering the TIL dysfunctional and ineffective. The goal of TIL therapy is to amplify and revitalize TILs and reintroduce them to the individual, where they will target the tumor and kill the cancer cells.[3]

**Requests for Amtagvi (lifileucel) will *require review by a medical director.***

## Coverage Determination

**Refer all requests or questions regarding Amtagvi (lifileucel) to the Corporate Transplant Department.**

| Phone | Fax | Email |
|---|---|---|
| 1-866-421-5663 | 502-508-9300 | transplant@humana.com |

Humana members may be eligible under the Plan for **Amtagvi (lifileucel)**, single dose infusion, when the following criteria are met[13]:

- Absence of limitations; **AND**
- Individual 18 years of age or older; **AND**
- Individual has unresectable or metastatic melanoma and **ALL** of the following:
  - Previously treated with a PD-1 blocking antibody and has not responded or stopped responding; **AND**
  - If *BRAF* V600 mutation positive, previously treated with a BRAF inhibitor (*with or without a MEK inhibitor*) and has not responded or stopped responding

## Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **Amtagvi (lifileucel)** for any indications other than those listed above including, but may not be limited to[13]:

- Individual has desire to become pregnant/reproduce OR unwilling to use effective contraception; **OR**
- Individual is pregnant or breastfeeding

A review of the current medical literature shows that the **evidence is insufficient** to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

## Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

| CPT® Code(s) | Description | Comments |
|---|---|---|
| No code(s) identified | | |
| **CPT® Category III Code(s)** | **Description** | **Comments** |
| No code(s) identified | | |
| **HCPCS Code(s)** | **Description** | **Comments** |
| C9399 | Unclassified drugs or biologicals | |
| J3490 | Unclassified drugs | |
| J3590 | Unclassified biologics | |
| **ICD-10-PCS Code(s)** | **Description** | **Comments** |
| XW033L7 | Introduction of Lifileucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7 | |
| XW043L7 | Introduction of Lifileucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7 | |

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9. Society for Immunotherapy of Cancer (SITC). Addendum 1: Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immunotherapy for the treatment of melanoma, version 3.0. https://sitcancer.org. *J Immunother Cancer*. Updated March 1, 2025.

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## Change Summary

01/01/2025 New Policy
07/01/2025 Annual Review, Coverage Change. Updated Coding Information