Molina Clinical Policy
Amtagvi (lifileucel)
Policy No. 450

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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Amtagvi (lifileucel, LN-144) is an adoptive T-cell therapy approved for the treatment of adults with unresectable or metastatic melanoma. Melanoma is a malignancy of melanocytes that accounts for the majority of skin cancer deaths. Melanoma is not limited to the skin and may occur in melanocyte-containing tissues, including mucosal sites of the gastrointestinal, respiratory, and genitourinary tracts. Melanoma risk may result from inherited mutations and/or acquired genetic changes from environmental exposures, for example UV radiation. Immunosuppression from medications or other causes also contribute to skin cancers.

The global incidence of melanoma standardized by age is 3.8 / 100,000 males and 3 / 100,000 females, with the average annual cost of treating melanoma at approximately 3.3 billion (Guy 2015). There are almost 15,000 new patients diagnosed with the most advanced forms of melanoma (stage III/IV) annually. The five-year survival rate for stage IV melanoma is 29.8% as of 2017 (Saginala et al. 2021). One of the most important predictors of clinical outcomes is the TNM (tumor, node, metastasis) staging system by the American Joint Committee on Cancer is In fact, the stage of disease at diagnosis may be the most important factor determining survival rates. Although the staging system is complex, in general, stages 0, 1 and 2 melanomas have not spread to other parts of the body. Stage 3 melanomas have spread to local-regional lymph nodes or lymphatic vessels, and stage 4 has metastatic spread. Early-stage melanomas are very treatable when detected.

Choice of surgical and/or medical therapies for melanoma are based on tumor location, spread, recurrence risk and risk of metastases. When such risks are low, surgery with high likelihood of cure is possible. When lesions become advanced, and spread, or become unresectable or metastatic, medical therapies can be used for adjuvant therapy. Development of medical therapies including targeted treatments and immunotherapy have decreased overall mortality. Targeted therapies work by blocking growth factors or other key steps in oncogenesis. BRAF inhibitors such as vemurafenib, dabrafenib, encorafenib are types of targeted therapy. These slow or shrink melanomas with BRAF mutations. MEK inhibitors also treat melanomas with BRAF mutations and include trametinib, cobimetinib and binimetinib. For those with KIT gene mutations, KIT inhibitors may be used (imatinib, dasatinib, nilotinib).

Immunotherapies such as immune checkpoint inhibitors (ICI) act at immune checkpoints. Immune checkpoints normally turn down an immune response to protect the body's healthy cells. Immunotherapies such as ICIs are used to turn up the immune system response when cancer is present by targeting proteins called PD-1 on T -cells and CTLA-4. Types of immunotherapies include Pembrolizumab, Nivolumab, ipilimumab, Atezolizumab, and Nivolumab/Relatlimab. Combinations of targeted therapies and immunotherapies are often used in the treatment of melanomas.

Other types of immune stimulators are Imiquimod, IL-2 (Interleukin-2), and T-VEC (Talimogene laherparepvec), a type of oncolytic viral therapy given intra-lesionally. Photodynamic therapy is another method of therapy for stages III/IV melanoma. Photodynamic therapy uses photosensitizing chemicals and light to create reactive oxygen species damaging melanoma cells and associated vessels. Lastly, chemotherapy and radiation therapy are available. However, cytotoxic chemotherapy has less of a role today given its overall response rate (4-12%) as compared to today’s targeted therapies. Radiation therapy is more often used as adjuvant therapy for metastatic disease.

Despite all these therapies, recurrence / relapse is the rule in advanced melanomas and as a result there is a high unmet need for efficacious therapies aimed at relapsed or recurrent melanoma.
Amtagvi (lifileucel, LN-144) is an adoptive T-cell therapy approved in February 2024 for the treatment of adults with unresectable or metastatic melanoma. It is a second line or later therapy that requires the metastatic melanoma to have been previously treated with a PD-1 blocking antibody and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. (Amtagvi Package insert, 2025)

Amtagvi is a tumor-derived autologous T-cell immunotherapy given as a one-time infusion. Amtagvi is a "living drug" and manufacture of each therapy is highly individualized. Manufacture is a 22-day process beginning with tumor tissue resection in the hospital followed by transport of the tissue to a facility expert in purifying and expanding effector T-cells that attack cancer. Once the T-cells are sufficient in number and type, the autologous therapy is shipped back to the hospital for infusion. The T-cells are not genetically modified. The strategy is to select the most active cells of the body's immune response and amplify them. Prior to re-infusion of the patient's Amtagvi cells, the patient undergoes pre-conditioning to lymphodeplete regulator T -cells that dampen effector T -cell immune function. Once lymphodepletion occurs and Amtagvi cells are infused, interleukin-2 is administered to help facilitate cell expansion in vivo.

One of the difficulties with Amtagvi is that patients need to be healthy enough for lymphodepletive chemotherapy and follow-up IL-2 therapy despite having advanced melanoma. Fatal treatment emergent adverse events (TEAE) related to Amtagvi per package insert were 7.5%. Causes of death included severe infections, organ hemorrhage, renal failure, respiratory failure, liver injury, bone marrow failure, and cardiac arrythmia.

RELATED POLICIES

MCP-184: Experimental and Investigational Services

COVERAGE POLICY

Amtagvi (lifileucel) may be **considered medically necessary** for the treatment of unresectable or metastatic melanoma when ALL the following criteria are met:

1. Member has unresectable or metastatic melanoma (Stage IIIc or Stage IV) that has progressed on therapy (documentation of current stage of disease required).
    a. Confirmation the member received one or more systemic therapies, including a programmed cell death protein-1 (PD-1) blocking antibody or combination PD-1 blocking antibody AND cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) inhibitor; and if proto-oncogene B-Raf (BRAF) V600 mutation-positive, a BRAF inhibitor or BRAF inhibitor in combination with mitogen-activated extracellular signal-regulated kinase (MEK) inhibitor (pathology and BRAF V600 mutation status required, along with current line of therapy)

2. Member has one or more measurable target lesions, as defined by RECIST (Response Evaluation Criteria in Solid Tumors) v1.1
    a. Lesions treated with irradiation or other local therapy < 3 months ago should NOT be selected as target lesions. If treatment was ≥ 3 months ago, and there has been disease progression in that lesion, it may be used as a target lesion
    b. Size of lesion (or aggregate of lesions resected) is ≥ 1.5 cm in diameter post-resection
    c. Surgical removal is possible with minimal morbidity (defined as any procedure for which expected hospitalization is ≤ 3 days)

3. Member is ≥ 18 years of age

4. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1

5. Member has an estimated life expectancy of ≥ 3 months

6. Member has adequate hematologic function defined by:
   a. Absolute neutrophil count (ANC) ≥ 1000/mm^3
   b. Hemoglobin (Hb) ≥ 9.0 g/dL
   c. Platelet ≥ 100,000/mm^3

7. Member has adequate organ function as defined by:
   a. Serum alanine transaminase (ALT)/serum glutamic-pyruvic transaminase (SGPT) and aspartate transaminase (AST)/serum glutamic-oxaloacetic transaminase (SGOT) ≤ 3 times the upper limit of normal (ULN); patients with liver metastasis ≤ 5 times ULN
   b. Estimated creatinine clearance (eCrCl) ≥ 40 mL/min using the Cockcroft-Gault formula
   c. Total bilirubin ≤ 2 mg/dL
   d. Patients with Gilbert's syndrome must have a total bilirubin ≤ 3 mg/dL

8. Member has recovered from all prior therapy-related adverse events to ≤ Grade 1 (per Common Terminology Criteria for Adverse Events [CTCAE] v4.03) prior to tumor resection unless the type of adverse event is not expected to worsen with preconditioning or other processes involved in the administration of lifileucel
   a. If member has ≥ Grade 2 diarrhea or colitis due to previous treatment with immune checkpoint inhibitor(s) a colonoscopy post-immune checkpoint inhibitor treatment must be obtained and be normal prior to tumor resection. If the member's prior therapy related diarrhea/colitis has resolved a colonoscopy is not required
   b. Adverse events related to alopecia or vitiligo are not prohibitive to lifileucel tumor resection and therapy

9. Member has a left ventricular ejection fraction (LVEF) > 45% or New York Heart Association (NYHA) functional classification < Class 1
   a. Members ≥ 60 years of age and who have a history of ischemic heart disease, chest pain, or clinically significant atrial and/or ventricular arrhythmias must have a cardiac stress test

10. Member has documented forced expiratory volume in 1 second (FEV1) of > 60%

11. Lesions being selected for TIL harvesting has not undergone palliative radiation therapy

12. Members of childbearing potential or their partners of childbearing potential must be willing to take the appropriate precaution to avoid pregnancy or fathering a child for the duration of treatment with a highly effective method of birth control during treatment and for 12 months after receiving therapy

13. Member has not received an organ allograft or prior cell transfer therapy

14. Member does not have melanoma of uveal/ocular origin

15. Member does not have a history of hypersensitivity to any component or excipient of Amtagvi or other drugs listed below:
   a. NMA-LD preconditioning regimen (cyclophosphamide, mesna, and fludarabine)
   b. Antibiotics (ABX) of the aminoglycoside group (i.e., streptomycin, gentamicin); except those who are skin-test negative for gentamicin hypersensitivity
   c. Any component of the Amtagvi product formulation including dimethyl sulfoxide (DMSO), human serum albumin (HSA), IL-2, and dextran-40

16. Member does not have symptomatic and/or untreated brain metastases (of any size and any number)
   a. Patients with definitively treated brain metastases must be stable for ≥ 14 days prior to beginning the NMA LD preconditioning regimen

17. Member is not on chronic systemic steroid therapy for any reason

18. Member does not have active medical illness(es) that would pose increased risk for Amtagvi therapy such as active systemic infections requiring systemic antibiotics, coagulation disorders, or other active major medical illnesses of the cardiovascular, respiratory, or immune system

19. Member does not have any form of primary immunodeficiency (such as severe combined immunodeficiency disease [SCID] and acquired immunodeficiency syndrome [AIDS])

20. Member does not have any irreversible wall movement abnormalities

21. Member has not had another primary malignancy within the previous 3 years (with the exception of carcinoma in situ of the breast, cervix, or bladder; localized prostate cancer; and non-melanoma skin cancer that has been adequately treated)

22. Member has not received a live or attenuated vaccine within 28 days of beginning the NMA-LD preconditioning regimen

23. Member is not pregnant or breastfeeding

Limitations and Exclusions
QUANTITY LIMITATIONS: FDA approved dosing with one-time dose per lifetime. Additional infusions of Amtagvi will not be authorized.

Continuation of Therapy
Amtagvi (lifileucel) is indicated as a one-time infusion only. Repeat treatment or re-administration of a dose is not supported by labeling or compendia and is not considered medically necessary.

DOCUMENTATION REQUIREMENTS: Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Accelerated approval for Amtagvi is based on results of the Phase 2 clinical trial NCT02360579. Since approval long term follow-up data has been published and is described below.

Phase 2 Trial
NCT02360579 is a global, multi-center, multi-cohort, open label, single-arm trial of Amtagvi in patients with advanced melanoma previously treated with checkpoint inhibitors and BRAF ± MEK targeted agents. The protocol began with patient tumor tissue resection, shipment to manufacturer, then selection and expansion of effector T-cells capable of recognizing tumor antigens. After the return of Amtagvi product back to the treating facility, patients underwent a non-myeloablative lymphodepletive regimen (NMA-LD), followed by a single lifileucel infusion, and lastly, up to 6 doses of IL-2. The protocol was optimized during the trial resulting in different treatment cohorts. Cohort 1 participants were treated with first generation, non-cryopreserved TILs. This initial process was discontinued in favor of second generation, cryopreserved TILs. The primary efficacy endpoint was ORR (objective response rate per RECIST v1.1) assessed by an IRC (independent review committee).

Supportive pooled data (n=153) includes cohorts 2 (66 patients) & cohort 4 (87 patients) in the C-144-01 study. Both cohorts 2 & 4 met the same eligibility criteria and were treated with the same second-generation TILs. Cohorts 2 & 4 were the main source of data for FDA approval. Cohort 3 was a re-treatment group and was not part of the data submission for FDA approval.

Results from Study C-144-01 show that lifileucel demonstrated a similar level of antitumor activity in both the pivotal cohort and the larger pooled population. In Cohort 4 (pivotal cohort), the objective response rate (ORR) assessed by an independent review committee was 31.5%, with a 95% confidence interval of 21.1% to 43.4%. In the supportive pooled analysis of 153 patients, the ORR was 31.4% (95% CI: 24.1% to 39.4%). With respect to median duration of response (mDOR), the median was not reached in either analysis, indicating durable responses among responders. In Cohort 4, responses ranged from 1.4+ to 26.3+ months, with a median follow-up of 18.6 months. In the pooled data set, response duration ranged from 1.4+ to 45.0+ months, with a longer median follow-up of 21.5 months, further supporting the durability of responses observed with lifileucel.

Table summarizing results from Study C-144-01

Clinical Attribute	Cohort 4 Pivotal	Supportive Pooled Data (n=153)
ORR by IRC (95% CI)	31.5% (21.1, 43.4)	31.4% (95% CI: 24.1, 39.4)
mDOR (95% CI)	Not reached (range 1.4+, 26.3+) Potential median follow-up 18.6 mo.	NR (range 1.4+, 45.0+) Potential median follow-up of 21.5 mo.

ORR = Objective Response Rate per RECIST v1.1 (Eisenhauer et al. 2009). ORR is a measure of how treatment impacts tumor burden. mDOR =median duration of response. DOR is a measure of the length of time a tumor continues to respond to a drug without the cancer growing or spreading. mDOR is the time from tumor response to tumor progression in 50% of patients responding for a shorter period and 50% responding for a longer period. IRC = Independent Review Committee.

Within the full analysis set of 153 trial participants, there were 8 complete responses and 40 partial responses. Baseline liver and brain metastasis were reported in 47.1% of the patients. Secondary endpoints: DOR (Durability of Response), PFS (Progression Free Survival), OS (Overall Survival), TEAE (Treatment Emergent Adverse Events) incidence and severity. Among the responders, 62.5%, 56.3% and 54.2% maintained durable responses at 6, 9 and 12 months respectively (Package insert Amtagvi).

Although most treatment emergent adverse events were manageable and decreased rapidly within 2 weeks after Amtagvi, there were deaths in the study. As reported by Chesney J. (2022), 6 deaths occurred within 30 days after infusion of lifileucel in the C-144-1 trial. Four of the six were attributed to adverse events. Three of the four adverse event related deaths were unrelated to lifileucel but were related to NMA-LD and or IL-2 (pneumonia, arrhythmia, acute respiratory failure). Investigators concluded the fourth death related to adverse events resulted from a combination of all components of the regimen (intra-abdominal hemorrhage). The other two of six deaths were unrelated to adverse events but were related to disease progression of the cancer itself.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Medina et al (2025) published 5-year follow-up results of cohort C-144-01 from phase 2 clinical trial (NCT02360579) after single lifileucel infusion. The study design is unchanged from the initial report described above. 153 participants received lifileucel, 43 were considered responders. 31.3% of responders completed the 5-year assessment. The primary endpoint was ORR and key secondary endpoints were DOR, OS and safety as per above. The ORR was 31.4% (complete response at 5.9%; and partial response of 25.5%). The median duration of response was 36.6 months. At 5 years overall survival (OS) was 19.7% and median OS 13.9 months. No new or late-onset adverse events attributable to lifileucel were observed. The incidence of death secondary to treatment related adverse events was 3.2%.

Kluger et al (2025) reported a subgroup analysis of C-144-01 (NCT02360579) looking at just the group with Mucosal melanoma and their response to lifileucel. This subgroup consisting of twelve patients had a higher ORR of 50% with median follow-up at 35.7 months as compared to the overall group's 31.4% (data cutoff was July 15, 2022).

An open label Phase 3 study, (TILVANCE-301; NCT05727904) of the efficacy and safety of lifileucel in combination with pembrolizumab in melanoma is ongoing. Another ongoing study is looking at lifileucel With Reduced Dose Fludarabine/Cyclophosphamide Lymphodepletion and Interleukin-2 for the Treatment of Patients With Unresectable or Metastatic Melanoma (NCT06151847).

Other studies include NCT07288203 which is the longer-term follow-up of lifileucel. NCT05640193 is looking at lifileucel in people with metastatic melanoma and brain metastasis. Efficacy of lifileucel is being looked at for other solid tumors as well.

National and Specialty Organizations

The **Institute for Clinical and Economic Review (ICER)** has not published an evidence report on lifileucel therapy yet.

The **National Institute for Health Care Excellence** (NICE) expects to publish its report for, "Lifileucel for previously treated unresectable or metastatic melanoma" July 10, 2026.

The **National Comprehensive Cancer Network (NCCN)** *Melanoma: Cutaneous* (v1.2026) guideline recommendations for patients with cutaneous melanoma who progress on systemic therapy, " "Patients who have received anti-PD-1-based therapy and, if applicable, BRAF/MEK inhibitors, should consider lifileucel if they are candidates for high-dose IL-2".

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
C9399	Unclassified drugs or biologicals [when specified as Amtagvi (Lifileucel)]
J3590	Unclassified biologics [when specified as Amtagvi (Lifileucel)]

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

04/08/2026	No changes to clinical criteria. Updated introduction and medical summary.
04/09/2025	No changes to clinical criteria. Updated references and medical summary. Also updated guideline section noting addition of lifileucel to NCCN guidelines.
04/10/2024	New policy. IRO Peer Review on March 24, 2024, by a practicing physician board-certified in Hematology Oncology.

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