MVP Health Care Medical Policy

Medicare Part B: Amtagvi (Lifileucel)

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	08/01/2026
Approval Date:	08/01/2026
Effective Date:	10/01/2026
Related Policies:	CAR T-Cell Therapy

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.

Drugs Requiring Prior Authorization under the medical benefit

J999 Amtagvi (Lifileucel)

Overview

Lifileucel is a tumor-derived autologous T-cell immunotherapy indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. This indication is approved under accelerated approval based on objective response rate (ORR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Medicaid Variation: Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products.

Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

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Indications/Criteria

Unresectable or metastatic melanoma

Amtagvi may be considered for coverage when ALL the following criteria are met:

- Prescribed by or in consultation with an oncologist
- Chart notes confirming a diagnosis of unresectable or metastatic melanoma
- Chart notes confirming the member has been previously treated with a PD-1 blocking antibody (such as Opdivo, Keytruda etc.). Documentation must include dates of use.
- For members with a positive BRAF V600 mutation, chart notes confirming the member has **also** been previously treated with a BRAF inhibitor (such as Zelboraf, Tafinlar, Braftovi, etc) with or without a MEK inhibitor (such as Mekinist, Cotellic, Mektovi, etc). Documentation must include dates of use.
- Documentation that the member will receive a lymphodepleting regimen of cyclophosphamide and fludarabine before Amtagvi infusion.
- Documentation that member has not received live vaccines 28 days prior to Amtagvi infusion
- Provider attestation that the member is eligible to receive post-lifileucel aldeskeukin (IL-2) therapy
- Documentation that the member does not have signs and symptoms of acute renal failure prior to therapy.
- Member is ≥ 18 years old
- For female members, a negative serum pregnancy test must be confirmed
- Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1.
- Hospitals administering Amtagvi must be appropriately certified to do so. Please see the link for certified treatment centers: AMTAGVI Now Approved Official Site
- Criteria and use of this agent must follow the FDA package label and the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. MVP reserves the right to deviate from the NCCN guidelines if new safety information becomes available prior to updated NCCN guidelines. The NCCN guidelines may be accessed at www.nccn.org

Amtagvi will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

Exclusions

The use of Amtagvi will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Member has been previously treated with Amtagvi
- Members with active systemic infections
- Members with any of the following as these were excluded in clinical trials:
    - Uncontrolled brain metastases
    - Organ allograft or prior cell transfer
    - Melanoma of uveal or ocular origin
    - Current systemic steroid therapy
    - Left ventricular ejection fraction (LVEF) less than 45% or New York Heart Association (NYHA) functional classification greater than Class 1
    - Forced expiratory volume in one second (FEV1) of less than or equal to 60%.
- Prescribed in combination with other CAR T-Cell therapy
- Previously treated with other CAR T-Cell therapy

References

1. Highlights of prescribing information ... [Internet]. Iovance Biotherapeutics ; Revised 09/2025 [cited 2026 June 30]. Available from: https://www.iovance.com/AMTAGVI_USPI/
2. National Comprehensive Cancer Network. NCCN Guidelines Version 2.2024 Melanoma: Cutaneous cutaneous_melanoma.pdf (nccn.org)