Amtagvi® (lifileucel)
(Intravenous)

Document Number: IC-0748

Last Review Date: 10/01/2026
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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for one treatment course (1 dose).
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- A single dose of Amtagvi containing a maximum of 72 x 10^9 of viable cells suspended in one or more member-specific infusion bags

III. Initial Approval Criteria [1]

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax**.** Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided for the following conditions:

- Member is at least 18 years of age; **AND**
- Member does not have uncontrolled brain metastases; **AND**
- Member does not have signs and symptoms of acute renal failure prior to treatment; **AND**
- Member does not have hemorrhage (grade 2 or higher) within 14 days prior to therapy; **AND**
- Member does not have a left ventricular ejection fraction (LVEF) less than 45% or New York Heart Association (NYHA) functional classification greater than Class 1; **AND**
- Member does not have forced expiratory volume in one second (FEV1) of less than or equal to 60%; **AND**
- Member does not have a clinically significant active systemic infection; **AND**
- Member is deemed eligible for IL-2 (aldesleukin) therapy; **AND**

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- Member will not receive concomitant prophylactic systemic corticosteroid therapy; **AND**

Cutaneous Melanoma † ‡ Φ [1-6]

- Member has a diagnosis of unresectable or metastatic melanoma; **AND**
- Member does not have uveal melanoma; **AND**
- Used as subsequent therapy after the following:
  - Programmed cell death protein-1 (PD-1) blocking antibody; **AND**
  - If BRAF V600 mutation-positive, a BRAF inhibitor with or without a MEK inhibitor

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria

Duration of authorization has not been exceeded (*refer to Section I*).

V. Dosage/Administration

Indication	Dose
Cutaneous Melanoma	• Amtagvi is provided as a single dose for infusion containing a suspension of tumor-derived T cells. The dose is supplied in 1 to 4 member specific IV infusion bag(s) in individual protective metal cassettes. Each dose contains 7.5 x 10^9 to 72 x 10^9 viable cells. • Confirm availability of Amtagvi and IL-2 (aldesleukin) prior to starting the lymphodepleting regimen. Administer a lymphodepleting chemotherapy regimen of cyclophosphamide 60 mg/kg IV with mesna daily for 2 days followed by fludarabine 25 mg/m^2 IV daily for 5 days before infusion of Amtagvi. • Infuse Amtagvi after 24 hours have elapsed following the last dose of fludarabine, but no later than 4 days. • Beginning 3 to 24 hours after Amtagvi infusion, administer intravenous IL-2 (aldesleukin) at 600,000 IU/kg every 8 to 12 hours for up to a maximum of 6 doses to support cell expansion in vivo. IL-2 (aldesleukin) should be administered in an inpatient setting under the supervision of a physician experienced in the use of anticancer agents.
– *Administer in an inpatient hospital setting under the supervision of a physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.* – *Amtagvi is for autologous use only. The member's identity must match the member identifiers on the drug cassette(s) and infusion bag(s).*	

VI. Billing Code/Availability Information

HCPCS Code(s):

- J9999 – Not otherwise classified, antineoplastic drug
- C9399 – Unclassified drugs or biologics

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NDC(s):

- Amtagvi contains 7.5 x 10^9 to 72 x 10^9 viable cells suspended in 1 to 4 patient-specific infusion bag(s): 73776-0001-xx

VII. References

1. Amtagvi [package insert]. Philadelphia, PA; Iovance Biotherapeutics Manufacturing, LLC; September 2025. Accessed August 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) lifileucel. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2026.
3. Referenced with permission from the NCCN Clinical Practice Guidelines (NCCN Guidelines®) Melanoma: Cutaneous. Version 2.2026. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed August 2026.
4. ClinicalTrials.gov. A Phase 2, Multicenter Study to Assess the Efficacy and Safety of Autologous Tumor Infiltrating Lymphocytes (LN-144) for Treatment of Patients With Metastatic Melanoma. https://clinicaltrials.gov/study/NCT02360579?intr=NCT02360579&rank=1.
5. Sarnaik A, Khushalani NI, Chesney JA, et al. Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients who progressed on multiple prior therapies including anti-PD-1. Journal of Clinical Oncology 2019 37:15_suppl, 2518-2518
6. Chesney J, Lewis KD, Kluger H, at al. Efficacy and safety of lifileucel, a one-time autologous tumor-infiltrating lymphocyte (TIL) cell therapy, in patients with advanced melanoma after progression on immune checkpoint inhibitors and targeted therapies: pooled analysis of consecutive cohorts of the C-144-01 study. J Immunother Cancer. 2022 Dec;10(12):e005755.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

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Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15,

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§50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	Wellpoint Federal
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	Wellpoint Federal
15	KY, OH	CGS Administrators, LLC

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