

Drug Policy: Amtagvi™ (lifileucel)

POLICY NUMBER UM ONC_1496	SUBJECT Amtagvi™ (lifileucel)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 04/10/24	APPROVAL DATE April 10, 2024	EFFECTIVE DATE April 26, 2024	COMMITTEE APPROVAL DATES 04/10/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Amtagvi (lifileucel) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The member has not experienced disease progression on the requested medication **AND**
2. The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization **AND**
3. Additional medication(s) are not being added to the continuation request.

B. Melanoma

1. Amtagvi (lifileucel) may be used in adult members with unresectable or metastatic melanoma previously treated with an immune checkpoint inhibitor (i.e. pembrolizumab, nivolumab, ipilimumab, atezolizumab) and if BRAF V600 mutation positive, a BRAF inhibitor (i.e. dabrafenib, encorafenib, vemurafenib) with or without a MEK inhibitor (i.e. binimetinib, cobimetinib, trametinib).

III. EXCLUSION CRITERIA

- A. Disease progression while taking Amtagvi (lifileucel).
- B. Concurrent use with other anticancer therapies.
- C. Dosing exceeds single dose limit of Amtagvi (lifileucel) 72×10^9 viable cells.
- D. Investigational use of Amtagvi (lifileucel) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
 - 1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
 - 2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
 - 3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
 - 4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
 - 5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
 - 6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
 - 7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Amtagvi prescribing information. Iovance Biotherapeutics Manufacturing LLC Philadelphia, PA 2024.
- B. Chesney J, et 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. *Journal for ImmunoTherapy of Cancer* 2022;10:e005755. DOI:10.1136/jitc-2022-005755

- C. Clinical Pharmacology Elsevier Gold Standard 2024.
- D. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2024.
- E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.
- F. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.
- G. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services:
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.