

Amtagvi (lifileucel)

Policy Number: 077

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization Required	X	X	X
No Prior Authorization			
Not covered			

Amtagvi is a tumor-derived autologous T cell immunotherapy, or tumor-infiltrating lymphocyte therapy, for the treatment of certain patients with advanced melanoma.

FDA-Approved Indication

Amtagvi is indicated for the treatment of:

- Adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 positive, a BRAF inhibitor with or without a MEK inhibitor.

Criteria

1. Criteria for Initial Approval

Authorization may be granted for treatment of when ALL of the following criteria are met:

- A. Age 18 or older
- B. Diagnosis of unresectable or metastatic melanoma (Stage IIIC or Stage IV) with BRAF mutation testing
- C. The patient has had progression of disease following treatment with anti-PD-1 based therapy (eg, nivolumab, pembrolizumab)
- D. If BRAF V600 mutation is present, the patient has had progression of disease following treatment with BRAF inhibition (eg, vemurafenib, dabrafenib, encorafenib)
- E. At least one metastasis with diameter ≥ 1.5 cm is resectable
- F. Eastern Cooperative Oncology Group performance status (ECOG PS) of 0 or 1
- G. Evidence of adequate hematologic parameters, liver and renal function within the past 3 months:
 1. Absolute neutrophil count $>1,000/\text{mm}^3$
 2. Hemoglobin >9 g/dL
 3. Platelets $>100,000/\text{mm}^3$
 4. Alanine transaminase (ALT) and aspartate transaminase <5 times the upper limit of normal
 5. Estimated GFR >40 mL/min
- H. Negative testing for HIV within the past 6 months
- I. Negative antibody testing for hepatitis B or C, or evidence of undetectable viral load within the past 6 months
- J. If the patient has known or suspected heart disease, an echocardiogram within the past 6 months shows left ventricular ejection fraction (LVEF) $\geq 45\%$
- K. If the patient has known or suspected lung disease, pulmonary function testing within the past 6 months shows forced expiratory volume in 1 second (FEV-1) $>60\%$ of predicted
- L. The treatment will be administered in an Amtagvi Authorized Treatment Center

2. Duration of Therapy
 - Single treatment course
 - Additional courses of therapy are considered experimental/investigational.

Exclusions

1. Organ allograft
2. Prior cell transfer therapy
3. Uveal/ocular melanoma
4. Hypersensitivity to lifileucel
5. Symptomatic and/or untreated brain metastases
6. Chronic systemic steroid therapy
7. Active systemic infections
8. Evidence of liver or kidney dysfunction
9. Administration of live or attenuated vaccine within 28 days of non-myeloablative lymphodepletion (NMA-LD),
10. LVEF <45%
11. FEV-1 ≤60% of predicted
12. Other primary malignancies, unless in remission for at least 3 years
13. Primary immunodeficiency

MassHealth Variation

Mass General Brigham Health Plan uses the [MassHealth Drug List](#) for coverage determinations for members of the MGB ACO. Criteria for Amtagvi are found in [Table 75: T-Cell Immunotherapies](#).

Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan’s medical policies are used for coverage determinations. At the time of Mass General Brigham Health Plan’s most recent policy review, Medicare has **no NCD or LCD for tumor-infiltrating lymphocyte therapy**.

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

This list of codes applies to commercial and MassHealth plans only.

Authorized CPT/HCPCS Codes	Code Description
J3490	Unclassified drugs
J3590	Unclassified biologics

Effective

February 2025: Annual Review. Added MassHealth Variation.
 May 2024: Effective Date.

References



Amtagvi [package insert]. Philadelphia: lovance, 2024.

Chesney J, Lewis KD, Kluger H, et al. Efficacy and safety of lifileucel, a onetime 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.

NCCN Clinical Practice Guidelines in Oncology- Cutaneous Melanoma Version 2.2023, April 3, 2024.
https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf, accessed April 11, 2024.

Sarnaik AA, Hamid O, Khushalani NI, et al. Lifileucel, a tumor-infiltrating lymphocyte therapy, in metastatic melanoma. 2021. *J Clin Oncol* 39:2656-2666.

