



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 04/16/2026

Amtagvi™ (lifleucel)

HCPCS: J3590

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
- a. FDA approved indication
 - b. FDA approved age
 - c. Prescribed by or in consultation with an oncologist
 - d. Must have progressive disease following at least one prior systemic therapy including a programmed cell death protein ligand-1 (PD-1) inhibitor and if BRAF V600 mutation-positive, a BRAF inhibitor or BRAF inhibitor in combination with a MEK inhibitor
 - e. Must have at least one measurable, resectable lesion that is a minimum of 1.5 cm in diameter post-resection
 - f. Must not have any of the following:
 - i. ECOG performance status > 1
 - ii. Active infection (e.g. viral, bacterial, fungal) such as HIV, active hepatitis B or active hepatitis C
 - iii. Creatinine clearance < 40 mL/min
 - iv. Left ventricular ejection fraction (LVEF) < 45%
 - v. Symptomatic and/or untreated brain metastases
 - g. Have not received prior treatment with any tumor infiltrating lymphocyte (TIL) therapy despite indication or any other genetically-modified TIL therapy or are being considered for treatment with any other genetically-modified TIL therapy
 - h. Only to be administered at a certified TIL treatment center
 - i. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list
 - j. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by BCBSM
 - k. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case by case basis until fully evaluated by the BCBSM Pharmacy and Therapeutics Committee

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B. Quantity Limitations, Authorization Period and Renewal Criteria

- a. Quantity Limits: Align with FDA recommended dosing
- b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time with the allowance of only one dose per lifetime
- c. Renewal Criteria: Not applicable as no further authorization will be provided

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Tumor infiltrating lymphocyte (TIL) therapy is a type of treatment that utilizes the body's own immune system to fight cancer. The immune system naturally creates TIL cells that can recognize distinctive markers on the surface of cancer cells and launch an attack. To make TIL therapy, a patient's TIL cells are collected from a portion of their resected tumor and then expanded outside the body before being infused back into the patient. Once the body is resupplied with TIL cancer-fighting immune cells, tumor cells are attacked and killed.
- TIL therapy has not been studied when given following prior treatment with any TIL therapy or following any other genetically-modified TIL therapy.
- Due to the risk of treatment-related deaths, prolonged severe cytopenia, severe infection, cardiopulmonary impairment, and kidney impairment, TIL therapy is only allowed to be given at certified inpatient treatment centers. The labeling requires patients be monitored for side effects in an intensive care facility and that specialists be available.
- Amtagvi 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.
- Safety and efficacy were established in the C-144-01 trial, a phase II, open-label, single-arm, multicenter study in patients with advanced melanoma who had progressed following a PD-1 inhibitor and BRAF ± MEK targeted agents if indicated. The primary efficacy analysis set included 82 patients who received Amtagvi, among these, 9 patients received Amtagvi at a dose less than 7.5×10^9 viable cells and did not achieve an objective response. Amtagvi was produced from harvested tumor specimens with an average manufacturing time of 23 days and median time to infusion of 34 days. Patients received a non-myeloablative lymphodepletion regimen, a single infusion of Amtagvi, and up to six doses of high-dose interleukin-2. The study excluded patients with an ECOG score of greater than 1, a creatinine clearance of less than or equal to 40 mL/minute, hemoglobin less than 9.0 g/dL, and left ventricular ejection fraction less than 45%. Patients were also excluded if they had an absolute neutrophil count less than 1000 cells/mm³, platelet count less than 100,000/mm³, symptomatic and/or untreated brain metastases, history of another primary malignancy that has not been in remission for at least 3 years prior to consideration of Amtagvi, infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy, a detectable HIV, hepatitis B or C viral load, or any primary immunodeficiency. Patients were required to have at least one measurable, resectable lesion that is a minimum of 1.5 cm in diameter post-resection. The primary endpoints included objective response rate (ORR) and duration of response (DoR). The ORR was 31.5% (95% CI: 21.1, 43.4) with 3 complete responses (CR) and 20 partial responses (PR). The median time to initial response was 1.5 months with the median DoR not reached after 18.6 months.

References:

1. Amtagvi [prescribing information]. Philadelphia, PA: Iovance Biotherapeutics Manufacturing LLC; September 2025.
2. Liu A. FDA approves Iovance's Amtagvi as first T-cell therapy for a solid tumor. 2024 Feb 17. Available at: <https://www.fiercepharma.com/pharma/fda-approves-iovances-amtagvi-first-cell-therapy-solid-tumor>. Accessed on February 19, 2024.
3. Chesney J, Lewis KD, Kluger H, 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. J Immunother Cancer. 2022; 10: e005755.
4. National Comprehensive Cancer Network. Melanoma: cutaneous (Version 1.2026). 2026 Feb 17. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed on March 1, 2026.

Policy History												
#	Date	Change Description										
1.5	Effective Date: 06/01/2026 P&T Date: 04/16/2026	Updated to remove requirement for absolute neutrophil count, hemoglobin, platelet count, liver function tests, history of another primary malignancy, uncontrolled infection or infection requiring long term antibiotics, HIV, hepatitis B or C infection, and any primary immunodeficiency. Also added requirements of no active infection, no prior allogenic stem cell transplant, no prior autologous stem cell transplant within 12 weeks, and updated the approval length to 6 months										
1.4	Effective Date: 04/10/2025	Annual review – no changes to the policy were made at this time										
1.3	Effective Date: 04/11/2024	New policy - this criteria replaces previously approved preliminary criteria										
1.2	Effective Date: 04/01/2024	UM medical management system update for MAPPO and BCNA <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
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1.1	Effective Date: 02/29/2024	UM medical management system update for BCBS and BCN <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
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1.0	Effective Date: 02/08/2024	Preliminary Drug Review											
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.*

Blue Cross Blue Shield/Blue Care Network of Michigan

Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

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PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. ☐ Male ☐ Female	Address
Diagnosis	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

- Is this request for: ☐ Initiation ☐ Continuation Date patient started therapy: _____
- Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
- Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
☐ Hospital outpatient facility (go to #4) Reason for Hospital Outpatient administration: _____
☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
- Please specify location of administration if hospital outpatient infusion: _____
- Please specify location of administration if hospital inpatient infusion: _____
- Please provide the NPI number for the place of administration: _____
- Initiation AND Continuation of therapy:**
 - What is the patient's diagnosis? _____
 - What other medication has the patient received for their condition? Please list _____
 - Please describe the response to previous therapies: _____
 - Will the patient be receiving any other treatment for the listed condition while on this medication? Please list: _____
 - Please list any labs values important for diagnosing or monitoring this patient's condition: _____
- Continuation of therapy:**
 - Has the patient progressed while on this medication? ☐ yes ☐ no
 - How has the patient's condition changed while on this medication?

☐ Improved: Please describe: _____
 ☐ Stable: please describe: _____
 ☐ Worsened; Please describe: _____
 ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

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7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021