

# **Utilization Review Policy 333**

Policy: Oncology (Injectable) – Amtagvi Utilization Management Medical Policy

Amtagvi<sup>™</sup> (lifileucel intravenous infusion – Iovance Biotherapeutics)

**EFFECTIVE DATE:** 5/15/2024 **LAST REVISION DATE:** 02/19/2025

**COVERAGE CRITERIA FOR:** All Aspirus Medicare Plans

#### **OVERVIEW**

Amtagvi, a tumor-derived autologous T cell immunotherapy, is indicated for the treatment of unresectable or metastatic melanoma in adults who have been previously treated with a programmed death receptor-1 (PD-1) blocking antibody, and if *BRAF V600* mutation positive, a BRAF inhibitor with or without a MEK inhibitor.<sup>1</sup>

## **Dosing Information**

Amtagvi is provided as a single dose for intravenous infusion containing a suspension of tumorderived T cells in 5% dimethyl sulfoxide. The dose contains between  $7.5 \times 10^9$  to  $72 \times 10^9$  viable cells and is supplied in one or more frozen infusion bags. The bags are stored in the vapor phase of liquid nitrogen (less than or equal to minus 150°C). Amtagvi is for autologous use only.

Prior to receiving Amtagvi, patients are pretreated with lymphodepleting chemotherapy consisting of cyclophosphamide 60 mg/kg intravenously with mesna for 2 days followed by fludarabine 25 mg/m<sup>2</sup> intravenously daily for 5 days. Amtagvi is administered as soon as possible, 24 hours after the last dose of fludarabine but no later than 4 days after the last dose of fludarabine.

### **Guidelines**

The National Comprehensive Cancer Network (NCCN) melanoma: cutaneous (version 2.2025 – January 28, 2025) treatment guidelines recommend Amtagvi as a "Preferred" high-dose therapy as second-line or subsequent treatment for metastatic or unresectable disease following progression on anti-PD-1 therapy and BRAF/MEK inhibitor therapy if *BRAF V600* mutation positive (category 2A).<sup>2,3</sup>

### Safety

Amtagvi has a Boxed Warning for treatment-related mortality, prolonged severe cytopenia, severe infection, and cardiopulmonary and renal impairment.<sup>1</sup>

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### **POLICY STATEMENT**

Prior Authorization is recommended for medical benefit coverage of Amtagvi. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Because of the specialized skills required for evaluation and diagnosis of patients treated with Amtagvi as well as the monitoring required for adverse events and long-term efficacy, approval requires Amtagvi to be prescribed by or in consultation with a physician who specializes in the condition being treated. The approval duration is 6 months to allow an adequate time frame to prepare and administer 1 dose of therapy.

**Automation:** None.

### **RECOMMENDED AUTHORIZATION CRITERIA**

Coverage of Amtagvi is recommended in those who meet the following criteria:

# **FDA-Approved Indication**

- **1. Melanoma.** Approve a single dose if the patient meets ALL of the following (A, B, C, D, E, F, and G):
  - A) Patient is ≥ 18 years of age; AND
  - B) Patient has unresectable or metastatic disease; AND
  - C) Patient has been treated with a programmed death receptor-1 (PD-1) blocking antibody or a programmed death-ligand 1 (PD-L1) blocking antibody; AND

    Note: Examples of PD-1/PD-L1 blocking antibodies includes Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), and Tecentriq (atezolizumab intravenous infusion).
  - D) If the patient is BRAF V600 mutation positive, the patient has been treated with a BRAF inhibitor with or without a MEK inhibitor; AND <a href="Note">Note</a>: Examples of BRAF inhibitors includes Braftovi (encorafenib capsules), Zelboraf (vemurafenib tablets), and Tafinlar (dabrafenib capsules).
  - **E)** Patient has received or is planning to receive lymphodepleting chemotherapy prior to infusion of Amtagvi; AND
  - F) Patient has NOT been previously treated with Amtagvi; AND
  - **G)** The medication is prescribed by or in consultation with an oncologist.

**Dosing.** The dose of Amtagvi is between 7.5 x  $10^9$  and 72 x  $10^9$  viable cells administered intravenously as a single dose.

#### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Amtagvi is not recommended in the following situations:

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**1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

#### **REFERENCES**

- 1. Amtagvi<sup>™</sup> intravenous infusion [prescribing information]. Philadelphia, PA: Iovance Biotherapeutics; February 2024.
- 2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: <a href="http://www.nccn.org">http://www.nccn.org</a>. Accessed on February 10, 2025. Search term: lifileucel.
- 3. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 2.2025 January 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: <a href="http://www.nccn.org">http://www.nccn.org</a>. Accessed on February 10, 2025.

#### **HISTORY**

Type of Revision	Summary of Changes	Review Date
New Policy		02/21/2024
Update	04/03/2024: The guideline section was updated with recommendations from the	N/A
	National Comprehensive Cancer Network.	
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
Annual Revision	No criteria changes.	02/19/2025
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/15/2025