PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Amtagvi Prior Authorization Policy
- Amtagvi™ (lifileucel intravenous infusion – Iovance Biotherapeutics)

REVIEW DATE: 02/21/2024

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.[1]

Dosing Information

Amtagvi is provided as a single dose for intravenous infusion containing a suspension of tumor-derived T cells in 5% dimethyl sulfoxide.[1] The dose contains between 7.5×10^9 to 72×10^9 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^2 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 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.[2,3]

Safety

Amtagvi has a Boxed Warning for treatment-related mortality, prolonged severe cytopenia, severe infection, and cardiopulmonary and renal impairment.[1]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Amtagvi. 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
     Note: 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Amtagvi is not recommended in the following situations:

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™ intravenous infusion [prescribing information]. Philadelphia, PA: Iovance Biotherapeutics; February 2024.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 3, 2024. Search term: lifileucel.
3. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 2.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 3, 2024.