Amtagvi (lifileucel)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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 mutation positive, a BRAF inhibitor with or without a MEK inhibitor.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Chart notes, medical record documentation or claims history supporting previous lines of therapy
- Recent laboratory results documenting hematological parameters
- Recent laboratory results and test results documenting adequate and stable organ function

Criteria for Initial Approval

Melanoma

Authorization of 3 months may be granted for treatment of unresectable or metastatic melanoma in members 18 years and older when all of the following criteria are met:

1. The member has progressed following prior treatment from each of the following drug categories:
   a. PD-1 blocking antibody (e.g., Keytruda, Opdivo)
   b. BRAF inhibitor (e.g., Braftovi, Tafinlar, Zelboraf) with or without a MEK inhibitor (e.g., Cotellic, Mekinist, Mektovi) if BRAF V600 mutation positive
2. The member does not have ANY of the following:
   a. Uveal or ocular melanoma
   b. Symptomatic and/or untreated brain metastases
   c. Organ allograft (except kidney transplant) or prior cell transfer
   d. Clinically significant active infection
3. The member meets ALL of the following hematologic parameters:

a. Absolute neutrophil count (ANC) ≥ 1000/mm^3
b. Hemoglobin (Hb) ≥ 9.0 g/dL
c. Platelet ≥ 100,000/mm^3

4. The member has adequate and stable kidney, liver, pulmonary and cardiac function as demonstrated by all of the following with no significant deterioration expected within 4-5 weeks after tumor resection as determined by the treating oncologist/hematologist:
   a. Serum alanine transaminase (ALT) and aspartate transaminase (AST) ≤ 3 times the upper limit of normal (ULN); patients with liver metastasis ≤ 5 times ULN
   b. Estimated creatinine clearance (eCrCl) ≥ 40 mL/min using the Cockcroft-Gault formula
   c. Total bilirubin ≤ 2 mg/dL with the exception of patients with Gilbert-Meulengracht syndrome; patients with Gilbert-Meulengracht syndrome may be included if their total bilirubin is < 3.0 times ULN
   d. Left ventricular ejection fraction ≥ 45%
   e. Forced expiratory volume in one second (FEV1) of greater than 60%
5. The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
6. The member has at least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5 cm in diameter post resection to generate tumor-infiltrating lymphocyte (TIL)
7. The member has not previously received tumor-derived autologous T cell immunotherapy (including lifileucel) in their lifetime for the treatment of melanoma

Continuation of Therapy

Repeat treatment of Amtagvi for any indication is considered investigational, as the safety and efficacy beyond one dose has not been studied. The evidence is insufficient to determine the effects on net health outcomes.

Dosing Limits Apply

Amtagvi approvals will be limited to one treatment per lifetime.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J3590 - Unclassified biologics

REFERENCES

- Amtagvi [package insert]. Philadelphia, PA: Iovance Biotherapeutics Manufacturing LLC; February 2024.
- Sarnaik et al., Lifileucel, a Tumor-Infiltrating Lymphocyte Therapy, in Metastatic Melanoma. J Clin Oncol. 2021 Aug 20;39(24):2656-2666. doi: 10.1200/JCO.21.00612. Epub 2021 May 12. Erratum in: J Clin Oncol. 2021 Sep 10;39(26):2972. PMID: 33979178; PMCID: PMC8376325.

POLICY HISTORY

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