Reference number(s)
6383-A

STANDARD MEDICARE PART B MANAGEMENT

AMTAGVI (lifileucel)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
Chart notes, medical record documentation or claims history supporting previous lines of therapy.

III. 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 received prior treatment with the following drug categories:
   i. PD-1 blocking antibody (e.g., Keytruda, Opdivo)
   ii. 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 has not received previous treatment with the requested medication.
3. The member does not have uveal or ocular melanoma.
4. The member does not have uncontrolled brain metastases.
5. The member has not had organ allograft (except kidney transplant) or prior cell transfer.
6. The member has adequate and stable kidney, pulmonary and cardiac function.
7. The member has an ECOG performance status of 0 or 1.
8. The member does not have clinically significant active infection.

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Amtagvi.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VI. REFERENCES

1. Amtagvi [package insert]. Philadelphia, PA: Iovance Biotherapeutics Manufacturing LLC; February 2024.