Medical Policy:

Amtagvi (lifileucel suspension) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.406	March 15, 2024	March 28, 2024

Definitions

Length of Authorization

One dose per lifetime. Coverage cannot be renewed.

Dosing Limits [Medical Benefit]

The dose is supplied in 1 to 4 patient-specific IV infusion bag(s) in individual protective metal cassettes. Each dose contains 7.5×10^9 to 72×10^9 viable cells.

Guideline

I. INITIAL

1. **Melanoma.**
    A. Patient is ≥ 18 years of age; **AND**
    B. Patient has unresectable or metastatic disease; **AND**
    C. Patient does not have uncontrolled brain metastases; **AND**

D. Patient does not have signs and symptoms of acute renal failure prior to treatment; **AND**
E. Patient does not have hemorrhage (grade 2 or higher) within 14 days prior to therapy; **AND**
F. Patient does not have a left ventricular ejection fraction (LVEF) less than 45% or New York Heart Association (NYHA) functional classification greater than Class 1; **AND**
G. Patient does not have forced expiratory volume in one second (FEV1) of less than or equal to 60%; **AND**
H. Patient does not have a clinically significant active systemic infection; **AND**
I. Patient is deemed eligible for IL-2 (aldesleukin) therapy (refer to manufacturer's prescribing label for more information); **AND**
J. Patient will not receive concomitant prophylactic systemic corticosteroid therapy; **AND**
K. Patient does not have uveal melanoma; **AND**
L. 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).
M. 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).
N. Patient has NOT been previously treated with Amtagvi; **AND**
O. The medication is prescribed by or in consultation with an oncologist.

Applicable Procedure Codes

Code	Description
J9999	Not otherwise classified, antineoplastic drug

Applicable NDCs

Code	Description
73776-0001-11	Amtagvi Suspension
73776-0001-12	Amtagvi plastic bag, injection

ICD-10 Diagnoses

Code	Description
C43.0	Malignant Melanoma Of Lip
C43.10	Malignant Melanoma Of Unspecified Eyelid, Including Canthus
C43.111	Malignant Melanoma Of Right Upper Eyelid, Including Canthus
C43.112	Malignant Melanoma Of Right Lower Eyelid, Including Canthus
C43.121	Malignant Melanoma Of Left Upper Eyelid, Including Canthus
C43.122	Malignant Melanoma Of Left Lower Eyelid, Including Canthus
C43.20	Malignant Melanoma Of Unspecified Ear And External Auricular Canal
C43.21	Malignant Melanoma Of Right Ear And External Auricular Canal
C43.22	Malignant Melanoma Of Left Ear And External Auricular Canal
C43.30	Malignant Melanoma Of Unspecified Part Of Face
C43.31	Malignant Melanoma Of Nose

C43.39	Malignant Melanoma Of Other Parts Of Face
C43.4	Malignant Melanoma Of Scalp And Neck
C43.51	Malignant Melanoma Of Anal Skin
C43.52	Malignant Melanoma Of Skin Of Breast
C43.59	Malignant Melanoma Of Other Part Of Trunk
C43.60	Malignant Melanoma Of Unspecified Upper Limb, Including Shoulder
C43.61	Malignant Melanoma Of Right Upper Limb, Including Shoulder
C43.62	Malignant Melanoma Of Left Upper Limb, Including Shoulder
C43.70	Malignant Melanoma Of Unspecified Lower Limb, Including Hip
C43.71	Malignant Melanoma Of Right Lower Limb, Including Hip
C43.72	Malignant Melanoma Of Left Lower Limb, Including Hip
C43.8	Malignant Melanoma Of Overlapping Sites Of Skin
C43.9	Malignant Melanoma Of Skin, Unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/28/2024	New Policy

References

1. Product Information: AMTAGVI suspension for intravenous infusion, lifileucel suspension for intravenous infusion. Iovance Biotherapeutics Manufacturing LLC (per FDA), Philadelphia, PA, 2024.