

## Medical Policy:

### Amtagvi (lifileucel suspension) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.406	February 18, 2025	March 28, 2024

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

### 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  $7.5 \times 10^9$  to  $72 \times 10^9$  viable cells.

### Guideline

#### I. INITIAL

##### 1. Melanoma

- A. Patient is  $\geq 18$  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
C43.111	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	2/18/2025	Removal from ICD-10
		C43.10 Malignant Melanoma Of Unspecified Eyelid, Including Canthus
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.