AMTAGVI™ (lifileucel) Suspension for IV infusion

Billing & Coding Guide

A resource for billing and coding

AMTAGVI® (lifileucel) Billing & Coding Guide

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AMTAGVI (lifileucel) Indication

AMTAGVI (lifileucel) is a tumor-derived autologous T cell immunotherapy 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.

This indication is approved under accelerated approval based on objective response rate (ORR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Important Safety Information (ISI)

WARNING: TREATMENT-RELATED MORTALITY, PROLONGED SEVERE CYTOPENIA, SEVERE INFECTION, CARDIOPULMONARY and RENAL IMPAIRMENT

- Monitor patients for prolonged severe cytopenia and monitor for internal organ hemorrhage
- Administer filgrastim or a biosimilar product to patients beginning Day 1 after AMTAGVI and continuing daily until the absolute neutrophil count (ANC) is greater than 1000 per mm^3 for 3 consecutive days, or per institutional standard
- Treat severe infections
- Monitor cardiopulmonary and renal functions throughout the treatment course

Administer in an inpatient hospital setting. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.

Treatment-Related Mortality

AMTAGVI is associated with treatment-related mortality. In the clinical trial, the treatment-related mortality rate was 7.5% (N=160), including 2 deaths during the lymphodepleting period, 6 deaths within 30 days, and 4 deaths 38 to 150 days following AMTAGVI administration. Adverse reactions associated with these deaths included severe infections (sepsis, pneumonia and encephalitis), internal organ hemorrhage (abdominal hemorrhage and intracranial hemorrhage), acute renal failure, acute respiratory failure, cardiac arrythmia, extensive ascites and liver injury and bone marrow failure. Because clinical trials are conducted under widely varying conditions, treatment-related mortality rates observed in the clinical trials of a drug may not reflect the rates observed in practice.

Prolonged Severe Cytopenia

Patients treated with AMTAGVI may exhibit Grade 3 or higher cytopenia for weeks or longer. Based on adverse event reporting, Grade ≥ 3 cytopenia or pancytopenia which did not resolve to ≤ Grade 2 or lasted beyond 30 days post AMTAGVI infusion occurred in 45.5% of melanoma patients who received AMTAGVI. Prolonged cytopenia included thrombocytopenia (30.1%), lymphopenia (19.9%), neutropenia (17.3%), leukopenia (14.7%) and pancytopenia (1.3%). Monitor blood counts after AMTAGVI infusion.

Internal Organ Hemorrhage

Patients treated with AMTAGVI may exhibit internal organ hemorrhage. Intraabdominal and intracranial hemorrhage can be life-threatening and have been associated with at least two deaths in patients who received AMTAGVI. Withhold or discontinue AMTAGVI infusion if internal organ hemorrhage is indicated, or if patient is deemed ineligible for IL-2 (aldesleukin) infusion. Patients with persistent or repeated thrombocytopenia after receiving AMTAGVI should not use anticoagulant(s) or must be under close monitoring if the patient must take an anticoagulant.

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Important Safety Information (Continued)

Severe Infection

Severe, life-threatening, or fatal infections occurred in patients after AMTAGVI infusion. Treatment-related infections (any severity) occurred in 26.9% of melanoma patients. Grade 3 or higher infections occurred in 13.5% of patients, including 10.9% of patients with infections of an unspecified pathogen and 3.8% of patients with infections of a specified pathogen.

Do not administer AMTAGVI to patients with clinically significant systemic infections. Monitor patients for signs and symptoms of infection before and after AMTAGVI infusion and treat appropriately. Administer prophylactic antimicrobials according to institutional guidelines.

Febrile neutropenia was observed in 46.8% of melanoma patients after AMTAGVI infusion. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care as medically indicated.

Cardiac Disorder

Patients treated with AMTAGVI may exhibit cardiac disorder. Grade ≥ 3 cardiac disorders related to the AMTAGVI regimen occurred in 9.0% (14/156) of patients who received AMTAGVI including tachycardia, atrial fibrillation, arrhythmia, acute myocardial infarction, cardiac ventricular thrombosis, cardiomyopathy, QT-prolongation. Cardiac arrhythmia resulted in one death among melanoma patients who received AMTAGVI.

Monitor patients with signs and symptoms of cardiac disorder before and after AMTAGVI infusion. Withhold or discontinue AMTAGVI if severe cardiac disorder is indicated, or if patient is deemed ineligible for IL-2 (aldesleukin) infusion.

Respiratory Failure

Patients treated with AMTAGVI may develop worsened respiratory function which has been associated with deaths. Monitor patients with signs and symptoms of respiratory failure before and after AMTAGVI infusion. Withhold or discontinue AMTAGVI infusion if severe acute respiratory failure is indicated, or if patient is deemed ineligible for IL-2 (aldesleukin) infusion.

Acute Renal Failure

Patients treated with AMTAGVI may develop worsened renal function which has been associated with deaths. Monitor patients with signs and symptoms of acute renal failure before and after AMTAGVI infusion. Withhold or discontinue AMTAGVI if severe acute renal injury is indicated, or if patient is deemed ineligible for IL-2 (aldesleukin) infusion.

Hypersensitivity Reactions

Allergic reactions, including serious hypersensitivity (e.g. anaphylaxis), may occur with the infusion of AMTAGVI. Acute infusion reactions (within 1 day of infusion) may include fever, rigors or chills, tachycardia, rash, hypotension, dyspnea, cough, chest tightness, and wheezing. These events generally resolve on the same day of infusion. Monitor patients during and after infusion for signs and symptoms of a severe reaction and treat promptly.

Adverse Reactions

The most common (incidence of ≥ 20%) non-laboratory adverse reactions were chills, pyrexia, fatigue, tachycardia, diarrhea, febrile neutropenia, edema, rash, hypotension, alopecia, infection, hypoxia, and dyspnea. The most common Grade 3 or 4 laboratory abnormalities (incidence of at least 10%) were thrombocytopenia, neutropenia, anemia, leukopenia, lymphopenia, and hypophosphatemia.

Other adverse reactions that occurred in < 10% of patients included eye disorders, immune system disorders (infusion-related reactions, anaphylactic reaction, cytokine release syndrome), and vitiligo.

You may report side effects to Iovance at 1-833-400-4682, or to the FDA, at 1-800-FDA-1088 or at www.fda.gov/medwatch.

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Contents

The information in this guide is valid as of Feb. 1, 2024. This guide does not offer any form of legal advice.

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You are solely responsible for ensuring that all services are medically appropriate and properly supported in accordance with payer-specific requirements. Iovance and its agents make no warranties or guarantees, express or implied, concerning the accuracy or appropriateness of this information for your particular use given the frequent changes in public and private payer billing. The use of this information does not guarantee payment or that any payment received will cover your costs.

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Introduction

AMTAGVI is a tumor-derived autologous T cell therapy administered as part of a one time treatment regimen comprised of multiple steps (or components). A specimen of tumor is resected, then prosected (trimmed and fragmented) to evaluate and prepare tumor tissue to send to manufacturing for T cell therapy, and shipped fresh to a centralized GMP facility. AMTAGVI (lifileucel) is administered after lymphodepletion and followed by administration of a short course of high-dose IL-2[1]. AMTAGVI should be administered in an inpatient hospital setting under the supervision of a physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available. It is the responsibility of the treating physician to select the appropriate site of service for each component of this treatment process. It is the responsibility of the surgeon to select the most appropriate procedure for tumor tissue procurement. For more information on dosing and administration, refer to the full prescribing information. Components of this process may take place in various sites of care, including inpatient and outpatient settings.

Patient Journey Overview

AMTAGVI (lifileucel) is for autologous use only and is available to patients through Authorized Treatment Centers (ATCs) deemed capable of tumor tissue procurement, receipt and storage of AMTAGVI (lifileucel), and AMTAGVI (lifileucel) regimen administration. Iovance's ATC authorization program is a component of Iovance's BLA and is monitored under FDA oversight.

Step 1	Step 2	Step 3	Step 4
Tumor Tissue Procurement	**Lymphodepletion**	**AMTAGVI (lifileucel) Administration** * † ‡	**Short Course of High-Dose IL-2 Administration** †
READ MORE	READ MORE	READ MORE	READ MORE

* 7.5×10^9 to 72×10^9 viable cells

† Administer in an inpatient hospital setting under the supervision of a physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.

‡ Administer prophylactic antimicrobials according to institutional guidelines.

About this Guide

This guide presents examples and codes that may be helpful when submitting claims related to AMTAGVI (lifileucel). Please be aware that coding and billing for AMTAGVI (lifileucel) and related components of the cell therapy regimen will vary based on patient circumstances and condition, services provided, payer requirements, and site of care.

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Access & Reimbursement Resources

AMTAGVI (lifileucel) may be covered by various third-party payers, such as commercial insurers, Medicare, and Medicaid, for its approved indication by the United States Food and Drug Administration (FDA) when administered at an Authorized Treatment Center (ATC). However, the extent of coverage can vary depending on the specific payer and the enrolled patient's plan.

Sample Letter of Medical Necessity

When evaluating individual patient insurance benefits and claims for AMTAGVI (lifileucel), third-party payers may require treating physicians to complete a Letter of Medical Necessity prior to a patient obtaining coverage for AMTAGVI (lifileucel) and related products and services. Typically, insurers offer coverage solely for products and services that they consider medically necessary for the diagnosis, treatment, or management of a condition or disease. Commercial insurers, Medicaid program coverage policies, Medicare, and local coverage determinations by Medicare Administrative Contractors (MACs) outline the definition of medical necessity as it pertains to their plans and programs. Payers may have specific documentation requirements outlined in their individual programs and coverage policies.

Payers requiring a Letter of Medical Necessity will assess whether AMTAGVI (lifileucel) is a covered benefit within their specific policies. Supporting evidence for medical necessity may include:

- Information regarding the patient's medical condition and medical history, including details about previous therapies or treatments.
- Anticipated treatment outcomes and objectives.
- A Statement or Letter of Medical Necessity from the healthcare provider.
- Supporting literature such as peer-reviewed studies, clinical practice guideline recommendations, and compendia listing(s).
- The prescribing information related to AMTAGVI (lifileucel).
- Availability of alternative treatment options.

Download a sample Letter of Medical Necessity for AMTAGVI (lifileucel).

Prior Authorization

Payers may require treating healthcare providers to obtain a Prior Authorization, also referred to as pre-authorization, before granting coverage for AMTAGVI (lifileucel). The specific requirements and process for a Prior Authorization may differ among third-party payers, and may be part of a standard process, or may have a dedicated process for oncology therapies or autologous therapies such as cell therapy. Healthcare providers should thoroughly review payer policies and adhere to required steps, timelines, forms, requests and documentation as they seek coverage and reimbursement for AMTAGVI (lifileucel). Payers may require direct collaboration with a dedicated case manager for prior authorization of cell therapies.

Please Note: Obtain necessary prior authorizations. Consider the potential need to coordinate prior authorization requests for different steps of the AMTAGVI (lifileucel) process depending on payer requirements.

Download a Prior Authorization Checklist for AMTAGVI (lifileucel).

Sample Letter of Appeal

In the event that a payer denies an initial coverage request or issues an unfavorable coverage determination, a healthcare provider may appeal the decision. An appeal is a challenge to a denial of benefits. A payer's notice of denial will typically contain information about the payer's rationale for the denial decision and instructions regarding submitting appeals. Often, appeals can be escalated if initial attempts are not successful. In some instances, a denial may be appealed by the treating physician requesting expedited peer-to-peer review with a payer representative.

Download a sample Letter of Appeal for AMTAGVI (lifileucel).

IOVANCE Cares™

IovanceCares™ Reimbursement Support for HCPs

IovanceCares™ Reimbursement Support is a component of IovanceCares™ which includes the IovanceCares Portal, IovanceCares Reimbursement and Patient Support, and IovanceCares Case Managers and Call Center. IovanceCares™ offers reimbursement support including benefit investigation, prior authorization assistance, and denials appeal assistance upon approval to assist with timely access to AMTAGVI (lifileucel).

- **Benefits Verification:** Assistance in obtaining patient benefits information from the primary and secondary payer
- **Prior Authorization Support:** Assistance with Prior Authorization process
- **Appeals:** Assistance with the appeals process with payer(s), should the Prior Authorization be denied

For more information or support, contact IovanceCares™ at 1-833-400-4682.

Coding Considerations

Correct coding for AMTAGVI (lifileucel) and related claims, including claims for steps in the cell therapy process, depends on the site or setting of care in which the products or services are delivered as well as individual payer policies. This Billing & Coding Guide presents general code sets and guidelines that are typically used by payers. Correct coding is the responsibility of the healthcare provider and should be appropriate to the site of care, payer-specific requirements, and the products and services delivered.

Inpatient Hospital Claims

AMTAGVI should be administered in an inpatient hospital setting under the supervision of a physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available. When AMTAGVI (lifileucel) is provided in the inpatient hospital setting, it may be included in a bundled payment amount that covers the inpatient stay.

For hospitals reimbursed under Medicare's Inpatient Prospective Payment System (IPPS), AMTAGVI (lifileucel) has been assigned to MS-DRG 018. This pre-MDC (Major Diagnostic Category) MS-DRG was originally established for CAR-T therapies but was then expanded and renamed to "Chimeric Antigen Receptor (CAR) T cell and Other Immunotherapies."[2]

While other third-party payers may also use a DRG-based grouping methodology, coding requirements and payment methods may vary by payer. For billing inpatient hospital claims, the types of code sets typically required include:

- ICD-10-CM Diagnosis Codes: International Classification of Diseases, 10th Revision, Clinical Modification
- ICD-10-PCS Procedure Codes: International Classification of Diseases, 10th Revision, Procedure Coding System
- Hospital Revenue Codes

Outpatient Hospital Claims

Some components of the AMTAGVI (lifileucel) treatment regimen may be provided in the outpatient hospital setting.

For billing outpatient claims, the types of code sets typically required include:

- ICD-10-CM Diagnosis Codes
- HCPCS Level II Codes
- Current Procedural Terminology (CPT®) Codes: Category I and Category III
- National Drug Codes (NDC)
- Hospital Revenue Codes

Coverage Summary Table*

Site of Care	Medicare Part A	Medicare Part B	Commercial Payers
Inpatient Hospital (acute care)	• IPPS • AMTAGVI (lifileucel) covered within MS-DRG 018	N/A	• Typically covered within the DRG • Individual case rates may apply • PA may be required • Payer Policies may vary
Outpatient Hospital Department (HOPD)	N/A	• OPPS • Products and administration services are covered separately	• Products and administration services may be covered separately • PA may be required • Payer Policies may vary

*Follow Prescribing Information regarding appropriate site of care for AMTAGVI (lifileucel). Choosing the appropraite site of care for any product or service is the responsibility of the treating physician. AMTAGVI should be administered in an inpatient hospital setting under the supervision of a physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.

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Coding Summary Table for AMTAGVI (lifileucel) regimen

Information	Code Type	Code Ranges and Descriptions
Diagnosis	ICD-10-CM	C43.0 through C43.9 Malignant Melanoma (see detail on Page 10) Z51.12 Encounter for antineoplastic immunotherapy
Tumor Tissue Procurement	CPT®	See detail on Page 11 for example CPT® codes applicable to outpatient billing
	ICD-10-PCS	See detail on Page 14 for example ICD-10-PCS codes applicable to inpatient billing
Lympho-depletion	HCPCS	J9073, J9074, J9075 Cyclophosphamide (see detail on Page 15) J9209 Injection, mesna, 200 mg* J9185 Injection, fludarabine phosphate, 50 mg
	CPT®	96413 Chemotherapy administration 96415 Chemotherapy administration 96417 Chemotherapy administration
	NDC	Various; refer to institutional standards
	Hospital Revenue Codes	0636 Pharmacy – Drugs Requiring Detailed Coding
AMTAGVI (lifileucel) Administration	MS-DRG	018 Chimeric Antigen Receptor (CAR) T cell and Other Immunotherapies
	11 digit NDC	73776-0001-11 AMTAGVI (lifileucel) See Page 16 for additional detail. 73776-0001-12 AMTAGVI Cassette
	ICD-10-PCS	XW033L7 Introduction of Lifileucel Immunotherapy into Peripheral Vein, Percutaneous approach, New Technology Group 7 XW043L7 Introduction of Lifileucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7
	Hospital Revenue Codes	0636 Pharmacy – Drugs Requiring Detailed Coding 0891 Special Processed Drugs – FDA Approved Cell Therapy
	HCPCS	J9999 Not otherwise classified, antineoplastic drugs C9399 Unclassified drugs or biologicals J3490 Unclassified drugs J3590 Unclassified biologics
Short Course of High-Dose IL-2 Administration†	HCPCS	J9015 Injection, aldesleukin, per single use vial
	11 digit NDC	73776-0022-01 Proleukin 22 million IU single-dose vial
	Hospital Revenue Codes	0636 Pharmacy – Drugs Requiring Detailed Coding
	ICD-10-PCS	3E03302 Introduction of High-Dose IL-2 into Peripheral Vein, Percutaneous Approach 3E04302 Introduction of High-Dose IL-2 into Central Vein, Percutaneous Approach

Codes listed for consideration in this guide are not intended to be promotional or to encourage or suggest use of a drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive, and additional codes may apply. Additional HCPCS and CPT® codes may be required for billing antineoplastic regimens depending on route of administration, administration of supportive care agents per institutional standards, and administration of hydration per institutional standards.

*Mesna is given with cyclophosphamide and was one of the supportive care regimens used in Iovance clinical trials.[1]

Beginning Day 1 after AMTAGVI administer filgrastim daily until the absolute neutrophil count (ANC) is greater than 1000 per mm^3 for 3 consecutive days, or per institutional standard. Use of other supportive care medicines is up to the physician's discretion.

†See Page 18 for details on applicability.

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Diagnosis Codes

AMTAGVI is a tumor-derived autologous T cell immunotherapy 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.

Diagnosis codes in the form of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes are used to report diagnoses and support the rationale for treatment as a component of documenting medical necessity.[3] These codes are used in both the inpatient and outpatient settings to classify diagnoses and conditions.

Claims forms require at least one diagnostic code to be listed. Diagnosis codes should reflect the highest level of specificity available.

ICD-10-CM diagnosis codes use between 3 to 7 characters to achieve the greatest level of specificity. A 3-character code should be used only if it cannot be further subdivided to a level of greater detail.

Payer requirements for diagnostic coding using ICD-10-CM codes vary. Please verify diagnostic coding requirements with each payer. Providers are encouraged to use the most appropriate code for the diagnosis.

The following is a list of ICD-10-CM codes for a diagnosis of malignant melanoma. Other codes may also apply. Selection of the appropriate code is the responsibility of the healthcare provider.

ICD-10-CM Diagnosis Codes for consideration[3]

C43	Malignant melanoma
C43.0	Malignant melanoma of lip
C43.1 – C43.122	Malignant melanoma of eyelid, including canthus
C43.2 – C43.22	Malignant melanoma of ear and external auricular canal
C43.3 – C43.39	Malignant melanoma of other and unspecified parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51 – C43.59	Malignant melanoma of trunk
C43.6 – C43.62	Malignant melanoma of upper limb, including shoulder
C43.7 – C43.72	Malignant melanoma of of lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified

If infusion for antineoplastic immunotherapy is the only reason for the patient encounter, physicians and hospitals may report the ICD-10-CM code Z51.12 as the primary diagnosis.

Z51.12	Encounter for antineoplastic immunotherapy

Additional diagnosis codes may be reported to identify secondary diagnoses. An example list of ICD-10-CMs for consideration in coding secondary diagnoses describing secondary lesions or metastatic sites of disease may include the following. Other codes may apply.

C77.0 – C77.9	Secondary and unspecified malignant neoplasm of lymph nodes
C78.00 – C78.89	Secondary malignant neoplasm of respiratory and digestive organs
C79.00 – C79.9	Secondary malignant neoplasm of other and unspecified sites

TIP:
Additional diagnosis (ICD-10-CM) codes may be required to sufficiently specify secondary lesions or metastatic sites.

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Step 1: Tumor Tissue Procurement

Procedures to obtain tumor tissue may vary extensively depending on individual patient circumstances and healthcare provider judgment. Obtain necessary prior authorizations. Consider the potential need to coordinate prior authorization requests for different steps of the AMTAGVI (lifileucel) process depending on payer requirements. These procedures are highly variable in terms of anatomic location and surgical approach required to access the tumor tissue, and may take place in an inpatient or outpatient setting.

Because of the variability of surgical procedures and methods during which tumor tissue may be procured, billing and coding likewise may vary considerably. Please consult with your institutional resources in surgical billing and coding in addition to the policies and requirements of any third-party payer with regard to submitting claims. The sections below describe some of the Common Procedural Terminology (CPT®) codes (used for outpatient procedures) and ICD-10-PCS Procedure Codes (used for inpatient procedures) that may be applicable to melanoma surgery.

The information in this section is not exhaustive in terms of containing all potentially applicable codes. Codes are provided as examples of a subset of potentially applicable codes, including other categories of codes, that may be required by a payer to submit a complete claim for such procedures.

At least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5 cm is required.[5] Authorized Treatment Centers (ATCs) will receive AMTAGVI (lifileucel) tumor tissue procurement supplies (TTPS) kits with reagents required for tumor tissue procurement and specimen shipping.

Review the Surgical Post Operative Report to Determine Appropriate Code Selection

To determine the appropriate code for the procedure, please review the complete surgical post operative report for the procedure and look for details including the approach and technique used. Look for details including:

- Location and depth of incision(s)
- Purpose of the procedure
- Detailed description of the procedure site
- Level of severity or risk of the procedure
- Complexity of the procedure
- Measurement and reporting of lesions in centimeters (cm)
- Pre- and post-operative diagnoses
- Anesthesia (general, local, regional)
- Number of surgeons and specialty; other clinician(s) involved
- Surgical findings

It is the responsibility of the billing physician to ensure that all billed codes including modifiers and add-on codes are used appropriately and accurately.

As of February 2024, there is no existing code for Tumor Tissue Procurement / Prosection.

Outpatient Procedures

Billing for outpatient procedures typically requires ICD-10-CM Diagnosis Codes, HCPCS Level II Codes, Current Procedural Terminology (CPT®) Codes, National Drug Codes (NDC), and Hospital Revenue Codes.

Depending on individual patient circumstance and scenario, tumor tissue procurement may occur during biopsy, excision, or more involved procedures such as resection. The most appropriate procedure should be determined by the surgeon. Appropriate procedure coding may require additional codes or modifiers and could include codes representing ultrasonic guidance or use of a robotic surgical system.

The following examples include CPT codes which describe outpatient biopsy and excision procedures related to melanoma surgery. The anatomical sites shown below were selected as examples because they were more common anatomical sites for tumor tissue procurement in Iovance clinical trials, but are not exhaustive. Tumor tissue procurement surgery is highly variable and other surgical procedures occurring at other anatomical sites may be possible for tumor tissue procurement. The selection of an appropriate procedure and the surgical technique used is up to the medical discretion of the surgeon. Some codes included in the code ranges below may not be applicable, including ones potentially used only for diagnostic procedures. Consult with the surgeon's surgical post-operative documentation regarding procedures performed, as well as any relevant billing and coding guidelines from a patient's payer, to determine the appropriate code(s) for any procedure. This list is provided as an example only, is not exhaustive, and does not include all possible anatomic sites nor possible CPT codes. For additional codes that may be appropriate, please consult the CPT® 2023 Professional Edition published by the American Medical Association (AMA).

Example CPT® Codes for Procedures[6]

Lymphatic System

38500, 38510 - 38531	Biopsy or excision of lymph node(s)
38570 - 38589	Laparoscopy procedures of lymph nodes
38700 - 38780	Lymphadenectomy procedures
38999	Unlisted procedure, hemic or lymphatic system

Other Soft Tissue

21011 - 21016	Excision and resection procedures, head (face, scalp)
21550 - 21603	Excision and resection procedures, neck or thorax
21920 - 21936	Excision and resection procedures, back or flank
22900 – 22905	Excision and resection procedures, abdomen
23065 - 23078, 23200 - 23220	Excision and resection procedures, shoulder
24065 - 24079, 24150 - 24152	Excision and resection procedures, upper arm
25065 - 25078	Excision and resection procedures, forearm or wrist
26111 – 26118	Excision and resection proedures, hand or fingers
27040 - 27049, 27057 - 27059	Excision and resection proedures, hip or pelvis
27323 - 27328, 27337 - 27339	Excision and resection proedures, thigh or knee area
27613 - 27619, 27632 - 27634	Excision and resection procedures, leg or ankle
28039 – 28047	Excision and resection proedures, foot or toe

As of February 2024, there is no existing code for Tumor Tissue Procurement / Prosection.

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Skin

11106 - 11107	Incisional biopsy procedures, skin
11600 - 11646	Excision, malignant lesion

Lung

32440 - 32491	Removal procedures of the lung
32503 - 32506	Resection procedures of the lung
32661 - 32674	Thoracoscopy (VATS) procedures
32999	Unlisted procedure, lungs and pleura

Liver

47100 - 47130	Excision procedures of the liver
47379	Unlisted laparoscopic procedure, liver

Breast

19081 - 19086, 19101	Biopsy procedures of breast
19120 - 19126	Excision procedures, breast lesions
19300 - 19307	Mastectomy procedures
19499	Unlisted procedure, breast

As of February 2024, there is no existing code for Tumor Tissue Procurement / Prosection.

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Inpatient Procedures

Billing for inpatient procedures typically requires ICD-10-CM Diagnosis Codes, ICD-10-PCS Procedure Codes, and Hospital Revenue Codes. It may be necessary to include two codes: an ICD-10 Diagnosis Code for melanoma and a second code which reflects the part of the body corresponding to the anatomic site of the metastasis being excised or resected. Below are ranges of ICD-10-PCS codes that include inpatient procedures that may be used for melanoma surgery. The ranges include codes for diagnostic and non-diagnostic procedures; the diagnostic procedures end in ZX and the non-diagnostic procedures end in ZZ.

Example ICD-10-PCS Codes for Procedures[7]

The following examples include ICD-10-PCS codes which describe inpatient biopsy and excision procedures related to melanoma surgery. The anatomical sites shown below were selected as examples because they were more common anatomical sites for tumor tissue procurement in Iovance clinical trials, but are not exhaustive. Tumor tissue procurement surgery is highly variable and other surgical procedures occurring at other anatomical sites may be possible for tumor tissue procurement. The selection of an appropriate procedure and the surgical technique used is up to the medical discretion of the surgeon. Some codes included in the code ranges below may not be applicable, including ones potentially used only for diagnostic procedures. Consult with the surgeon's surgical post-operative documentation regarding procedures performed, as well as any relevant billing and coding guidelines from a patient's payer, to determine the appropriate code(s) for any procedure. This list is provided as an example only, is not exhaustive, and does not include all possible anatomic sites nor possible ICD-10-PCS codes. For additional codes that may be appropriate, please consult the ICD-10-PCS Reference Manual.

Lymphatic and Hemic Systems

07B00ZZ through 07BP4ZZ	Procedure Code Range for Body System 7, Operation B (Excision). See examples.

Subcutaneous Tissue and Fascia

0JB00ZZ through 0JBR3ZZ	Procedure Code Range for Body System J, Operation B (Excision). See examples.

Respiratory System (Lung)

0BB10ZZ through 0BBT4ZZ	Procedure Code Range for Body System B, Operation B (Excision). See example.
0BTH0ZZ through 0BTJ4ZZ	Procedure Code Range for Body System B, Operation T (Resection). See example.

Hepatobiliary System and Pancreas (Liver)

0FB00ZZ through 0FB24ZZ	Procedure Code Range for Body System F, Operation B (Excision). See example.

Skin and Breast

0HB0XZZ through 0HBY8ZZ	Procedure Code Range for Body System H, Operation B (Excision). See examples.

Step 2 : Lymphodepletion

Prior to administration of AMTAGVI (lifileucel), a preparative lymphodepletion regimen is initiated, consisting of cyclophosphamide (60 mg/kg) with mesna once daily for 2 days followed by fludarabine (25 mg/m^2) once daily for 5 days, with appropriate supportive care per institutional standards.[1]

Lymphodepletion may be delivered in outpatient or inpatient settings of care depending on the individual patient situation and the best clinical judgement of the treating physician. It is up to the care team to determine the appropriate setting of care for delivery of the lymphodepletion regimen. The codes below may be helpful in the outpatient setting.

If the lymphodepletion regimen is administered during a hospital inpatient administration, charges for all drugs administered in this step may be submitted as a cumulative charge. Payers may vary in their requirements; therefore, providers should verify prior to patient treatment.

HCPCS Codes ("J Codes")

J9073	Injection, cyclophosphamide (ingenus), 5 mg
J9074	Injection, cyclophosphamide (sandoz), 5 mg
J9075	Injection, cyclophosphamide, not otherwise specified, 5 mg
J9209	Injection, mesna*, 200 mg
J9185	Injection, fludarabine phosphate, 50 mg

CPT® Codes[6]

96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique, each additional hour (list separately in addition to code for primary procedure)
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)

NDC Codes

Various NDC Codes may be needed for this regimen depending on products used at your institution. Please refer to institutional standards for NDC coding.

Hospital Revenue Codes

0636	Pharmacy – Drugs Requiring Detailed Coding

Complete claims for this regimen and associated products and services, including supportive care and hydration, may require additional CPT® and HCPCS codes as well as ICD-10-CM diagnosis codes, National Drug Codes (NDC), and Hospital Revenue Codes.

*Mesna is given with cyclophosphamide and was one of the supportive care regimens used in Iovance clinical trials.[1]

Use of other supportive care medicines is up to the physician's discretion.

AMTAGVI™ (lifileucel) Suspension for IV infusion

Please see pages throughout and accompanying Full Prescribing Information, including BOXED WARNINGS, for additional Important Safety Information.

Step 3: AMTAGVI (lifileucel) Administration

AMTAGVI (lifileucel) is a tumor-derived autologous T cell immunotherapy 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. This indication is approved under accelerated approval based on objective response rate (ORR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Administer in an inpatient hospital setting under the supervision of a physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.

ICD-10-PCS Procedural Codes[7]

These codes may be reported for inpatient facility services associated with AMTAGVI (lifileucel) administration.

XW033L7	Introduction of Lifileucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7
XW043L7	Introduction of Lifileucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

MS-DRG[2]

AMTAGVI (lifileucel) is assigned to MS-DRG 018, "Chimeric Antigen Receptor (CAR) T cell and Other Immunotherapies. For Medicare admissions, the ICD-10-PCS code for [AMTAGVI] must be listed as the principal procedure code to appropriately align the admission with established payment under MS-DRG 018. Providers should confirm coding requirements with other payers prior to treatment.

MS-DRG 018	Chimeric Antigen Receptor (CAR) T cell and Other Immunotherapies

Revenue Codes

Medicare and other payers require inclusion of revenue codes for billing purposes when providing inpatient or outpatient hospital department services. Revenue codes are used on claim forms to categorize costs under broad hospital revenue centers. Examples of pharmacy revenue centers are below. For Medicare bills on the CMS-1450 (UB-04) claim form, each line item must be accompanied by a revenue code. Please follow NUBC standards, CMS guidance (where applicable), and standard revenue coding practices of your institution.

0636	Pharmacy – Drugs Requiring Detailed Coding
0891	Pharmacy – Specialized Processed Drugs – FDA approved cell therapy

HCPCS Codes

As a new FDA approved cell therapy, AMTAGVI does not have a specific HCPCS code assigned. Until a code is assigned, payers may require use of a miscellaneous drug code. Providers should verify specific code requirements with each payer.

J9999	Not otherwise classified, antineoplastic drugs	J3490	Unclassified drugs
J3590	Unclassified biologics	C9399	Unclassified drugs or biologicals

NDC Reporting for AMTAGVI

AMTAGVI is supplied in 1 to 4 infusion bag(s), with each bag containing approximately 100 mL to 125 mL of frozen suspension of tumor-derived T cells in 5% DMSO, 0.5% albumin (human), and 300 IU/mL IL-2 (aldesleukin). Each bag is contained within a protective metal cassette. National Drug Codes (NDCs) are unique identifiers assigned to drug products. These codes serve as a standardized system for product identification and facilitate the tracking and communication of information about drugs. The NDC is required on Medicare claims for dual-eligible beneficiaries, Medicaid fee-for-service claims, and claims for some private payers. Confirm with payers if an NDC is needed and the format the payer requires (10 or 11 digits). Payer requirements for NDC use and format may vary for commercial and federal insurance payers. Payers may further request to include the NDC Unit of Measure, NDC Units, and NDC Qualifier for payment of claims.

NDC Code[1]

73776-0001-11	AMTAGVI (lifileucel) NDC in 11-digit format
73776-001-11	AMTAGVI (lifileucel) NDC in 10-digit format
73776-0001-12	AMTAGVI (lifileucel) Cassette NDC in 11-digit format
73776-001-12	AMTAGVI (lifileucel) Cassette NDC in 10-digit format

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Reimbursement Methodologies: Commercial Payers

Some commercial payers may expect or require that Authorized Treatment Centers (ATCs) contract with them prospectively and on a patient-specific basis prior to initiating the process for AMTAGVI (lifileucel) therapy. Health care providers may need to communicate directly with commercial payers for specific coverage and reimbursement processes including methods such as Single Case Agreements. Because commercial plans and benefit designs are variable, ATCs and treating physicians should contact a patient's commercial payer directly to understand coverage and reimbursement considerations for any component of the AMTAGVI (lifileucel) process.

Reimbursement Methodologies: Medicare[2]

AMTAGVI should be administered in an inpatient hospital setting under the supervision of a physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available. When AMTAGVI (lifileucel) is administered in the inpatient hospital setting, it may be included in a bundled payment amount that covers the inpatient stay. Medicare MS-DRG 018, originally designated for CAR-T therapies for payment under IPPS, is described as "Chimeric Antigen Receptor (CAR) T cell and Other Immunotherapies," and AMTAGVI (lifileucel) has also been assigned to this DRG. While some other third-party payers also use a DRG-based grouping methodology, coding requirements and payment methods may vary by payer.

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Step 4: Short Course of High-Dose IL-2 Administration

Within 3 to 24 hours of completing AMTAGVI (lifileucel) infusion, a short course of high-dose IL-2 is administered every 8 to 12 hours for up to 6 doses to support cell expansion in vivo.[1] Administer in an inpatient setting under the supervision of a physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.

Aldesleukin (IL-2) dosing following AMTAGVI (lifileucel) may differ from IL-2 dosing when used as single agent therapy.

Healthcare providers should confirm whether a payer requires that high-dose IL-2 procedure codes be reported on claim forms. If confirmed as appropriate, the ICD-10-PCS code for the delivery of high-dose IL-2 would be listed as the secondary procedure code on CMS 1450 forms.

When a short course of high-dose IL-2 is administered as part of the AMTAGVI (lifileucel) process, it is important to report the AMTAGVI (lifileucel) ICD-10-PCS procedure code in the principal procedure position on the CMS 1450 claim form, and not the ICD-10-PCS procedure code for high-dose IL-2.

When the primary purpose for an inpatient admission is administration of AMTAGVI (lifileucel), payers may or may not require the inclusion of specific codes related to the administration of high-dose IL-2. Payers may prefer that the charges for any other drug or biological outside the administration of AMTAGVI (lifileucel) are cumulatively reported under a pharmacy-related revenue code. ATCs and the treating physician should confirm requirements with each individual patient's payer(s) prior to treating patients. For Medicare, reporting the high-dose IL-2 ICD-10-PCS procedure codes should be confirmed with your respective Medicare Administrative Contractor (MAC). If payers do require line-item designation of high-dose IL-2, one of the following codes may or may not apply.

For more information regarding aldesleukin (IL-2) dosing and administration in the context of this regimen, please refer to the AMTAGVI (lifileucel) package insert / Prescribing Information. Coding requirements and payment methods may vary by payer.

ICD-10-PCS Procedural Codes[7]

3E03302	Introduction of High-Dose IL-2 into Peripheral Vein, Percutaneous Approach
3E04302	Introduction of High-Dose IL-2 into Central Vein, Percutaneous Approach

HCPCS

J9015	Injection, aldesleukin, per single use vial

NDC

73776-0022-01	Proleukin 22 million IU single-dose vial

You are solely responsible for ensuring that all services are medically appropriate and properly supported in accordance with payer-specific requirements. Iovance and its agents make no warranties or guarantees, express or implied, concerning the accuracy or appropriateness of this information for your particular use given the frequent changes in public and private payer billing. The use of this information does not guarantee payment or that any payment received will cover your costs.

Sample CMS-1450 Claims Form

Following treatment, healthcare providers must file a claim with a patient's health insurer for the consideration of payment. Hospital services and procedures are billed using the CMS-1450 claim form. This form is suitable for use in billing multiple third-party payers, and some payers may not require all data elements. The CMS-1450 form requires patient information, insurance policy number, codes describing the billed services, national provider identifier (NPI) number, and revenue codes as specified.

Please refer to the Medicare Claims Processing Manual, Pub. 100-04, Chapter 25, available at the following link for more information:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf

Many providers file the CMS-1450 claim form electronically rather than using the paper version. The 837I (Institutional) is the format used by hospitals to electronically submit claims. ANSI ASC X12N 837I (Institutional) Version 5010A2 is the current electronic claim version.

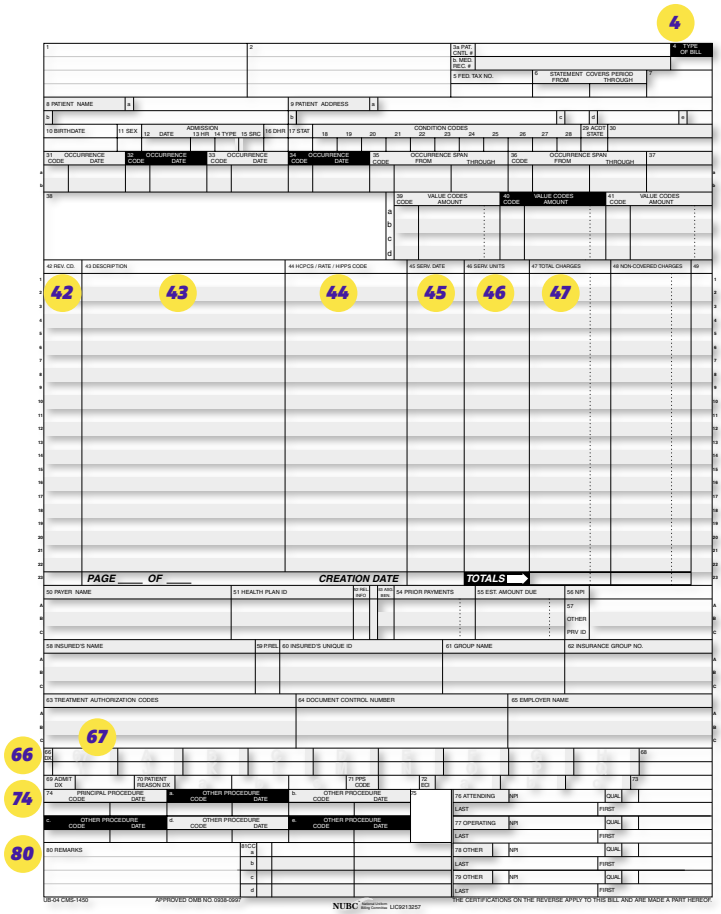
Please refer to this additional information from CMS on electronic claims:

https://www.cms.gov/medicare/billing/electronicbillingeditrans/healthcareclaims.html

Reminders for Submitting Claims

- Review payer policies for coding requirements.
- Investigate each patient's benefits and confirm coverage.
- **Obtain necessary prior authorizations. Consider the potential need to coordinate prior authorization requests for different steps of the AMTAGVI (lifileucel) process depending on payer requirements.**
- Appropriately confirm or reference any single case agreements.
- Have supporting information—such as statement of medical necessity, product invoice(s), clinical records or medical chart notes, and Prescribing Information (PI)—on hand.
- Use correct billing codes in the correct sequence.
- Complete claims fully and include additional documentation as required.
- Claims may need to be submitted with paper forms if additional documentation is required that cannot be sent electronically.
- Submit claims in accordance with ASA (American Surgical Association) requirements and payer guidelines.
- Submit claims fully and accurately in a timely fashion.
- **It is the healthcare provider's responsibility to select the proper codes and ensure accuracy of all statements used in seeking coverage and reimbursement for an individual patient.**

Sample CMS-1450 Claims Form for Inpatient Hospital Facilities



4 **Form Locator (FL) 4:** Enter code for type of bill (0111 for inpatient hospital).

42 **FL 42:** Enter the appropriate revenue codes corresponding to the HCPCS code in Field 44.

43 **FL 43:** Enter the descriptions corresponding to the revenue codes in Field 42. Some payers require reporting NDC in FL 43; requirements may vary.

44 **FL 44:** Enter the appropriate HCPCS/CPT codes and modifiers if required by payer.

45 **FL 45:** Enter dates of service.

46 **FL 46:** Enter appropriate number of units of service (report 1 unit for AMTAGVI (lifileucel) administration).

47 **FL 47:** Enter total charges.

66 **FL 66:** Identify the type of ICD diagnosis code used (Enter a "0" for ICD-10-CM).

67 **FL 67 and 67A-67Q:** Enter the appropriate diagnosis code. Refer to Page 10 for potentially relevant diagnostic codes for patients treated with AMTAGVI (lifileucel).

74 **FL 74:** Enter relevant ICD-10-PCS codes with corresponding dates of service.

80 **FL 80:** Enter drug-identifying information as required by payer (such as drug name, NDC 11-digit format, dose, route of administration, or similar).

Payers may also request additional information to be sent electronically or by other format beyond what is required for the CMS-1450 form.

The information presented in this guide is collected from diverse sources, is for educational purposes, is general in scope, and may change without prior notice. A number of factors impact third-party payment for medical products and services. Coverage and reimbursement for any specific product or service can differ significantly based on the payer, plan, patient, and setting of care. You are solely responsible for ensuring that all services are medically appropriate and properly supported in accordance with payer-specific requirements. Iovance and its agents make no warranties or guarantees, express or implied, concerning the accuracy or appropriateness of this information for your particular use given the frequent changes in public and private payer billing. The use of this information does not guarantee payment or that any payment received will cover your costs. The information provided in this guide does not guarantee an individual coverage benefit or reimbursement for any product or service. While Iovance has compiled a general list of codes, individual patient situations and scenarios vary, and the healthcare provider should make coding determinations in compliance with relevant regulations and payer guidance.

AMTAGVI™ (lifileucel) Suspension for IV infusion

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AMTAGVI (lifileucel) Indication

AMTAGVI (lifileucel) is a tumor-derived autologous T cell immunotherapy 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.
This indication is approved under accelerated approval based on objective response rate (ORR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Important Safety Information (ISI)

WARNING: TREATMENT-RELATED MORTALITY, PROLONGED SEVERE CYTOPENIA, SEVERE INFECTION, CARDIOPULMONARY and RENAL IMPAIRMENT

- Monitor patients for prolonged severe cytopenia and monitor for internal organ hemorrhage
- Administer filgrastim or a biosimilar product to patients beginning Day 1 after AMTAGVI and continuing daily until the absolute neutrophil count (ANC) is greater than 1000 per mm^3 for 3 consecutive days, or per institutional standard
- Treat severe infections
- Monitor cardiopulmonary and renal functions throughout the treatment course

Administer in an inpatient hospital setting. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.

Treatment-Related Mortality

AMTAGVI is associated with treatment-related mortality. In the clinical trial, the treatment-related mortality rate was 7.5% (N=160), including 2 deaths during the lymphodepleting period, 6 deaths within 30 days, and 4 deaths 38 to 150 days following AMTAGVI administration. Adverse reactions associated with these deaths included severe infections (sepsis, pneumonia and encephalitis), internal organ hemorrhage (abdominal hemorrhage and intracranial hemorrhage), acute renal failure, acute respiratory failure, cardiac arrythmia, extensive ascites and liver injury and bone marrow failure. Because clinical trials are conducted under widely varying conditions, treatment-related mortality rates observed in the clinical trials of a drug may not reflect the rates observed in practice.

Prolonged Severe Cytopenia

Patients treated with AMTAGVI may exhibit Grade 3 or higher cytopenia for weeks or longer. Based on adverse event reporting, Grade ≥ 3 cytopenia or pancytopenia which did not resolve to ≤ Grade 2 or lasted beyond 30 days post AMTAGVI infusion occurred in 45.5% of melanoma patients who received AMTAGVI. Prolonged cytopenia included thrombocytopenia (30.1%), lymphopenia (19.9%), neutropenia (17.3%), leukopenia (14.7%) and pancytopenia (1.3%). Monitor blood counts after AMTAGVI infusion.

Internal Organ Hemorrhage

Patients treated with AMTAGVI may exhibit internal organ hemorrhage. Intraabdominal and intracranial hemorrhage can be life-threatening and have been associated with at least two deaths in patients who received AMTAGVI. Withhold or discontinue AMTAGVI infusion if internal organ hemorrhage is indicated, or if patient is deemed ineligible for IL-2 (aldesleukin) infusion. Patients with persistent or repeated thrombocytopenia after receiving AMTAGVI should not use anticoagulant(s) or must be under close monitoring if the patient must take an anticoagulant.

Severe Infection

Severe, life-threatening, or fatal infections occurred in patients after AMTAGVI infusion. Treatment-related infections (any severity) occurred in 26.9% of melanoma patients. Grade 3 or higher infections occurred in 13.5% of patients, including 10.9% of patients with infections of an unspecified pathogen and 3.8% of patients with infections of a specified pathogen.

Do not administer AMTAGVI to patients with clinically significant systemic infections. Monitor patients for signs and symptoms of infection before and after AMTAGVI infusion and treat appropriately. Administer prophylactic antimicrobials according to institutional guidelines.

Febrile neutropenia was observed in 46.8% of melanoma patients after AMTAGVI infusion. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care as medically indicated.

Cardiac Disorder

Patients treated with AMTAGVI may exhibit cardiac disorder. Grade ≥ 3 cardiac disorders related to the AMTAGVI regimen occurred in 9.0% (14/156) of patients who received AMTAGVI including tachycardia, atrial fibrillation, arrhythmia, acute myocardial infarction, cardiac ventricular thrombosis, cardiomyopathy, QT-prolongation. Cardiac arrhythmia resulted in one death among melanoma patients who received AMTAGVI.

Monitor patients with signs and symptoms of cardiac disorder before and after AMTAGVI infusion. Withhold or discontinue AMTAGVI if severe cardiac disorder is indicated, or if patient is deemed ineligible for IL-2 (aldesleukin) infusion.

Respiratory Failure

Patients treated with AMTAGVI may develop worsened respiratory function which has been associated with deaths. Monitor patients with signs and symptoms of respiratory failure before and after AMTAGVI infusion. Withhold or discontinue AMTAGVI infusion if severe acute respiratory failure is indicated, or if patient is deemed ineligible for IL-2 (aldesleukin) infusion.

Acute Renal Failure

Patients treated with AMTAGVI may develop worsened renal function which has been associated with deaths. Monitor patients with signs and symptoms of acute renal failure before and after AMTAGVI infusion. Withhold or discontinue AMTAGVI if severe acute renal injury is indicated, or if patient is deemed ineligible for IL-2 (aldesleukin) infusion.

Hypersensitivity Reactions

Allergic reactions, including serious hypersensitivity (e.g. anaphylaxis), may occur with the infusion of AMTAGVI. Acute infusion reactions (within 1 day of infusion) may include fever, rigors or chills, tachycardia, rash, hypotension, dyspnea, cough, chest tightness, and wheezing. These events generally resolve on the same day of infusion. Monitor patients during and after infusion for signs and symptoms of a severe reaction and treat promptly.

Adverse Reactions

The most common (incidence of ≥ 20%) non-laboratory adverse reactions were chills, pyrexia, fatigue, tachycardia, diarrhea, febrile neutropenia, edema, rash, hypotension, alopecia, infection, hypoxia, and dyspnea. The most common Grade 3 or 4 laboratory abnormalities (incidence of at least 10%) were thrombocytopenia, neutropenia, anemia, leukopenia, lymphopenia, and hypophosphatemia.

Other adverse reactions that occurred in <10% of patients included eye disorders, immune system disorders (infusion-related reactions, anaphylactic reaction, cytokine release syndrome), and vitiligo.

You may report side effects to Iovance at 1-833-400-4682, or to the FDA, at 1-800-FDA-1088 or at www.fda.gov/medwatch.

AMTAGVI™ (lifileucel) Suspension for IV infusion

IOVANCE Cares™

About IovanceCares™

IovanceCares provides comprehensive support to patients, caregivers, and healthcare providers throughout the Iovance treatment journey. IovanceCare includes the IovanceCares Portal, IovanceCares Reimbursement and Patient Support, and IovanceCares Case Manager Team & Call Center.

IovanceCares Reimbursement Support

IovanceCares offers Reimbursement Support including benefits verification, prior authorization assistance, and denial appeals assistance.

IovanceCares Patient Support

IovanceCares offers patient support resources and other financial assistance for eligible patients.

Contact IovanceCares

IovanceCares Case Managers are available to provide personalized support to healthcare professionals and patients throughout each step of treatment with Iovance therapy.

For support and questions, call us Monday-Friday from 8:00 am-9:00 pm EST at 1 (833) 400-IOVA to speak to your dedicated Case Manager.

References

1. AMTAGVI [Package Insert]. Iovance Biotherapeutics Inc., 2024.

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Billing & Coding Guide

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