CARVYKTI®
(ciltacabtagene autoleucel) Suspension for IV Infusion

Access & Reimbursement Guide

Johnson&Johnson

LEGEND BIOTECH

Indications

INDICATIONS AND USAGE

CARVYKTI® (ciltacabtagene autoleucel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least 1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide.

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Important Safety Information

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, PROLONGED and RECURRENT CYTOPENIA, and SECONDARY HEMATOLOGICAL MALIGNANCIES

Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with CARVYKTI®. Do not administer CARVYKTI® to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), which may be fatal or life-threatening, occurred following treatment with CARVYKTI®, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with CARVYKTI®. Provide supportive care and/or corticosteroids as needed.

Parkinsonism and Guillain-Barré syndrome and their associated complications resulting in fatal or life-threatening reactions have occurred following treatment with CARVYKTI®.

Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), including fatal and life-threatening reactions, occurred in patients following treatment with CARVYKTI®. HLH/MAS can occur with CRS or neurologic toxicities.

Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery occurred following treatment with CARVYKTI®.

Secondary hematological malignancies, including myelodysplastic syndrome and acute myeloid leukemia, have occurred following treatment with CARVYKTI®.

CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS Program.

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How to Use This Guide

Introduction

The administration of CARVYKTI® (ciltacabtagene autoleucel) is part of a larger CAR-T process. This guide presents codes and examples that may be helpful when submitting CARVYKTI® claims for the inpatient hospital and outpatient sites of care. As with all CAR-T cell therapies, coding and billing for CARVYKTI® will vary based on individual circumstances, including services provided, payer requirements, site of care, and patient's condition.

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all CPT®* and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Johnson & Johnson that these codes will be appropriate or that reimbursement will be made. This document is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. We strongly recommend you consult the payer organization for its reimbursement policies.

Each button is clickable and will jump to specific sections.

CAR-T=chimeric antigen receptor-T cell; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System.

*CPT® is a registered trademark of the American Medical Association, 2023.

Please see **Important Safety Information** and read full **Prescribing Information**, including Boxed Warning, for CARVYKTI®.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

Coverage for CARVYKTI® (ciltacabtagene autoleucel)

Third-party payers (eg, commercial insurers, Medicare, Medicaid) may cover CARVYKTI® for its approved FDA indication, when administered in an authorized site of care, under the patient's medical benefit. However, coverage may vary depending on the payer and the patient's specific plan.

CMS issued an NCD for CAR-T cell therapy (NCD 110.24).[2] CMS covers autologous treatment for cancer with T cells expressing at least one CAR when administered in healthcare facilities included in the FDA's REMS system and used for a medically accepted indication.[2]

CARVYKTI® Coverage Summary

Site of Care	Medicare Part A	Medicare Part B	Commercial Insurance
• Inpatient hospital (acute care)	• IPPS • 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
• HOPD	• N/A	• OPPS • Product and administration services are covered separately	• May be covered under the medical benefit • PA may be required • Product and service typically covered separately • Payer policies may vary
• Physician practice	• N/A	• PFS • Product and administration services are covered separately	• May be covered under the medical benefit • PA may be required • Product and service typically covered separately • Payer policies may vary

Medical Necessity | **Prior Authorization** | **Appeals**

CARVYKTI® can only be administered in Certified Treatment Centers.

CAR=chimeric antigen receptor; CAR-T=chimeric antigen receptor-T cell; CMS=Centers for Medicare and Medicaid Services; DRG=Diagnosis-Related Group; FDA=U.S. Food and Drug Administration; HOPD=hospital outpatient department; IPPS=Inpatient Prospective Payment System; MS-DRG=Medicare Severity Diagnosis-Related Group; NCD=national coverage determination; OPPS=Outpatient Prospective Payment System; PA=prior authorization; PFS=Physician Fee Schedule; REMS=Risk Evaluation and Mitigation Strategy.

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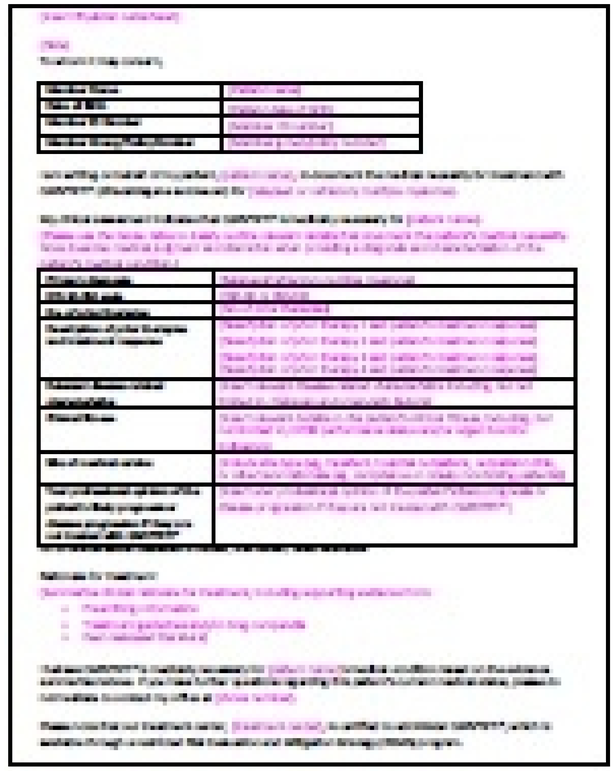
Medical Necessity

Medical necessity refers to healthcare services or supplies needed to diagnose or treat an illness, injury, condition, disease or its symptoms, and that meet accepted standards of medicine. Generally, insurers provide coverage only for health-related services that they define or determine to be medically necessary. Commercial insurers, Medicaid program coverage policies, Medicare NCDs, and Medicare Administrative Contractors' local coverage determinations define medical necessity requirements. These documents contain guidance on covered diagnoses, required documentation, and limitations of coverage for specific medical services or items.

When third-party payers review CARVYKTI® (ciltacabtagene autoleucel) claims, they will first determine if the CAR-T cell therapy is covered under their policies. Next, payers will look for evidence supporting medical necessity, which may include:

- Information about the patient's medical condition and history, including previous therapies/treatments
- Expected outcome(s) of treatment
- A provider's statement/letter of medical necessity
- Supporting literature (eg, peer-reviewed studies and compendia monographs)
- Prescribing Information
- Availability of other treatment alternatives

Some payers may require that treating physicians complete a letter of medical necessity before patients can obtain coverage for CARVYKTI®.



Click here to download the CARVYKTI® Sample Letter of Medical Necessity

CAR-T=chimeric antigen receptor-T cell; NCD=national coverage determination.

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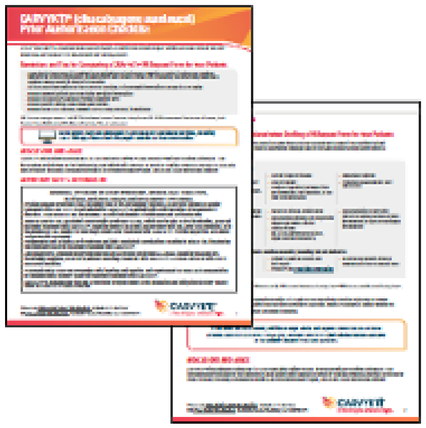
Prior Authorization

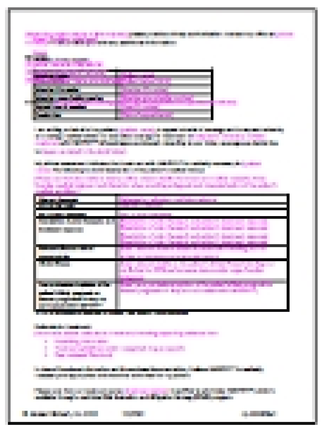
Prior authorization (also referred to as pre-authorization or "pre-auth") is a common payer process that requires providers to substantiate why a therapy or service is medically necessary before coverage will be authorized. CAR-T cell therapy commonly requires PA; however, the requirements and processes can vary by payer. Some payers may handle CAR-T requests through their routine PA process, while others may use a dedicated, therapy-specific approach. When requesting coverage for CARVYKTI® (ciltacabtagene autoleucel), it is essential to review the specific payer policies and adhere to their required steps and timeline. This may include contacting a therapy-specific team, submitting dedicated forms, or engaging directly with a case manager.



Click here to download the CARVYKTI® Prior Authorization Checklist

Appeals

An appeal is any of the procedures used to challenge a payer's denial of benefits that a beneficiary believes they are entitled to receive. If a payer denies an initial request for coverage (ie, issues an adverse or "unfavorable" coverage determination), that decision may be appealed. The payer's notice of denial should include the reason for that decision, as well as instructions for filing an appeal. The appeals process is generally designed with progressive levels, allowing beneficiaries to continue advancing their request if initial efforts are not successful. The appeals process for Medicare Parts A and B includes 5 levels, beginning with redetermination. Although non-Medicare payer policies can vary, most plans also allow multiple levels of appeal.



Click here to download the CARVYKTI® Sample Letter of Appeal

CAR-T=chimeric antigen receptor-T cell; PA=prior authorization.

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Coding Considerations

Correct coding for CARVYKTI® (ciltacabtagene autoleucel) claims depends on the site of care in which it is administered, as well as on individual payer policies. This guide presents code sets and guidelines generally used by payers for both the inpatient and outpatient hospital settings. As individual payer policies may vary, please refer to specific payer requirements when submitting claims for CARVYKTI®.

	Inpatient Hospital	Outpatient Hospital	Physician Office
Diagnosis	ICD-10-CM	ICD-10-CM	ICD-10-CM
CARVYKTI®	NDC* HCPCS code* Revenue codes ICD-10-PCS	NDC* HCPCS code JW and JZ modifiers Revenue codes 340B modifiers CAR-T specific modifiers	HCPCS code CAR-T specific modifiers JW and JZ modifiers NDC*
Procedure and Services	Revenue codes	Revenue codes CPT® codes	CPT® codes

CARVYKTI® can only be administered in Certified Treatment Centers.

CAR-T=chimeric antigen receptor-T cell; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; ICD-10-PCS=International Classification of Diseases, 10th Revision, Procedure Coding System; NDC=National Drug Codes.

*As required by payer.

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Inpatient Hospital

When provided in the inpatient hospital setting, CARVYKTI® (ciltacabtagene autoleucel) and its administration are not paid separately but rather are included in a bundled payment amount that covers the inpatient stay. Medicare has assigned CAR-T cell therapies to MS-DRG 018 for payment under IPPS. Other payers commonly use a DRG-based grouping methodology, but coding requirements and payment methods may vary. The types of code sets commonly required for billing CARVYKTI® provided in the inpatient hospital setting include:

- Diagnosis Codes: ICD-10-CM
- Procedure Codes: ICD-10-PCS
- Revenue Codes

Outpatient Hospital

When provided in the outpatient hospital setting, CARVYKTI® and its administration may be paid separately. Medicare has assigned CAR-T cell therapy administration to APC 5694 for payment under OPPS. Other payers, including managed Medicare plans (Medicare Advantage) will typically pay for the product and service separately; however, coding requirements and payment methodologies may vary. Code types commonly required for billing CARVYKTI® provided in the outpatient hospital setting include:

- Diagnosis Codes: ICD-10-CM
- HCPCS Code
- CPT® Codes
- NDCs
- Revenue Codes
- Modifiers

Physician Office

When provided in the physician office setting, and billed on professional claims, CARVYKTI® and its administration service will typically be paid separately. Coding requirements and payment methodologies may vary. Code types commonly required for billing CARVYKTI® provided in the physician office setting include:

- Diagnosis Codes: ICD-10-CM
- HCPCS Code
- CPT Codes
- NDCs
- Modifiers

CARVYKTI® can only be administered in Certified Treatment Centers.

APC=Ambulatory Payment Classification; CAR-T=chimeric antigen receptor-T cell; CPT=Current Procedural Terminology; DRG=Diagnosis-Related Group; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; ICD-10-PCS=International Classification of Diseases, 10th Revision, Procedure Coding System; IPPS=Inpatient Prospective Payment System; MS-DRG=Medicare Severity Diagnosis-Related Group; NDC=National Drug Codes; OPPS=Outpatient Prospective Payment System.

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Diagnosis Codes: ICD-10-CM

- These codes use 3 to 7 alpha and numeric characters for highest level of specificity[3]
- Payer requirements for ICD-10-CM codes will vary. It is essential to verify the correct diagnosis coding with each payer. The codes below are provided for your consideration when prescribing CARVYKTI® (ciltacabtagene autoleucel)

ICD-10-CM Diagnosis Codes for Consideration*

Code[4]	Description[4]
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
Z51.12	Encounter for antineoplastic immunotherapy

FDA=U.S. Food and Drug Administration; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

*These codes 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.

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HCPCS Code

- Effective October 1, 2022, CARVYKTI® (ciltacabtagene autoleucel) has been assigned a unique Q-code for use in all sites of care and by all payers

HCPCS Level II Product Code[5]

Site of Care	HCPCS Code	Description	Requirement
Physician office Outpatient hospital Inpatient hospital*	**Q2056**	Ciltacabtagene autoleucel, up to 100 million autologous BCMA-directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose	• For all payers and sites of care

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage for any specific service by the Medicare and/or Medicaid program. HCPCS codes are used to describe a product, procedure, or service on an insurance claim. Payers such as Medicare Administrative Contractors and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage, and what payment rules are to be applied to such claims.

*While HCPCS codes are not typically required for hospital inpatient claims, some payers may require HCPCS codes when reporting CAR-T cell therapy. Please refer to specific payer policy.

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BCMA=B-cell maturation antigen; CAR=chimeric antigen receptor; CAR-T=chimeric antigen receptor-T cell; HCPCS=Healthcare Common Procedure Coding System.

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340B Modifiers

- When CARVYKTI® (ciltacabtagene autoleucel) is acquired via the 340B Drug Pricing Program Discount, Medicare requires reporting an appropriate modifier on outpatient hospital facility claims
- JG and TB modifiers are informational and do not influence payment
- Modifier selection depends on the entity type and the drug's status indicator

Reporting 340B Modifiers[6]

Modifier	Description	Indication and Placement
JG	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes	• Must be reported by hospitals (except for rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes only • To be reported on the same claim line as the drug HCPCS code for all 340B-acquired drugs
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities	• Must be reported by hospitals designated as "select entities" (rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes • Must be reported by all OPPS providers for passthrough drugs (status indicator "G") purchased through the 340B drug discount program • To be reported on the same claim line as the drug HCPCS code for all 340B-acquired drugs

HCPCS=Healthcare Common Procedure Coding System; OPPS=Outpatient Prospective Payment System; PPS=Prospective Payment System.

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JW and JZ Modifiers

- The JW and JZ modifier policy applies to all providers and suppliers who buy and bill separately payable drugs under Medicare Part B[7]
- Medicare requires reporting the JW and JZ modifiers on claims from the physician's office and hospital outpatient settings[7]

Reporting JW and JZ Modifiers

Modifier[7]	Description[7]	Indication and Placement[8]
JW	Drug amount discarded/not administered to any patient	• Unused drug remains after applicable dose is administered from single-use vial • Append the modifier to the HCPCS drug code on a line separate from the administered dose and document the administered and discarded amounts in the medical record
JZ	No discarded drug amounts	• Applies to single-dose drug containers or packages to confirm that there are no amounts of drugs or biologicals that were unused and discarded • Append the modifier to the HCPCS drug code on the claim line with the administered amount

CARVYKTI® can only be administered in Certified Treatment Centers.

HCPCS=Healthcare Common Procedure Coding System.

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NDC

- The NDC is required on Medicare claims for dual-eligible beneficiaries, for Medicaid rebates[9], and by some private payers[10]
- The FDA registers NDCs using a 10-digit format, but billing typically requires an 11-digit format, created by adding a leading zero to the middle sequence
- The requirements for reporting NDCs on medical claims may vary, but typically payers will require the 11-digit format, the NDC qualifier, the NDC unit of measure, and the quantity

CARVYKTI® (ciltacabtagene autoleucel) NDC

FDA-Specified 10-Digit NDC[1] (5-3-2 format)	11-Digit NDC (5-4-2 format)	Description[1]	Quantity	NDC Qualifier	NDC Unit of Measure	NDC Qualifier
57894-111-01	**57894-0111-01**	70-mL infusion bag, containing a frozen suspension of genetically modified autologous T cells	Single dose	N4	UN	1
57894-111-02	**57894-0111-02**	30-mL infusion bag, containing a frozen suspension of genetically modified autologous T cells				

FDA=U.S. Food and Drug Administration; NDC=National Drug Codes.

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ICD-10-PCS

- The ICD-10-PCS is a procedure classification system used to report procedures performed in inpatient hospital healthcare settings. New technology (section X) codes fully represent the specific procedure described in the code title and do not require additional codes from other sections of ICD-10-PCS[11]
- The following ICD-10-PCS codes may be reported for inpatient facility services associated with CARVYKTI® (ciltacabtagene autoleucel) administration

ICD-10-PCS Codes

ICD-10-PCS Code[12]	Description[12]	Implications for FY 2024 Medicare IPPS
XW033A7	Introduction of Ciltacabtagene Autoleucel into **Peripheral** vein, Percutaneous Approach, New Technology Group 7	• Assigned to MS-DRG 018 (CAR-T cell and other immunotherapies)[13] • Effective October 1, 2023, CARVYKTI® is no longer eligible for an NTAP[13]
XW043A7	Introduction of Ciltacabtagene Autoleucel into **Central** vein, Percutaneous Approach, New Technology Group 7	

CAR-T=chimeric antigen receptor-T cell; FY=fiscal year; ICD-10-PCS=International Classification of Diseases, 10th Revision, Procedure Coding System; IPPS=Inpatient Prospective Payment System; MS-DRG=Medicare Severity Diagnosis-Related Group; NTAP=new technology add-on payment.

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Revenue Codes

- Medicare and other payers require revenue codes to bill for inpatient and outpatient hospital products and services
- Revenue codes assign costs to broad categories of hospital revenue centers
- For Medicare, the following revenue codes are required for billing inpatient and outpatient hospital CAR-T cell therapy services

Revenue Codes

Revenue Code[14]	Description	Medicare*	Non-Medicare Payers†
0871	Cell Collection	• Do not report charges twice • Charges for cell collection, processing, and storage may be reported under separate revenue codes (0871, 0872, and 0873), for tracking purposes only • Alternatively, charges may be reported as a single line item, with the product charge, under 0891	• Requirements for revenue code reporting may vary by payer. Please refer to local payer policies
0872	Specialized Biologic Processing and Storage—Prior to Transport		
0873	Storage and Processing After Receipt of Cells From Manufacturer		
0874	Infusion of Modified Cells		
0891	Special Processed Drugs—FDA-Approved Cell Therapy		

CAR-T=chimeric antigen receptor-T cell; FDA=U.S. Food and Drug Administration.
*Medicare fee-for-service; billing requirements for Medicare Advantage may vary by payer.
†Alternative revenue codes may apply.

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CPT® Codes

- Medicare requires specific procedure codes for billing outpatient CAR-T cell therapy services

CPT® Category III Codes

CPT® Category III Code[14]	Descriptor[15]	CY 2024 Payment Status Under Medicare OPPS*	Corresponding Hospital Revenue Code[17]
Preparation			
0537T	CAR-T therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day	Not paid under OPPS[16]	**0871**
0538T	CAR-T therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)		**0872**
0539T	CAR-T therapy; receipt and preparation of CAR-T cells for administration		**0873**
Administration			
0540T	CAR-T therapy; CAR-T cell administration, autologous	Paid under APC 5694[16]	**0874**

APC=Ambulatory Payment Classification; CAR-T=chimeric antigen receptor-T cell; CPT=Current Procedural Terminology; CY=calendar year; OPPS=Outpatient Prospective Payment System.

*Non-Medicare payer requirements may vary. Please refer to local payer policies for coding requirements and payment information.

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CAR-T Specific Modifiers

- Medicare only covers CAR-T cell therapy if it is administered at a healthcare facility that is enrolled as a REMS-participating site
- The KX modifier, used on CAR-T cell therapy claims, indicates the service is provided by or in an FDA REMS-approved facility
- For professional claims involving CARVYKTI® (ciltacabtagene autoleucel), additional modifiers are required, as detailed in the following chart

Modifiers[17]

Modifier	Description	Significance	Requirements and Placement
KX	Requirements specified in the medical policy have been met	Acknowledges that the CAR-T cell administration service was performed in an FDA REMS-approved facility	• Required on claims submitted by hospital outpatient facilities (CMS-1450) and Part B professional claims (CMS-1500) • Reported on the same claim line as the CAR-T code (Q2056)
LU	Fractionated payment of CAR-T therapy	Informs the MAC that the service is fractionated, allowing submission of multiple claims for CAR-T cell products on the same date of service	• Required on Part B professional claims (CMS-1500) • Providers will need to bill a total of 10 fractional units (0.1 each) to reach the total Medicare-allowed payment amount • The total fractional units shall not exceed 1 unit • Must be reported in addition to KX • Reported on the same claim line as the CAR-T code (Q2056)
76	Repeat procedure or service by same physician or other qualified healthcare professional	For subsequent claims billed on the same date of service, assists with preventing duplicate denials	• Applies to Part B professional claims (CMS-1500) • Reported on subsequent claims in addition to KX and LU • Reported on the same claim line as the CAR-T code (Q2056)

CAR-T=chimeric antigen receptor-T cell; CMS=Centers for Medicare and Medicaid Services; FDA=U.S. Food and Drug Administration; MAC=Medicare Administrative Contractor; REMS=risk evaluation and mitigation strategy.

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The CMS-1450 (UB-04) Claim Form

The Form CMS-1450, also known as the UB-04, is a uniform institutional provider bill suitable for use in billing multiple third-party payers. It is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from hospitals, including HOPDs. Because it serves many payers, a particular payer may not need some data elements. For detailed guidance on completing the CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 25, available at **CMS.gov**

Electronic Healthcare Claims (CMS-1450)

The 837I (Institutional) is the standard format used by institutional providers to transmit healthcare claims electronically. The ANSI ASC X12N 837I (Institutional) Version 5010A2 is the current electronic claim version. Data elements in the uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837I and the CMS-1450 on their websites. For more information on electronic claims, please see the CMS website at **CMS.gov**

The CMS-1500 Claim Form

The Form CMS-1500 is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims from suppliers and non-institutional providers that qualify for a waiver from the Administrative Simplification Compliance Act requirement for electronic submission of claims. It has also been adopted by the TRICARE Program. For detailed guidance on completing the CMS-1500 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at **CMS.gov**

Electronic Healthcare Claims (CMS-1500)

The 837P (Professional) is the standard format used by healthcare providers and suppliers to transmit healthcare claims electronically. The ANSI ASC X12N 837P (Professional) Version 5010A1 is the current electronic claim version. Data elements in the CMS uniform electronic billing specifications are consistent with the hard copy data set to the extent that one processing system can handle both. Medicare Administrative Contractors may include a crosswalk between the ASC X12N 837P and the CMS-1500 on their websites. For more information on electronic claims, please see the CMS website at **CMS.gov**

Sample CMS-1450 Claim Form (Inpatient)

Sample CMS-1450 Claim Form (Outpatient)

Sample CMS-1500 Claim Form

ANSI=American National Standards Institute; ASC=Accredited Standards Committee; CMS=Centers for Medicare and Medicaid Services; HOPD=hospital outpatient department.

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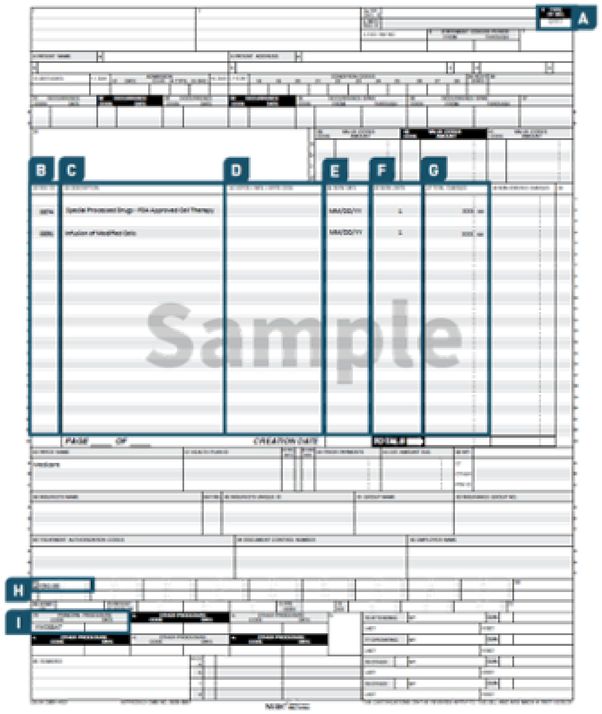
Sample CMS-1450 (UB-04) Claim Form for Inpatient Hospital Facilities



The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage for any specific service by the Medicare and/or Medicaid program. HCPCS codes are used to describe a product, procedure, or service on an insurance claim. Payers such as Medicare Administrative Contractors and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage and what payment rules are to be applied to such claims.

A **FL 4:** Enter code for type of bill:
- **0111** for inpatient hospital

B **FL 42:** List revenue codes in ascending order for each reported line:
- Medicare: **0874** for CARVYKTI® (ciltacabtagene autoleucel) and **0891** for CAR-T infusion
- Non-Medicare payer requirements for revenue codes may vary

C **FL 43:** Enter narrative description for corresponding revenue codes.
Note: Some payers may require reporting the NDC in FL 43; reporting requirements may vary.

D **FL 44:** Medicare does not require HCPCS codes on inpatient claims. If required by a non-Medicare payer, enter relevant HCPCS and CPT® codes, along with any applicable modifiers:
- CARVYKTI® — **Q2056**
- CAR-T infusion — **0540T** or as required by payer

E **FL 45:** Enter the corresponding dates of service.

F **FL 46:** Enter the units of service:
- CARVYKTI® — report **1 unit**
- CAR-T infusion — report **1 unit**

G **FL 47:** Enter total charges for each reported line.
*Note: Do not report charges twice. Charges for cell collection, processing, and storage may be reported under separate revenue codes (**0871**, **0872**, and **0873**), for tracking purposes only. Alternatively, charges may be reported as a single line item, with product charge, under 0891.*

H **FL 66:** Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter diagnoses in priority order:
- For example: **C90.00** – Multiple myeloma not having achieved remission

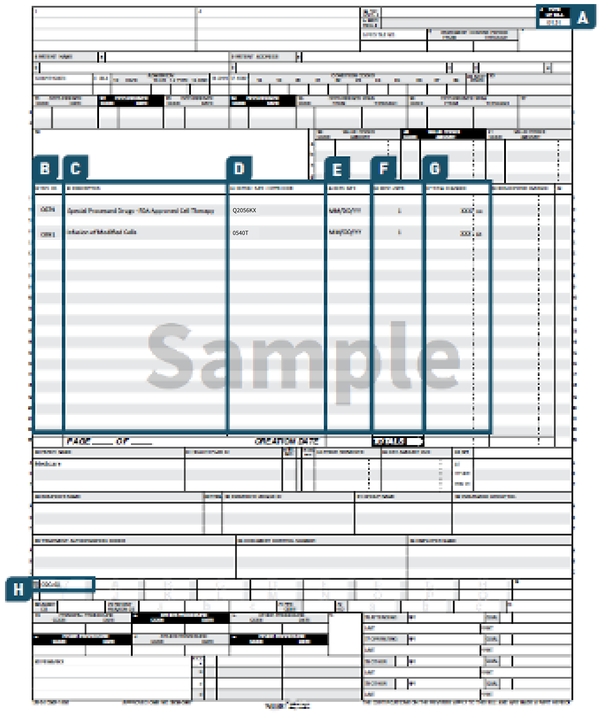
I **FL 74:** Enter relevant ICD-10-PCS procedure codes with corresponding dates of service:
- **XW033A7** – Introduction of Ciltacabtagene Autoleucel into Peripheral Vein, Percutaneous Approach, New Technology Group 7
- **XW043A7** – Introduction of Ciltacabtagene Autoleucel into Central Vein, Percutaneous Approach, New Technology Group 7

CAR-T=chimeric antigen receptor-T cell; CMS=Centers for Medicare and Medicaid Services; CPT=Current Procedural Terminology; FL=form locator; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; ICD-10-PCS=International Classification of Diseases, 10th Revision, Procedure Coding System; NDC=National Drug Code.

Please see **Important Safety Information** and read full **Prescribing Information**, including Boxed Warning, for CARVYKTI®.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

Sample CMS-1450 (UB-04) Claim Form for Outpatient Hospital Facilities



The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage for any specific service by the Medicare and/or Medicaid program. HCPCS codes are used to describe a product, procedure, or service on an insurance claim. Payers such as Medicare Administrative Contractors and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage and what payment rules are to be applied to such claims.

A **FL 4:** Enter code for type of bill:
- **0131** for outpatient hospital

B **FL 42:** List revenue codes in ascending order for each reported line:
- Medicare: **0874** for CARVYKTI® (ciltacabtagene autoleucel) and **0891** for CAR-T infusion
- Non-Medicare payer requirements for revenue codes may vary

C **FL 43:** Enter narrative description for corresponding revenue codes.
Note: Some payers may require reporting the NDC in FL 43; reporting requirements may vary.

D **FL 44:** Enter relevant HCPCS Level II and CPT® codes along with any applicable modifiers:
- CARVYKTI® — **Q2056**
- CAR-T infusion
  - — Medicare: **0540T**
  - — Non-Medicare — 0540T or as required by payer

E **FL 45:** Enter the corresponding dates of service.

F **FL 46:** Enter the units of service:
- CARVYKTI® — report **1 unit**
- CAR-T infusion — report **1 unit**

G **FL 47:** Enter total charges for each reported line.

H **FL 66:** Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter diagnoses in priority order.
- For example: **C90.02** – Multiple myeloma in relapse

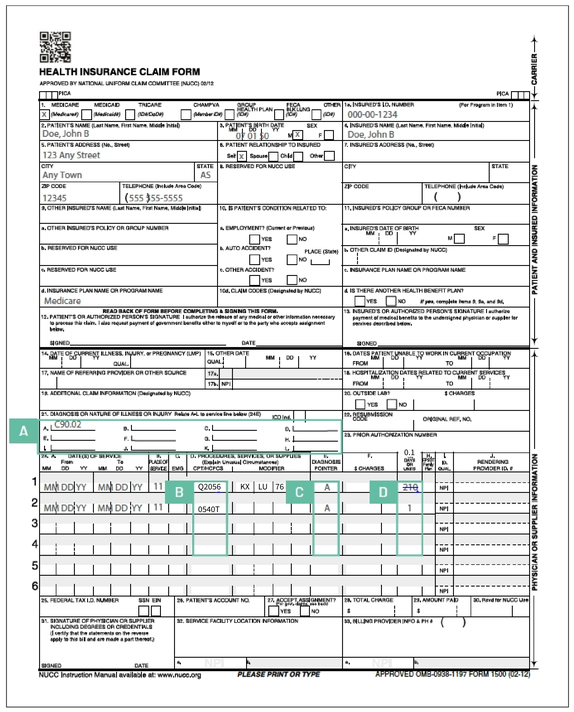
CAR-T=chimeric antigen receptor-T cell; CMS=Centers for Medicare and Medicaid Services; CPT=Current Procedural Terminology; FL=form locator; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

Please see **Important Safety Information** and read full **Prescribing Information**, including Boxed Warning, for CARVYKTI®.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

Sample CMS-1500 Claim Form for Physician Offices

Claim #2 of 10 for same date-of-service



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE (Medicare#) X | MEDICAID (Medicaid#) | TRICARE (ID#/DoD#) | CHAMPVA (Member ID#) | GROUP HEALTH PLAN (ID#) | FECA BLK LUNG (ID#) | OTHER (ID#)
1a. INSURED'S I.D. NUMBER: 000-00-1234 (For Program in Item 1)
2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, John B
3. PATIENT'S BIRTH DATE: 01 01 50 SEX: M X F
4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, John B
5. PATIENT'S ADDRESS (No., Street): 123 Any Street
6. PATIENT RELATIONSHIP TO INSURED: Self X Spouse Child Other
7. INSURED'S ADDRESS (No., Street):
CITY: Any Town STATE: AS
8. RESERVED FOR NUCC USE
CITY: STATE:
ZIP CODE: 12345 TELEPHONE (Include Area Code): (555)555-5555
ZIP CODE: TELEPHONE (Include Area Code): ( )
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial):
10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) YES NO; b. AUTO ACCIDENT? YES NO PLACE (State); c. OTHER ACCIDENT? YES NO
11. INSURED'S POLICY GROUP OR FECA NUMBER
a. OTHER INSURED'S POLICY OR GROUP NUMBER
b. RESERVED FOR NUCC USE
c. RESERVED FOR NUCC USE
d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare
10d. CLAIM CODES (Designated by NUCC)
a. INSURED'S DATE OF BIRTH MM DD YY; SEX M F
b. OTHER CLAIM ID (Designated by NUCC)
c. INSURANCE PLAN NAME OR PROGRAM NAME
d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below. SIGNED DATE
13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize payment of medical benefits to the undersigned physician or supplier for services described below. SIGNED
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL
15. OTHER DATE MM DD YY QUAL
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a 17b NPI
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
20. OUTSIDE LAB? YES NO $ CHARGES
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. Relate A-L to service line below (24E) ICD Ind.
A. C90.02 B. C. D. E. F. G. H. I. J. K. L.
22. RESUBMISSION CODE ORIGINAL REF. NO.
23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 MM DD YY	MM DD YY	11		B Q2056	KX LU 76	C A	D 210			NPI	
2 MM DD YY	MM DD YY	11		0540T		A	1			NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN
26. PATIENT'S ACCOUNT NO.
27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO
28. TOTAL CHARGE $
29. AMOUNT PAID $
30. Rsvd for NUCC Use
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) SIGNED DATE
32. SERVICE FACILITY LOCATION INFORMATION
33. BILLING PROVIDER INFO & PH # ( )
a. NPI b. a. NPI b.

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER | PATIENT AND INSURED INFORMATION | PHYSICIAN OR SUPPLIER INFORMATION

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage for any specific service by the Medicare and/or Medicaid program. HCPCS codes are used to describe a product, procedure, or service on an insurance claim. Payers such as Medicare Administrative Contractors and/or state Medicaid programs use HCPCS codes in conjunction with other information to determine whether a drug, device, procedure, or other service meets all program requirements for coverage and what payment rules are to be applied to such claims.

A **Item 21:** Indicate diagnoses using appropriate ICD-10-CM Codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.

B **Item 24D:** Indicate appropriate CPT®, HCPCS codes and applicable modifiers.

- **CARVYKTI® (ciltacabtagene autoleucel)– Q2056** plus modifiers: **KX, LU, and 76** (note: KX and LU must appear on each claim; 76 is required on claims #2-10[17])
- **CARVYKTI® Administration**
  - — Medicare – **0540T**
  - — Non-Medicare – 0540T or as required by payer

C **Item 24E:** Refer to the diagnosis for this service (see Item 21). Enter only one diagnosis pointer per line.

D **Item 24G:** Enter the units for items/services provided.

- **CARVYKTI®**

  Q2056 – Enter fractional units of 0.1 on 10 successive claims (total, 1 unit), for the same date of service[17]
- **CARVYKTI® Administration**

  0540T – Enter 1 unit

CARVYKTI® can only be administered in Certified Treatment Centers.

CMS=Centers for Medicare and Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

Please see **Important Safety Information** and read full **Prescribing Information**, including Boxed Warning, for CARVYKTI®.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

Indications

INDICATIONS AND USAGE

CARVYKTI® (ciltacabtagene autoleucel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least 1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide.

Please see **Important Safety Information** and read full **Prescribing Information**, including Boxed Warning, for CARVYKTI®.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

Important Safety Information

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, PROLONGED and RECURRENT CYTOPENIA, and SECONDARY HEMATOLOGICAL MALIGNANCIES

Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with CARVYKTI®. Do not administer CARVYKTI® to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), which may be fatal or life-threatening, occurred following treatment with CARVYKTI®, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with CARVYKTI®. Provide supportive care and/or corticosteroids as needed.

Parkinsonism and Guillain-Barré syndrome (GBS) and their associated complications resulting in fatal or life-threatening reactions have occurred following treatment with CARVYKTI®.

Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), including fatal and life-threatening reactions, occurred in patients following treatment with CARVYKTI®. HLH/MAS can occur with CRS or neurologic toxicities.

Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery occurred following treatment with CARVYKTI®.

Secondary hematological malignancies, including myelodysplastic syndrome and acute myeloid leukemia, have occurred in patients following treatment with CARVYKTI®. T-cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies, including CARVYKTI®.

CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS Program.

Please see **Important Safety Information** and read full **Prescribing Information**, including Boxed Warning, for CARVYKTI®.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

Increased early mortality - In CARTITUDE-4, a (1:1) randomized controlled trial, there was a numerically higher percentage of early deaths in patients randomized to the CARVYKTI® treatment arm compared to the control arm. Among patients with deaths occurring within the first 10 months from randomization, a greater proportion (29/208; 14%) occurred in the CARVYKTI® arm compared to (25/211; 12%) in the control arm. Of the 29 deaths that occurred in the CARVYKTI® arm within the first 10 months of randomization, 10 deaths occurred prior to CARVYKTI® infusion, and 19 deaths occurred after CARVYKTI® infusion. Of the 10 deaths that occurred prior to CARVYKTI® infusion, all occurred due to disease progression, and none occurred due to adverse events. Of the 19 deaths that occurred after CARVYKTI® infusion, 3 occurred due to disease progression, and 16 occurred due to adverse events. The most common adverse events were due to infection (n=12).

Cytokine release syndrome (CRS), including fatal or life-threatening reactions, occurred following treatment with CARVYKTI®. Among patients receiving CARVYKTI® for RRMM in the CARTITUDE-1 & 4 studies (N=285), CRS occurred in 84% (238/285), including ≥Grade 3 CRS (ASTCT 2019) in 4% (11/285) of patients. Median time to onset of CRS, any grade, was 7 days (range: 1 to 23 days). CRS resolved in 82% with a median duration of 4 days (range: 1 to 97 days). The most common manifestations of CRS in all patients combined (≥10%) included fever (84%), hypotension (29%) and aspartate aminotransferase increased (11%). Serious events that may be associated with CRS include pyrexia, hemophagocytic lymphohistiocytosis, respiratory failure, disseminated intravascular coagulation, capillary leak syndrome, and supraventricular and ventricular tachycardia. CRS occurred in 78% of patients in CARTITUDE-4 (3% Grade 3 to 4) and in 95% of patients in CARTITUDE-1 (4% Grade 3 to 4).

Identify CRS based on clinical presentation. Evaluate for and treat other causes of fever, hypoxia, and hypotension. CRS has been reported to be associated with findings of HLH/MAS, and the physiology of the syndromes may overlap. HLH/MAS is a potentially life-threatening condition. In patients with progressive symptoms of CRS or refractory CRS despite treatment, evaluate for evidence of HLH/MAS.

Ensure that a minimum of two doses of tocilizumab are available prior to infusion of CARVYKTI®.

Of the 285 patients who received CARVYKTI® in clinical trials, 53% (150/285) patients received tocilizumab; 35% (100/285) received a single dose, while 18% (50/285) received more than 1 dose of tocilizumab. Overall, 14% (39/285) of patients received at least one dose of corticosteroids for treatment of CRS.

Monitor patients at least daily for 10 days following CARVYKTI® infusion at a REMS-certified healthcare facility for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for at least 4 weeks after infusion. At the first sign of CRS, immediately institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids.

Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time.

Please see **Important Safety Information** and read full **Prescribing Information**, including Boxed Warning, for CARVYKTI®.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Neurologic toxicities, which may be severe, life-threatening, or fatal, occurred following treatment with CARVYKTI®. Neurologic toxicities included ICANS, neurologic toxicity with signs and symptoms of parkinsonism, GBS, immune mediated myelitis, peripheral neuropathies, and cranial nerve palsies. Counsel patients on the signs and symptoms of these neurologic toxicities, and on the delayed nature of onset of some of these toxicities. Instruct patients to seek immediate medical attention for further assessment and management if signs or symptoms of any of these neurologic toxicities occur at any time.

Among patients receiving CARVYKTI® in the CARTITUDE-1 & 4 studies for RRMM, one or more neurologic toxicities occurred in 24% (69/285), including ≥Grade 3 cases in 7% (19/285) of patients. Median time to onset was 10 days (range: 1 to 101) with 63/69 (91%) of cases developing by 30 days. Neurologic toxicities resolved in 72% (50/69) of patients with a median duration to resolution of 23 days (range: 1 to 544). Of patients developing neurotoxicity, 96% (66/69) also developed CRS. Subtypes of neurologic toxicities included ICANS in 13%, peripheral neuropathy in 7%, cranial nerve palsy in 7%, parkinsonism in 3%, and immune mediated myelitis in 0.4% of the patients.

Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS): Patients receiving CARVYKTI® may experience fatal or life-threatening ICANS following treatment with CARVYKTI®, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS.

Among patients receiving CARVYKTI® in the CARTITUDE-1 & 4 studies, ICANS occurred in 13% (36/285), including Grade ≥3 in 2% (6/285) of the patients. Median time to onset of ICANS was 8 days (range: 1 to 28 days). ICANS resolved in 30 of 36 (83%) of patients with a median time to resolution of 3 days (range: 1 to 143 days). Median duration of ICANS was 6 days (range: 1 to 1229 days) in all patients including those with ongoing neurologic events at the time of death or data cut off. Of patients with ICANS 97% (35/36) had CRS. The onset of ICANS occurred during CRS in 69% of patients, before and after the onset of CRS in 14% of patients respectively.

Immune Effector Cell-associated Neurotoxicity Syndrome occurred in 7% of patients in CARTITUDE-4 (0.5% Grade 3) and in 23% of patients in CARTITUDE-1 (3% Grade 3). The most frequent ≥2% manifestations of ICANS included encephalopathy (12%), aphasia (4%), headache (3%), motor dysfunction (3%), ataxia (2%) and sleep disorder (2%).

Monitor patients at least daily for 10 days following CARVYKTI® infusion at the REMS-certified healthcare facility for signs and symptoms of ICANS. Rule out other causes of ICANS symptoms. Monitor patients for signs or symptoms of ICANS for at least 4 weeks after infusion and treat promptly. Neurologic toxicity should be managed with supportive care and/or corticosteroids as needed.

Please see **Important Safety Information** and read full **Prescribing Information**, including Boxed Warning, for CARVYKTI®.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Parkinsonism: Neurologic toxicity with parkinsonism has been reported in clinical trials of CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & 4 studies, parkinsonism occurred in 3% (8/285), including Grade ≥ 3 in 2% (5/285) of the patients. Median time to onset of parkinsonism was 56 days (range: 14 to 914 days). Parkinsonism resolved in 1 of 8 (13%) of patients with a median time to resolution of 523 days. Median duration of parkinsonism was 243.5 days (range: 62 to 720 days) in all patients including those with ongoing neurologic events at the time of death or data cut off. The onset of parkinsonism occurred after CRS for all patients and after ICANS for 6 patients.

Parkinsonism occurred in 1% of patients in CARTITUDE-4 (no Grade 3 to 4) and in 6% of patients in CARTITUDE-1 (4% Grade 3 to 4).

Manifestations of parkinsonism included movement disorders, cognitive impairment, and personality changes. Monitor patients for signs and symptoms of parkinsonism that may be delayed in onset and managed with supportive care measures. There is limited efficacy information with medications used for the treatment of Parkinson's disease for the improvement or resolution of parkinsonism symptoms following CARVYKTI® treatment.

Guillain-Barré syndrome: A fatal outcome following GBS occurred following treatment with CARVYKTI® despite treatment with intravenous immunoglobulins. Symptoms reported include those consistent with Miller-Fisher variant of GBS, encephalopathy, motor weakness, speech disturbances, and polyradiculoneuritis.

Monitor for GBS. Evaluate patients presenting with peripheral neuropathy for GBS. Consider treatment of GBS with supportive care measures and in conjunction with immunoglobulins and plasma exchange, depending on severity of GBS.

Immune mediated myelitis: Grade 3 myelitis occurred 25 days following treatment with CARVYKTI® in CARTITUDE-4 in a patient who received CARVYKTI® as subsequent therapy. Symptoms reported included hypoesthesia of the lower extremities and the lower abdomen with impaired sphincter control. Symptoms improved with the use of corticosteroids and intravenous immune globulin. Myelitis was ongoing at the time of death from other cause.

Peripheral neuropathy occurred following treatment with CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & 4 studies, peripheral neuropathy occurred in 7% (21/285), including Grade ≥3 in 1% (3/285) of the patients. Median time to onset of peripheral neuropathy was 57 days (range: 1 to 914 days). Peripheral neuropathy resolved in 11 of 21 (52%) of patients with a median time to resolution of 58 days (range: 1 to 215 days). Median duration of peripheral neuropathy was 149.5 days (range: 1 to 692 days) in all patients including those with ongoing neurologic events at the time of death or data cut off.

Please see **Important Safety Information** and read full **Prescribing Information**, including Boxed Warning, for CARVYKTI®.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Peripheral neuropathies occurred in 7% of patients in CARTITUDE-4 (0.5% Grade 3 to 4) and in 7% of patients in CARTITUDE-1 (2% Grade 3 to 4). Monitor patients for signs and symptoms of peripheral neuropathies. Patients who experience peripheral neuropathy may also experience cranial nerve palsies or GBS.

Cranial nerve palsies occurred following treatment with CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & 4 studies, cranial nerve palsies occurred in 7% (19/285), including Grade ≥3 in 1% (1/285) of the patients. Median time to onset of cranial nerve palsies was 21 days (range: 17 to 101 days). Cranial nerve palsies resolved in 17 of 19 (89%) of patients with a median time to resolution of 66 days (range: 1 to 209 days). Median duration of cranial nerve palsies was 70 days (range: 1 to 262 days) in all patients including those with ongoing neurologic events at the time of death or data cut off. Cranial nerve palsies occurred in 9% of patients in CARTITUDE-4 (1% Grade 3 to 4) and in 3% of patients in CARTITUDE-1 (1% Grade 3 to 4).

The most frequent cranial nerve affected was the 7th cranial nerve. Additionally, cranial nerves III, V, and VI have been reported to be affected.

Monitor patients for signs and symptoms of cranial nerve palsies. Consider management with systemic corticosteroids, depending on the severity and progression of signs and symptoms.

Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS): Among patients receiving CARVYKTI® in the CARTITUDE-1 & 4 studies, HLH/MAS occurred in 1% (3/285) of patients. All events of HLH/MAS had onset within 99 days of receiving CARVYKTI®, with a median onset of 10 days (range: 8 to 99 days) and all occurred in the setting of ongoing or worsening CRS. The manifestations of HLH/MAS included hyperferritinemia, hypotension, hypoxia with diffuse alveolar damage, coagulopathy and hemorrhage, cytopenia and multi-organ dysfunction, including renal dysfunction and respiratory failure.

Patients who develop HLH/MAS have an increased risk of severe bleeding. Monitor hematologic parameters in patients with HLH/MAS and transfuse per institutional guidelines. Fatal cases of HLH/MAS occurred following treatment with CARVYKTI®.

HLH is a life-threatening condition with a high mortality rate if not recognized and treated early. Treatment of HLH/MAS should be administered per institutional standards.

CARVYKTI® REMS: Because of the risk of CRS and neurologic toxicities, CARVYKTI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS.

Further information is available at https://www.carvyktirems.com/ or 1-844-672-0067.

Please see **Important Safety Information** and read full **Prescribing Information**, including Boxed Warning, for CARVYKTI®.

CARVYKTI® (ciltacabtagene autoleucel) Suspension for IV Infusion

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Prolonged and Recurrent Cytopenias: Patients may exhibit prolonged and recurrent cytopenias following lymphodepleting chemotherapy and CARVYKTI® infusion.

Among patients receiving CARVYKTI® in the CARTITUDE-1 & 4 studies, Grade 3 or higher cytopenias not resolved by day 30 following CARVYKTI® infusion occurred in 62% (176/285) of the patients and included thrombocytopenia 33% (94/285), neutropenia 27% (76/285), lymphopenia 24% (67/285) and anemia 2% (6/285). After Day 60 following CARVYKTI® infusion 22%, 20%, 5%, and 6% of patients had a recurrence of Grade 3 or 4 lymphopenia, neutropenia, thrombocytopenia, and anemia respectively, after initial recovery of their Grade 3 or 4 cytopenia. Seventy-seven percent (219/285) of patients had one, two or three or more recurrences of Grade 3 or 4 cytopenias after initial recovery of Grade 3 or 4 cytopenia. Sixteen and 25 patients had Grade 3 or 4 neutropenia and thrombocytopenia, respectively, at the time of death.

Monitor blood counts prior to and after CARVYKTI® infusion. Manage cytopenias with growth factors and blood product transfusion support according to local institutional guidelines.

Infections: CARVYKTI® should not be administered to patients with active infection or inflammatory disorders. Severe, life-threatening, or fatal infections, occurred in patients after CARVYKTI® infusion.

Among patients receiving CARVYKTI® in the CARTITUDE-1 & 4 studies, infections occurred in 57% (163/285), including ≥Grade 3 in 24% (69/285) of patients. Grade 3 or 4 infections with an unspecified pathogen occurred in 12%, viral infections in 6%, bacterial infections in 5%, and fungal infections in 1% of patients. Overall, 5% (13/285) of patients had Grade 5 infections, 2.5% of which were due to COVID-19. Patients treated with CARVYKTI® had an increased rate of fatal COVID-19 infections compared to the standard therapy arm.

Monitor patients for signs and symptoms of infection before and after CARVYKTI® infusion and treat patients appropriately. Administer prophylactic, pre-emptive and/or therapeutic antimicrobials according to the standard institutional guidelines. Febrile neutropenia was observed in 5% of patients after CARVYKTI® infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids and other supportive care, as medically indicated. Counsel patients on the importance of prevention measures. Follow institutional guidelines for the vaccination and management of immunocompromised patients with COVID-19.

Viral Reactivation: Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure and death, can occur in patients with hypogammaglobulinemia. Perform screening for Cytomegalovirus (CMV), HBV, hepatitis C virus (HCV), and human immunodeficiency virus (HIV) or any other infectious agents if clinically indicated in accordance with clinical guidelines before collection of cells for manufacturing. Consider antiviral therapy to prevent viral reactivation per local institutional guidelines/clinical practice.

Please see **Important Safety Information** and read full **Prescribing Information**, including Boxed Warning, for CARVYKTI®.

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Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypogammaglobulinemia: can occur in patients receiving treatment with CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & 4 studies, hypogammaglobulinemia adverse event was reported in 36% (102/285) of patients; laboratory IgG levels fell below 500mg/dl after infusion in 93% (265/285) of patients. Hypogammaglobulinemia either as an adverse reaction or laboratory IgG level below 500mg/dl, after infusion occurred in 94% (267/285) of patients treated. Fifty six percent (161/285) of patients received intravenous immunoglobulin (IVIG) post CARVYKTI® for either an adverse reaction or prophylaxis.

Monitor immunoglobulin levels after treatment with CARVYKTI® and administer IVIG for IgG <400 mg/dL. Manage per local institutional guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

Use of Live Vaccines: The safety of immunization with live viral vaccines during or following CARVYKTI® treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during CARVYKTI® treatment, and until immune recovery following treatment with CARVYKTI®.

Hypersensitivity Reactions occurred following treatment with CARVYKTI®. Among patients receiving CARVYKTI® in the CARTITUDE-1 & 4 studies, hypersensitivity reactions occurred in 5% (13/285), all of which were ≤Grade 2. Manifestations of hypersensitivity reactions included flushing, chest discomfort, tachycardia, wheezing, tremor, burning sensation, non-cardiac chest pain, and pyrexia.

Serious hypersensitivity reactions, including anaphylaxis, may be due to the dimethyl sulfoxide (DMSO) in CARVYKTI®. Patients should be carefully monitored for 2 hours after infusion for signs and symptoms of severe reaction. Treat promptly and manage patients appropriately according to the severity of the hypersensitivity reaction.

Secondary Malignancies: Patients treated with CARVYKTI® may develop secondary malignancies. Among patients receiving CARVYKTI® in the CARTITUDE-1 & 4 studies, myeloid neoplasms occurred in 5% (13/285) of patients (9 cases of myelodysplastic syndrome, 3 cases of acute myeloid leukemia, and 1 case of myelodysplastic syndrome followed by acute myeloid leukemia). The median time to onset of myeloid neoplasms was 447 days (range: 56 to 870 days) after treatment with CARVYKTI®. Ten of these 13 patients died following the development of myeloid neoplasms; 2 of the 13 cases of myeloid neoplasm occurred after initiation of subsequent antimyeloma therapy. Cases of myelodysplastic syndrome and acute myeloid leukemia have also been reported in the post marketing setting. T-cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies, including CARVYKTI®. Mature T-cell malignancies, including CAR-positive tumors, may present as soon as weeks following infusions, and may include fatal outcomes.

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Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Secondary Malignancies (cont'd)**:** Monitor life-long for secondary malignancies. In the event that a secondary malignancy occurs, contact Janssen Biotech, Inc. at 1-800-526-7736 for reporting and to obtain instructions on collection of patient samples.

Effects on Ability to Drive and Use Machines: Due to the potential for neurologic events, including altered mental status, seizures, neurocognitive decline or neuropathy, patients receiving CARVYKTI® are at risk for altered or decreased consciousness or coordination in the 8 weeks following CARVYKTI® infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery during this initial period, and in the event of new onset of any neurologic toxicities.

ADVERSE REACTIONS

The most common nonlaboratory adverse reactions (incidence greater than 20%) are pyrexia, cytokine release syndrome, hypogammaglobulinemia, hypotension, musculoskeletal pain, fatigue, infections-pathogen unspecified, cough, chills, diarrhea, nausea, encephalopathy, decreased appetite, upper respiratory tract infection, headache, tachycardia, dizziness, dyspnea, edema, viral infections, coagulopathy, constipation, and vomiting. The most common Grade 3 or 4 laboratory adverse reactions (incidence greater than or equal to 50%) include lymphopenia, neutropenia, white blood cell decreased, thrombocytopenia, and anemia.

Please read full Prescribing Information, including Boxed Warning, for CARVYKTI®.

cp-258862v9

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