ASTCT®
American Society for
Transplantation and Cellular Therapy

ASTCT **CAR-T THERAPY CODING** AND **BILLING** GUIDE

Last updated July 2026.

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INTRODUCTION

Chimeric Antigen Receptor T-cell therapy (CAR-T) is a type of immune effector cell therapy which represents an advancement in the treatment of certain hematologic malignancies. The currently approved CAR-T therapy products are personalized, autologous therapies, which involve steps of cell collection, processing and administration to a patient. Many potential future iterations of CAR-T are under clinical trial, including allogeneic products and those used to treat solid tumors or immune system disorders. The novel nature of CAR-T therapies means that providers have many questions about appropriate coding and billing for hospital inpatients and outpatients.

Scope of This Guide

The American Society for Transplantation and Cellular Therapy (ASTCT) has made this guide available to provide a comprehensive review of accurate and complete coverage and coding information for CAR-T cell therapy and its related ancillary services. The guide addresses U.S. Food and Drug Administration (FDA) approved commercial products, as well as products administered as part of a clinical trial or expanded access program (EAP). It also provides some hospital billing guidance and aims to clarify the major billing differences and considerations between government and private payers. The guide does not address the specific Medicare billing requirements for administration of CAR-T in free-standing physician practices. Providers remain responsible for confirming eligibility and coverage with each prospective patient's payer, and for checking payer-specific policies for information on prior authorization, coding, and billing. This guide also does not address non-CAR-T cell immune effector cell immunotherapies, such as Tumor Infiltrating Lymphocytes (TILs), T-cell Receptor (TCR) therapies, or other types of cell and gene therapies, such as autologous stem-based gene therapies. Providers should refer to a product's own coding and billing guide for information on coding and billing for non-CAR-T cell therapies.

This guide is based on the standardized electronic transaction and code set standards adopted under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 Administrative Simplification Act provisions. HIPAA covered entities – including health plans, health care clearinghouses, and health care providers that conduct covered electronic transactions are required to comply with these standards.

This guide was developed and is maintained by Nimitt Consulting, Inc. on behalf of the American Society for Transplantation and Cellular Therapy (ASTCT) (2020–Present).

> *The American Society for Transplantation and Cellular Therapy (ASTCT) Government Relations Committee has made this guide available to provide a comprehensive review of accurate and complete coding and billing for CAR-T cell therapy and its related ancillary services for hospitals, regardless of the product used.*

HOSPITAL CONSIDERATIONS REGARDING CAR-T PATIENT STATUS

Confirming the status of the patient (inpatient or outpatient) at each step in the CAR-T episode of care is key to understanding coverage, coding, and billing of CAR-T services.

The inpatient or outpatient status of a hospital patient is critically important, since it determines the code sets used to report CAR-T services, hospital claim requirements, and, ultimately, reimbursement.

Medicare's Definition of Patient Status

A hospital "inpatient" is defined by Medicare as a patient who is expected to require at least two midnights of medically necessary hospital care or a one-night hospital stay when the medical record supports the need for inpatient-level care.

Determining that a patient requires an inpatient level of hospital care involves complex medical decision-making. An inpatient admission to the hospital requires a clinician's order for admission. While Medicare generally considers an inpatient admission to be appropriate when a patient is expected to need two or more nights of medically necessary hospital care[1], commercial payers may certify or pre-authorize an inpatient stay or outpatient services. Commercial payers often rely upon proprietary tools, such as Milliman or InterQual®, to determine if the severity of illness and intensity of services supports an inpatient admission.

A hospital "outpatient" is defined by Medicare as a patient who needs hospital-level care, but who is not expected to require either overnight or two nights of hospital-level care.

These patients can receive diagnostic and therapeutic services, including observation services, can remain in the hospital overnight, and be treated in the same nursing unit as other inpatients. No different than a hospital's operating suites, which are used to treat both outpatients and inpatients, hospital outpatient care is not location dependent. Specifically, outpatients may be treated in what would be considered typically inpatient locations, such as the Intensive Care Unit (ICU), while retaining their outpatient status.

Orders and Patient Status

Clinician orders, whether electronic or written, are required for all hospital services, including all CAR-T services, and may be considered to be the start of the charge capture process. At cell collection and product administration, clinician orders must specify the status of the patient as an outpatient or inpatient, since the status can change with updated orders as the patient's care progresses. While health care providers often refer to patients being treated in a certain location or setting as determining outpatient or inpatient status—i.e. "in the outpatient setting"—the status of the patient as a hospital outpatient or inpatient is technically determined by the clinician's order.

Cell collection is primarily rendered to hospital outpatients, but administration can be furnished to either an outpatient or inpatient. When cell collection or administration occurs on outpatient status, the clinician may subsequently order an inpatient admission if complications arise that necessitate an inpatient admission. Alternatively, the clinician may order outpatient observation services to further evaluate the patient as an outpatient. A patient may remain outpatient until discharge or may require an inpatient admission order.

> Observation care is a ***service***, not a patient status.

HOSPITAL CONSIDERATIONS REGARDING CAR-T PATIENT STATUS *(CONTINUED)*

Observation Services and Patient Status

Observation care is a service, not a patient status.[2] Observation care is required to be ordered by a physician or another individual who is authorized by state licensure and hospital staff bylaws to admit patients to the hospital or order outpatient tests.[3] Workflow in hospitals often requires ordering clinicians to label outpatients that they order to be treated on a specific nursing unit as "observation" or "observation patients." This workflow issue has added to the mistaken impression that observation is a status rather than an outpatient service.

Observation care is a service because it must be ordered by a clinician for a particular patient to allow time for the clinician to obtain diagnostic tests, order treatments and re-assess the patient to decide whether the patient requires inpatient-level hospital care or can be discharged either home or to another post-acute care location. When observation care is ordered, it is expected that the outpatient will receive nurse monitoring as well as the ordered diagnostic and therapeutic services.

Observation care is time-based and ends when all clinical and/or medical interventions have been completed, and the clinician either orders that the patient be discharged or admitted as an inpatient. Generally, observation services are not expected to exceed 48 hours in duration except in rare and exceptional cases. Medicare will cover up to 72 hours of observation services, if necessary.[4]

A patient may also be discharged after receiving an outpatient administration of CAR-T and then subsequently, due to complications of CAR-T, be admitted as an inpatient to the same hospital within Medicare's three-day payment window and therefore subject to payment under the Inpatient Prospective Payment System (IPPS). In this case, all outpatient services within the 3 days prior to admission (1 day prior for PPS-exempt hospitals), including but not limited to the administration procedure and the product itself, would be included on the inpatient claim. Any outpatient procedures will need to be coded with ICD-10-PCS (International Classification of Diseases, 10th Revision, Procedure Coding System) codes and reported on the inpatient claim as well.

> Coverage for CAR-T therapy and related services varies by payer and the patient's specific insurance benefits.

COVERAGE FOR CAR-T THERAPY

Coverage for CAR-T therapy and related services varies by payer and the patient's specific insurance benefits. There are, however, some overarching coverage considerations by type of payer that are important for hospitals to know and understand.

Coverage for Medicare Fee-For-Services (FFS) Beneficiaries

On August 7, 2019, the federal Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Decision (NCD) memorandum for autologous CAR T-cell therapy, which applies to Medicare beneficiaries.[5] The NCD ensures consistent national coverage of CAR-T for Medicare beneficiaries because all A/B Medicare Administrative Contractors (MAC) are required to follow the decision.[6,7]

In the NCD, CMS stated that autologous CAR-T products expressing at least one chimeric antigen receptor (CAR) are covered when they are used for a medically accepted indication.[8] In the NCD, CMS defined a "medically accepted indication" as either an FDA-approved indication (according to the product's FDA label), or when an FDA-approved CAR-T product's use was indicated in one or more CMS-approved compendia.[9]

Routine costs for patients who are enrolled in clinical trials for non-FDA approved autologous CAR-T therapies are specifically covered by CMS, per NCD 310.1 - Routine Cost in Clinical Trials.[10] NCD 310.1 outlines instances where routine costs associated with qualifying clinical trials for cellular therapies that are not specifically addressed in the CAR-T NCD.[11] Medicare does not provide reimbursement when non-FDA-approved autologous CAR-T is used outside of the clinical trial parameters.[12]

Coverage for Medicare Advantage (Part C) Beneficiaries

CMS requires Medicare Advantage (MA) plans to provide the same coverage to their enrollees as exists for Medicare Fee For Service (FFS) beneficiaries.[13] While the terms of the CAR-T NCD should apply to beneficiaries enrolled in MA plans; those plans may administer the NCD with additional requirements—such as prior authorization.

Therefore, it is important for providers to check with their MA plans about any specific prior authorization and billing requirements. Patient benefits may also vary across different MA plans; variations may exist for out-of-network restrictions, referral requirements, and patient cost-sharing, based on site and patient status.

COVERAGE FOR CAR-T THERAPY *(CONTINUED)*

Coverage for Commercial Plan Beneficiaries

Non-governmental payers are often referred to as "commercial" payers, private insurers, third-party payers, health plans, managed care organizations, etc. CAR-T is covered by many, if not most, commercial payers. The plan's benefit design would ultimately govern if CAR-T was a covered benefit. The medical policies that determine patient eligibility are based on the FDA's label but often have additional requirements for treatment qualification.

Therefore, it is important to review each patient's individually applicable medical plan and policy to identify additional specifications and/or eligibility requirements.

Commercial coverage policies may temporarily **lag behind** both new CAR-T product approvals and label expansions for existing FDA-approved CAR-T products. For this reason, hospitals need to be ready to substantiate coverage requests with appropriate patient-specific information and supportive clinical publications and references.

Coverage for Medicaid Patients

Coverage of CAR-T therapy for Medicaid beneficiaries may vary between states due to limited Federal coverage requirements. Therefore, it is important for providers who serve Medicaid beneficiaries to research the Medicaid state benefit documents and Medicaid Managed Care medical policies to determine eligibility and coverage.[14]

ICD-10-CM DIAGNOSIS CODING

Diagnosis coding for CAR-T therapy patients is important to explain the medical necessity of the services. This affects both inpatient and outpatient claims. It is important to code the diagnosis being treated by the CAR-T product, any complications related to the CAR-T therapy administration, and any relevant co-morbid conditions impacting medical decision-making and/or the patient's care.

Some payers may have policies that specify the diagnoses for which they will cover CAR-T therapy. The diagnosis codes provided in the table to the right should be verified with each patient's payer to ensure coverage. Additionally, clinician documentation to support a particular diagnosis must be present in the patient's medical record, because coding professionals can only code to the level of specificity provided in the medical record.

Diagnosis Coding for CAR-T Product Indication

CAR-T therapy has been approved for a range of indications; for certain payers, FDA-approved CAR-T therapy may also be prescribed for a patient with a compendia-supported indication, such as in the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium.[15]

The table on the right provides the common ranges of diagnosis codes and indications for current FDA-approved products.

Given the broad range of diagnosis codes for the many indications that might be treated with a CAR-T product (either as part of FDA-approved use or in a clinical trial), this guide does not provide a comprehensive list of codes.

Providers are encouraged to review product-specific manufacturer guides for additional specificity on diagnosis coding for particular products. These guides typically show precise codes to the 5th digit of the ICD-10-CM code for the ranges in the table to the right.

ICD-10-CM CODE RANGE	RANGE DESCRIPTION
C82.0X	Follicular lymphoma grade I
C82.1X	Follicular lymphoma grade II
C82.3X	Follicular lymphoma grade IIIa
C82.4X	Follicular lymphoma grade IIIb
C82.5X	Diffuse follicle center lymphoma
C82.6X	Cutaneous follicle center lymphoma
C82.8X	Other types of follicular lymphoma
C82.9X	Follicular lymphoma, unspecified
C83.0X	Small cell B-cell lymphoma
C83.1X	Mantle cell lymphoma
C83.3X	Diffuse large B-cell lymphoma[16]
C83.5X	Lymphoblastic (diffuse) lymphoma
C83.9X	Non-follicular (diffuse) lymphoma, unspecified
C85.1X	B-cell lymphoma, unspecified
C85.2X	Mediastinal (thymic) large b-cell lymphoma
C85.8X	Other specified types of non-Hodgkin lymphoma
C90.0X	Multiple myeloma
C90.1X	Plasma cell leukemia
C90.2X	Extramedullary plasmacytoma
C90.3X	Solitary plasmacytoma
C91.0X	Acute lymphoblastic leukemia
Z51.12	Encounter for antineoplastic immunotherapy[17]
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Diagnosis Coding for Complications of CAR-T Therapy

CAR-T therapy is associated with specific complications, such as Cytokine Release Syndrome (CRS) and Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS). As CAR-T use grew and more instances of

ICD-10-CM DIAGNOSIS CODING *(CONTINUED)*

complications were observed; the ASTCT noted the need for consistent grading and terminology. The ASTCT organized a consensus conference consisting of clinicians, federal agency representatives, and researchers in the field to reach agreed-upon definitions of the grades of CRS and ICANS.[18] As a result of this effort, five grades were generated for each type of complication. View more information about the **grading of CRS and ICANS**.

The National Center for Health Statistics (NCHS) implemented new ICD-10-CM diagnosis codes for the five grades of CRS on October 1, 2020; at the same time, NCHS approved new codes to recognize the five grades of ICANS, which became available for use beginning on October 1, 2021.

It is important for the provider to document a causal relationship between the CAR-T infusion and the complications that arise, such as CRS or ICANS.

To properly report CRS and ICANS conditions due to CAR-T infusions, coders will have to use at least two codes:

- **First**, code for the underlying condition represented by a complication "T" code. For immune effector cell (IEC) therapies, such as CAR-T, the NCHS created three "complications" T-codes.[19] The coder would select the appropriate T-code based on the encounter type.
- **In addition**, a code from the CRS or ICANS code range would be selected based on the grade if documented or the selection of unspecified (if the grade is not documented).

COMPLICATIONS CODES	
CODE	**DESCRIPTION**
T80.82XA	Complication of immune effector cellular therapy, initial encounter
T80.82XD	Complication of immune effector cellular therapy, subsequent encounter
T80.82XS	Complication of immune effector cellular therapy, sequela
CRS CODES	
CODE	**DESCRIPTION**
D89.831	Cytokine release syndrome, grade 1
D89.832	Cytokine release syndrome, grade 2
D89.833	Cytokine release syndrome, grade 3
D89.834	Cytokine release syndrome, grade 4
D89.835	Cytokine release syndrome, grade 5
D89.839	Cytokine release syndrome, grade unspecified
ICANS CODES	
CODE	**DESCRIPTION**
G92.00	Immune effector cell-associated neurotoxicity syndrome, grade unspecified
G92.01	Immune effector cell-associated neurotoxicity syndrome, grade 1
G92.02	Immune effector cell-associated neurotoxicity syndrome, grade 2
G92.03	Immune effector cell-associated neurotoxicity syndrome, grade 3
G92.04	Immune effector cell-associated neurotoxicity syndrome, grade 4
G92.05	Immune effector cell-associated neurotoxicity syndrome, grade 5

PROCEDURE CODING

Delivering a CAR-T episode of care requires many services across several departments. These services need to be ordered, documented, and coded correctly for the facility to receive reimbursement. This section focuses on the coding of different procedural services that are associated with the administration of CAR-T products—such as cell collection, cell processing, and the infusion/administration of the cells.

Hospital departments use Common Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), and National Uniform Billing Committee (NUBC) revenue codes to establish charges in the charge description master (CDM) for various services. After a service is completed, coders will read the medical record documentation and assign the most appropriate diagnosis and procedure codes.

CPT Codes

The American Medical Association (AMA) has released CPT codes to describe CAR-T services and, pursuant to AMA CPT coding guidance, these are the most specific CPT codes to report CAR-T services. The AMA CPT book states, ***"the most specific code should be reported when available, rather than using codes that approximate the service and if a specific code is not available then an unlisted code should be reported."***[20]

The AMA originally released Category III CPT codes 0537T-0540T, effective 2019-2024, to describe the services for CAR-T. Effective January 2025, these codes have been deleted and replaced by Category I CPT codes 38225-38228, as described here.

These codes are the most specific codes available for autologous CAR-T therapy services. Given the use of the word "autologous" in the description, these codes should not be reported for allogeneic CAR-T therapy services. In this case, given that there is not a specific CPT code available for reporting allogeneic CAR-T services, providers should consider reporting an unlisted CPT code 38999. Unlisted CPT codes, at times, are not accepted by payers.

In these cases, providers should work with their payer contracting representative or the managed care contracting group to discuss HIPAA transaction sets and how to approach the payer to discuss the situation.

Sharing the language from the CPT manual published by the AMA may be helpful, since the AMA is one of the HIPAA adopted-code sets for reporting physician services and other medical procedures.[21, 22]

Cell Collection and Cell Processing Services

CAR-T cell therapy involves the collection of a patient's T-cells from the blood. Cell collection may be performed directly by the hospital staff, or the hospital may contract or arrange with a service provider to collect the cells. Clinician orders are required for the cell collection procedure to occur. Patients may receive separate hydration or other drug administration services on the day of cell collection if their physiological condition necessitates these services and the clinician orders the services.

CELL COLLECTION IS REPORTED WITH CPT CODE 38225

The NUBC established a series of new revenue codes for cell and gene therapy products and services to report charges for procedures performed by staff for the acquisition and injection/infusion of genetically modified cells.[23] The revenue code for cell collection is 0871.

CELL PROCESSING (OUTBOUND AND INBOUND) IS REPORTED WITH CPT CODES 38226 & 38227

Due to the significant chain of custody and lab processing services that are associated with CAR-T manufacturing, the AMA has divided the lab processing services into an outbound processing code (38226) and an inbound processing code (38227). The NUBC has also established unique revenue codes for these lab processing services: 0872 and 0873, respectively. These are per-day codes, so if the lab has orders to conduct cell processing that spans more than one day, the lab would report the appropriate code for each date of service. Similar to cell collection, cell processing services are ordered by the clinician and cell lab documentation should be present in the patient's medical record to support reporting these services.

PROCEDURE CODING *(CONTINUED)*

It is also important to note that, while Medicare tracks the CAR-T codes for utilization, Medicare does not provide payment for CPT codes 38225-38227 because it considers these services to be part of the product HCPCS code (see section below). It is, however, still possible to report these codes on Medicare outpatient claims as the services occur; the codes will receive a rejection, but CMS will receive the information for its tracking purposes. Medicare provides several different reporting options in order for providers to avoid rejections, such as reporting these services on the patient's inpatient administration claim or by reporting a product charge inclusive of these service charges.[24]

The cell processing CPT codes 38226 and 38227 describe several different processing services, including, when required by the product's protocol, cryopreservation prior to shipment (38226) and thawing after receipt of the product (38227), as well the steps involved in proper storage, quality checks, maintaining appropriate chain of custody, placement in container for shipping (38226) and appropriate handling and storage after receipt (38227).[25] Clinical examples of the use of these codes, and detailed descriptions of the services described by them, can be found in the June 1, 2019 publication of the CPT Assistant on Cellular and Gene Therapy.[26]

Note that this CPT assistant and Medicare's billing instructions were released when the previous Category III CPT codes 0537T-0539T were in effect, but both are still applicable to the current CPT codes 38225-38227. CMS further discussed payment policy for these codes in the CY 2026 MPFS Final Rule.[27]

The table below shows the recommended revenue codes and CPT codes for reporting cell collection and cell processing services.

View cell collection and cell processing services coding grid.

CPT CODES		
REVENUE CODE	**CODE**	**DESCRIPTION**
0871: Cell/gene therapy – cell collection	38225	Chimeric antigen receptor T-cell (CAR-T) therapy; harvest of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
0872: Cell/gene therapy – specialized biologic processing and storage – prior to transport	38226	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)
0873: Cell/gene therapy – storage and processing after receipt of cells from manufacturer	38227	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration

PROCEDURE CODING *(CONTINUED)*

Administration of CAR-T

For inpatient facility claims, procedure codes from ICD-10-PCS are reported for the administration of CAR-T therapy. For outpatient hospital and professional claims, CPT codes are reported for the administration procedure, associated services, and the individual products. For hospital claims, NUBC established revenue code 0874 for the administration of modified cells via infusion and 0875 for administration of modified cells via injection.

ICD-10-PCS Coding Section

All of the CAR-T administration ICD-10-PCS procedure codes are located within Section X, New Technology.

Current ICD-10-PCS Coding

As of October 1, 2021, providers can select codes for all CAR-T products and procedures from the **XW0 table**.

All CAR-T product-specific procedure codes are in table XW0 along with product-agnostic codes to report autologous and allogeneic products that are under study.

Products that have been FDA-approved, or that expect imminent approval, and those that are expected to be approved, will likely request new product-specific ICD-10-PCS codes. New CAR-T codes may be added to the XW0 table at the request of stakeholders, upon approval by CMS of the request. The complete and most recent XW0 table can be found on the CMS ICD-10 webpage under "ICD-10-PCS Code Tables and Index."[28] The table below shows the list of current ICD-10-PCS CAR-T codes.

CPT Coding for CAR-T Administration

For outpatient hospital and professional claims, a CPT code must be used to report the administration of CAR-T. The CPT book states: ***"the most specific code should be reported when available, rather than using codes that approximate the service and if a specific code is not available then an unlisted code should be reported."***[29]

The CPT code to report autologous CAR-T therapy administration is 38228.

ICD-10-PCS CAR-T ADMINISTRATION CODES

CODE	DESCRIPTION
XW033C7 XW043C7	Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy (peripheral vein or central vein approach)
XW033G7 XW043G7	Introduction of allogeneic engineered chimeric antigen receptor t-cell immunotherapy (peripheral vein or central vein approach)
XW033H7 XW043H7	Introduction of axicabtagene ciloleucel immunotherapy (peripheral vein or central vein approach)
XW033J7 XW043J7	Introduction of tisagenlecleucel immunotherapy (peripheral vein or central vein approach)
XW033K7 XW043K7	Introduction of idecabtagene vicleucel immunotherapy (peripheral vein or central vein approach)
XW033M7 XW043M7	Introduction of brexucabtagene autoleucel immunotherapy (peripheral vein or central vein approach)
XW033N7 XW043N7	Introduction of lisocabtagene maraleucel immunotherapy (peripheral vein or central vein approach)
XW033A7 XW043A7	Introduction of ciltacabtagene autoleucel (peripheral vein or central vein approach)
XW0338A XW0438A	Introduction of obecabtagene autoleucel (peripheral vein or central vein approach)

PROCEDURE CODING *(CONTINUED)*

It is not appropriate to report CPT code 38228 for other types of cell therapy products, since the description of this code is specific to autologous CAR-T.

This means that the administration of an allogeneic CAR-T therapy or an autologous natural killer (NK) or tumor-infiltrating lymphocyte (TIL) therapy cannot be reported with 38228. Typically, an unlisted code (such as 38999, accompanied by an explanation), could be reported, but this should be discussed with individual payers.

Historically, CMS has required modifier -KX on CAR-T claims to indicate that services were furnished in an FDA Risk Evaluation and Mitigation Strategy (REMS)-approved facility, consistent with Medicare's NCD 110.24.[30] The FDA eliminated all REMS requirements for CAR-T therapies on June 27, 2025.[31]

On December 9, 2025, CMS issued a formal transmittal titled, "Removal of Chimeric Antigen Receptor (CAR) T-cell Therapy and Risk Evaluation Mitigation Strategy (REMS) – NCD 110.24 and the "KX' Modifier for CAR-T Cell Therapy Claims.[32] This transmittal had an effective date of June 26, 2025, and an implementation date of February 6, 2026. The transmittal instructs MACs to discontinue the REMS and KX modifier requirements. Part B MACs shall no longer require modifier -KX to be appended to claims for CAR T-cell therapies. Part A MACs shall no longer require CAR T-cell therapy services to be submitted by or performed in an FDA REMS approved facility.

Claims with dates of service prior to June 27, 2025, require modifier -KX. Denied claims with a date of service on or after June 27, 2025, and prior to the February 6, 2026 implementation date may be appealed.

View a CAR-T administration coding grid.

CPT CODE FOR CAR-T ADMINISTRATION

REVENUE CODE	CODE	DESCRIPTION
0874: Cell/gene therapy – infusion of modified cells	**38228**	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous

PRODUCT CODING

HCPCS Level II product codes have been created to describe FDA-approved CAR-T products. Outpatient claims for CAR-T administration must have a HCPCS Level II code identifying the product to receive a payment based on the Average Sales Price (ASP) of that product. Current CAR-T products have been assigned a Q-code, although some may first have a temporary HCPCS C-code assigned upon pass-through payment status approval prior to a new HCPCS assignment.

Billing Unclassified HCPCS Codes

After the FDA approves a product, it may take time before a product-specific HCPCS code is released (applications deadlines are quarterly and codes are released upon CMS review and approval). Therefore, the use of an unspecified code may be necessary in the interim. In these cases, Medicare requires C9399 and the National Drug Code (NDC) be reported.[33]

In Transmittals 10891 and 11774, CMS clarified its instructions on an additional circumstance in which to bill C9399 and other unclassified HCPCS codes such as J3590: when the dose administered exceeded the description included in the HCPCS code for that product. Because the CAR-T product's FDA labels include the maximum number of cells that are to be infused, and the HCPCS code descriptors align with the FDA label description, CMS considers it off-label use to administer a dose greater than that included in the description. CMS indicated in Transmittal 11774 that this situation should be extremely rare. Providers billing for a CAR-T therapy case in this circumstance should carefully review transmittals 10891 and 11774 for instructions.[34,35]

Reporting of CAR-T Product HCPCS Codes on Inpatient Claims

Product-specific HCPCS codes may be reported on Medicare inpatient claims per the NUBC manual, but this is less common, since hospitals report the ICD-10-PCS codes which capture both the administration of the product and the product name. Non-Medicare payers may require product-specific HCPCS codes to be reported. These payers may also accept or require the separate reporting of cell collection and cell processing services that are described by the CAR-T CPT codes for tracking purposes or for separate payment, depending on arrangements between the provider and payer. For this reason, a provider may choose to report the NDC code(s) for the product rather than the HCPCS code on inpatient claims.

Revenue Codes and CAR-T Product HCPCS Coding

The NUBC established revenue codes to report charges for cell and gene therapy products, as it had for services, like cell collection (see page 10). To report CAR-T product charges on inpatient or outpatient claims, use revenue code 0891. This is an extension of pharmacy for FDA-approved cell therapy products (0892 should be used only to report gene therapies). The NUBC is a HIPAA designated standard maintenance organization (DSMO), therefore providers should use, and payers must accept, the NUBC-established appropriate revenue codes.

HCPCS Modifiers and the CAR-T Codes

For Medicare beneficiaries, CMS requires a modifier to be billed with the CAR-T therapy HCPCS product code in certain circumstances. In transmittal 11774, CMS issued billing instructions when submitting professional claims for the CAR-T therapy product and administration for Places of Service 11 (office) or 49 (independent clinic). Due to the inability of the current system to process these claims due to the field length topping out at 7 digits, CMS created a new modifier, -LU, to allow for fractionated billing of the HCPCS code. **However, this modifier is not applicable to hospital outpatient departments. CMS states that hospital providers do not need to change their billing and will continue to bill 1 unit for the CAR-T therapy product HCPCS code.**[36]

In the CY 2023 Medicare Physician Fee Schedule (MPFS) final rule[37], CMS finalized the requirement that providers report either the JW modifier or the JZ modifier for certain separately payable drugs and biologicals furnished under Medicare Part B, effective July 1, 2023. The JW modifier indicates the amount of a drug discarded from a single-dose container that is eligible for payment under Part B, while the JZ modifier indicates that no amount was discarded.

In the OPPS context, CMS stated that "separately payable drugs and biologicals" generally include those assigned status indicator "K" (Non–Pass-Through Drugs and Non-implantable Biologicals) or "G" (Pass-Through Drugs and Biologicals), which includes applicable CAR-T products. For the latest information on modifier JW and JZ, review the CMS' FAQ **here**.

Current CAR-T Product HCPCS Codes

The table below has product-specific codes for FDA-approved CAR-T products and includes codes to report newly approved products that are pending release of a specific HCPCS code. CMS releases new HCPCS product codes on a quarterly basis. It is important for providers to check for code updates in quarterly Transmittals and the quarterly updates of Addendum B found on the CMS website, **here**.

See the table on the following page for the current CAR-T product HCPCS codes.

View a product coding grid.

PRODUCT CODING *(CONTINUED)*

REVENUE CODE	CODE	DESCRIPTION
0891: Special Processed Drugs – FDA Approved Cell Therapy	C9399	Unclassified drugs or biologicals
	J3490	Unclassified drugs
	J3590	Unclassified biologics
	Q2042	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose
	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 car-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose
	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-CD19 CAR-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
	Q2055	Idecabtagene vicleucel, up to 510 million autologous anti-B-cell maturation antigen (BCMA) directed CAR-positive T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose
	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose
	Q2058	Obecabtagene autoleucel, 10 up to 400 million CD19 CAR-positive viable T-cells, including leukapheresis and dose preparation procedures, per infusion[38]

Understand grouping, negotiated contracts and clinical trial reimbursement methodologies that impact how you are required to submit billing for each patient.

REIMBURSEMENT METHODOLOGIES

Many payers, including CMS, other government payers, and many commercial payers—use a Diagnosis-Related Group (DRG)-based grouping reimbursement methodology. A DRG-based methodology assigns patients who have similar conditions (or who underwent similar procedures) into specific groupings for the purpose of providing reimbursement for hospital inpatients. The exact groupings and payments vary by payer.

Payers may use Medicare's Medicare Severity Diagnosis Related Groups (MS-DRGs) and Ambulatory Payment Classification (APC) groupings, or use different payment methodologies, including an altogether different grouping system; they may or may not provide separate payment for FDA approved CAR-T products.

For hospital outpatients, Medicare provides payment using outpatient groupings called APC groups. Similar to how it structures DRGs, CMS groups individual CPT/HCPCS codes of similar type or resource use into a single APC. The agency assigns a single payment rate to the APC, which then applies to all CPT codes within the APC. For Medicare outpatient product payment, the appropriate CAR-T product C- or Q-code (as described in the coding section), along with the NDC, would be reported on the claim.

Commercial payers typically reimburse under a negotiated contract methodology, such as a single case rate for the episode of care, which specifies how payment for the product is handled. The CAR-T product may be paid based on the Wholesale Acquisition Cost (WAC) amount while the patient care costs are paid according to the negotiated case rate.

CLINICAL TRIAL, EXPANDED ACCESS AND NO COST PRODUCT BILLING

The development of CAR-T products is ongoing, with multiple clinical trials underway at any given time. ***Clinical trial billing is likely to be a constant in this field and may present billing challenges for providers.***

Medicare Clinical Trial Billing

For non-Medicare payers, providers must check with the payer regarding any special requirements around clinical trial or expanded access billing.

Medicare requires all clinical trial claim forms to contain specific billing indicators; these include condition code 30, value code D4, modifiers Q1 (Routine clinical service provided in a clinical research study that is in an approved clinical research study) or/and Q0 (Investigational clinical service provided in a clinical research study that is in an approved clinical research study), the National Clinical Trial (NCT) number, and diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program). Reporting CAR-T clinical trial cases in this way will trigger CMS to pay the appropriate reduced MS-DRG 018 amount, since no product cost was incurred.[39]

For a clinical trial case where the CAR-T product is not the item under investigation (i.e. the patient is enrolled in a clinical trial, but the hospital still incurred the cost of the CAR-T product), the provider should enter "Diff Prod Clin Trial" into Billing Note NTE02 on the electronic claim 837I or in the remarks field on a paper claim (form locator 80) to receive the full MS-DRG 018 payment amount, since the hospital incurred the product cost.[40]

Medicare Expanded Access Billing

In some instances, an FDA-approved CAR-T product may not meet manufacturing release specifications, yet the physician may proceed with administration to a patient under an expanded access program.

For CAR-T expanded access cases, as of October 1, 2022, CMS instructs providers to submit condition code 90. Prior to October 1, 2022, CMS had identified expanded access claims by instructing providers to enter "Expand Acc Use" into the claims field Billing Note NTE02 on the electronic claim 837I, or in the remarks field on a paper claim (form locator 80).[41]

Using condition code 90 will result in the appropriate reduced MS-DRG 018 payment amount.

No Cost Product Billing

As of October 1, 2025, Medicare has specified that cases where an immunotherapy product is "not purchased in the usual manner, such as provided at no cost" (i.e., compassionate use, a replacement product scenario, and/or manufacturer assistance program) need to include "PROD NO COST" as a billing note on an electronic claim or in the remarks field on a paper claim.[42] Reporting no cost products in this way will trigger CMS to pay the appropriate reduced MS-DRG 018 amount.

Value Code 90[43]

The NUBC is one of HIPAA's designated standards maintenance organizations (DSMO). The NUBC maintains instructions and code sets that are applicable to institutional claims and incorporates code sets from other HIPAA authorities (like the AMA's CPT codes), which are relevant to CAR-T billing scenarios. The NUBC has established a value code to allow the reporting of actual product acquisition cost. This may facilitate claims processing for commercial payers and avoid the need to attach the product invoice or may enable reporting a value of zero (0) when a product cost is not incurred because the patient is in a clinical trial, received the product under an expanded access protocol, or did not incur the cost of the product. The provider should check with the payer's policy or contract to determine if this is required to be reported.

REVENUE INTEGRITY PROCESS

Below is a summary of the revenue integrity process to help various staff better ensure patient eligibility, coverage, charge capture, documentation, and accurate claims reporting and validation.

Prior to Service Delivery

ELIGIBILITY

- Determine eligibility and insurance plan priority for all plans; check whether the patient has a supplemental catastrophic plan.
- Perform coordination of benefits (COB) as determined by plan eligibility.

COVERAGE

- For each plan for which eligibility was verified, confirm benefits for the entire CAR-T episode of care.
- Attempt to obtain the published Affordable Care Act (ACA)-required benefit summary for each plan.
- Research any published coverage policies from each plan and confirm the requirement for prior authorization.
- Obtain current out-of-pocket (OOP) maximums for the patient under each plan.
- Review published coverage policies against the following patient-specific information to confirm coverage:
  - Primary diagnosis and corresponding ICD-10-CM code;
  - Relevant disease-related characteristics (e.g., histology, prognostic factors);
  - Prior regimens/lines of therapy and treatment response; and
  - Clinical fitness (e.g., Eastern Cooperative Oncology Group (ECOG) performance status, organ function indicators).
- If the patient is to be enrolled in a clinical trial, determine the payer's policies regarding coverage and payment of routine costs in a clinical trial and determine if prior authorization is required.

PRIOR AUTHORIZATION

- Submit the prior authorization request following the payer's instructions.
- Carefully review the documentation requirements and furnish a clear and concise summary to the payer and/or to the patient's clinician who may be involved in a peer-to-peer review process.
- Determine whether an expedited prior authorization process is available and whether this process should be followed due to the patient's clinical condition.
- Confirm prior authorization for each step of the treatment:
  - Cell collection (38225);
  - Cell lab processing – outbound (38226) to the manufacturer, inbound (38227) to the provider from the manufacturer, and preparation for administration; and
  - Administration (38228), whether outpatient or part of an inpatient stay.

REVENUE INTEGRITY PROCESS *(CONTINUED)*

Concurrent With Service Delivery

CHARGE CAPTURE AND DOCUMENTATION

- **Confirm the following:**
  - Presence of a written, authenticated order for cell collection, cell processing, and administration.
  - Nursing/cell lab documentation of cell collection procedure (also, providers should consider tying charge capture of the procedure 38225 charge to completed clinical documentation in the electronic medical record [EMR]).
  - The presence of cell laboratory documentation of outbound cell processing according to the applicable manufacturer instructions/requirements (providers should consider tying charge capture of the procedure 38226 charge to completed clinical documentation in the EMR).
  - Cell laboratory documentation of inbound/receipt of cells and any processing (e.g., thawing) according to applicable manufacturer instructions/requirements and clinician orders (providers should consider tying charge capture of the procedure 38227 charge to completed clinical documentation in the EMR).
  - Nursing/cellular lab documentation of the administration procedure (providers should consider tying charge capture of the procedure 38228 charge to completed clinical documentation in the EMR).
- Review for orders, medication administration record (MAR) and other applicable clinical documentation for any ancillary services.
- For inpatients, confirm the presence of the inpatient admission order from the clinician.
- For any hourly observation services provided after administration, confirm presence of clinician order of observation services, and clinician progress notes reflecting periodic re-assessment of the patient until a decision to discharge or admit the patient as an inpatient.
- The product charge may come from pharmacy or the cell laboratory, and this typically affects documentation of the product and administration procedure. Confirm documentation of the administration procedure in the MAR or other records developed by the cell laboratory and/or nursing to document the administration procedure of the specific product.

After Service Provision

CLAIM SUBMISSION

- Confirm payer-specific billing requirements based on whether outpatient or inpatient hospital claims will be submitted.
- Confirm the correct principal and admitting ICD-10-CM diagnosis codes.
- Review HCPCS Level II and National Drug Code (NDC) reporting requirements for the product used on inpatient and outpatient claims.
- Review for correct revenue codes for cell collection (0871), cell lab processing (0872-0873), product administration (0874), and the CAR-T product charge (0891).
- Review for correct CPT codes on outpatient claims for CAR-T services.

REVENUE INTEGRITY PROCESS *(CONTINUED)*

- Review to ensure the accuracy of units billed, that the prior authorization number is on the claim (if applicable), and that correct dates of services are reported.
- If under clinical trial, review for:
  - Appropriate condition codes, value codes, modifiers, NCT number, and diagnosis code Z00.6; and
  - Other payer-specific reporting requirements needed to bill for routine costs.
- If product under clinical trial is not CAR-T:
  - When the CAR T-Cell therapy or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product review for the presence of "Diff Prod Clin Trial" as a billing note on an electronic claim (NTE02) or in the remarks field (FL 80) on a paper claim.
- If under expanded access:
  - Review for the presence of the NUBC condition code 90 and presence of the note "Expand Acc Use" in the Billing Note NTE02 or remarks field (if a Medicare account).[44]
- If product was provided at no cost:
  - Review for the presence of "PROD NO COST" as a billing note on an electronic claim (NTE02) or in the remarks field (FL 80) on a paper claim.

TRACKING AFTER SUBMISSION & RESOLVING DENIALS

Given the high dollar charges for CAR-T cases, providers may want to track these claims post-submission and review the remittance advice (RA) carefully.

- Consider using a cumulative tracking sheet for all CAR-T cases since inception of the program and divided by fiscal year to track total charges for the episode of care; whether administered inpatient or outpatient; product type; payer; reimbursement and whether there were denials, appeals, and, if appealed, whether the denial was overturned.
  - It may be useful to regularly circulate this tracking sheet, or a high-level summary, to the clinical department, treating clinicians, and any relevant leadership and/or executives.
- Resolve any claim rejections quickly and be prepared to submit additional documentation to the payer, including medical records.
- If records are requested to process the claim or provided as part of an appeal, include the prior authorization number on any documents submitted and organize the records submitted so that key coverage and medical necessity information is easily referenced in the medical record (including the covered diagnosis for CAR-T therapy, previously tried and failed treatments with details of any results, inadequate response, or adverse events). If appropriate, also include additional supporting documents such as peer-reviewed journal articles, medical literature, treatment studies or clinical trials, consensus statements, or treatment guidelines (e.g., ASTCT, National Comprehensive Cancer Network [NCCN] or American Society of Hematology [ASH]).

REVENUE INTEGRITY PROCESS *(CONTINUED)*

EXPECTED REIMBURSEMENT

Upon initiation of CAR-T services at the hospital, it is best practice for the payer's contracting department staff to initiate discussions with each of the hospital's major commercial payers to better understand the applicability of any existing contracts to CAR-T and how the reimbursement methodology would work. This will inform if a contract amendment is needed and/or if single case agreements (SCA) should be pursued in the interim. This will help with any resolution needed on an individual case.

The following is suggested to help verify accurate reimbursement:

- Carefully review the applicable payer contract and whether CAR-T is included under the contract or whether a separate single patient or case agreement needs to be developed.
- Partner with the payer contracting team to proactively reach out to the patient's payer and understand reimbursement terms for the case.
- Check that all requirements outlined are met for eligibility, coverage, coding, and claim submission.
- For commercial payers, identify the payment methodology for the payer and whether the patient received the CAR-T product as an outpatient or inpatient. Determine the applicable payment formula for each claim and each type of CAR-T service (such as cell collection; lab processing; cell therapy administration; and post-administration management of the patient, including addressing any complications which may or may not require further hospital services).
- For payers that utilize MS-DRG-based methodologies for inpatient administration of CAR-T, determine the base rate, wage adjustment, other hospital-specific adjustments, outlier threshold, hospital overall cost-to-charge ratio, and the total covered billed charges on the inpatient claim to estimate payment.

CODING GRIDS

Click each button below to see the current coding grids.

CODING OPTIONS FOR ADMINISTRATION OF CAR-T

CODING OPTIONS FOR THE REPORTING OF CELL COLLECTION AND PROCESSING

CODES FOR REPORTING COMPLICATIONS ASSOCIATED WITH CAR-T

CODING OPTIONS FOR REPORTING CAR-T PRODUCTS

REFERENCES

The website links provided in this coding and billing guide are included for informational and reference purposes only. Please be aware that external websites may update, modify, relocate, or remove their content at any time. As a result, some links may become outdated, inactive, or directed to information that has changed. We recommend reviewing the source organization's official website or conducting an updated search if a link does not function or the referenced content appears to have been altered.

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