CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 13460	**Date: December 23, 2025**
	Change Request 14247

SUBJECT: Update to the Internet Only Manual (IOM) for Inpatient Billing of Chimeric Antigen Receptor (CAR) T-Cell Therapy in Publication (Pub.) 100-04; Chapter 32 Billing Requirements for Special Services, Section 400.3 Payment Requirements

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update Chapter 32 Billing Requirements for Special Services, Section 400.3 Payment Requirements, for submission of remarks and new condition code processing when billing for Chimeric Antigen Receptor (CAR) T-Cell and other immunotherapies.

EFFECTIVE DATE: October 1, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 26, 2026

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	32/400/400.3/Payment Requirements

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:
Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 13460	Date: December 23, 2025	Change Request: 14247

SUBJECT: Update to the Internet Only Manual (IOM) for Inpatient Billing of Chimeric Antigen Receptor (CAR) T-Cell Therapy in Publication (Pub.) 100-04; Chapter 32 Billing Requirements for Special Services, Section 400.3 Payment Requirements

EFFECTIVE DATE: October 1, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 26, 2026

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update Chapter 32 Billing Requirements for Special Services, Section 400.3 Payment Requirements, for submission of remarks and new condition code processing when billing for Chimeric Antigen Receptor (CAR) T-Cell and other immunotherapies.

II. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) created MS-DRG 018 "Chimeric Antigen Receptor (CAR) T-Cell Immunotherapy" in Fiscal Year (FY) 2021 for cases that include procedures describing CAR-T cell therapies. Beginning FY 2022, the title was revised to "Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies". A DRG weight adjustment factor is applied to claims that group to MS-DRG 018 for clinical trial and expanded access use immunotherapy cases, where the immunotherapy product is not purchased in the usual manner. CMS recently became aware that there are other instances in which the immunotherapy product is not purchased in the usual manner, such as provided at no cost. Beginning in FY 2026, in cases where the immunotherapy product is not purchased in the usual manner, such as provided at no cost, the payment adjustment will be applied.

This CR updates Pub. 100-04, Chapter 32, Section 400.3 with inpatient billing instructions for providers to notify the Medicare Administrative Contractor (MAC) of a case where the immunotherapy product is not purchased in the usual manner, such as provided at no cost. This CR also includes billing instructions for payment requirement scenarios involving purchased products when billing for products of a different clinical trial, and expanded access use of cases involving CAR-T and other immunotherapies.

B. Policy: These billing instructions apply to existing policy as described in §412.85.

III. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
14247.1	Medicare contractors shall be aware of the manual updates in Pub 100-04, Chapter 32, Section 400.3.	X								

IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

Impacted Contractors: A/B MAC Part A

V. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

VI. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

400.3 - Payment Requirements

(Rev.13460; Issue: 12-23-25; Effective: 10-01-25; Implementation: 01-26-26)

Inpatient

The A/B MAC billing requirements will allow for CAR T-cell therapy when the services are submitted on the following TOB: 11X. Type of facility and setting determines the basis of payment:

For services performed in inpatient hospitals, TOB 11X, under the Inpatient PPS is based on the Medicare Severity-Diagnosis Related Group (MS-DRG).

For services performed in Critical Access Hospital (CAH) inpatient TOB 11X, payment is based on 101% of reasonable cost.

Effective for discharges occurring or after October 1, 2022, CMS makes an adjustment to the payment amount for clinical trial and expanded access use immunotherapy cases that group to MS-DRG 018. Under this policy, a payment adjustment is applied to claims that group to MS-DRG 018 and include ICD-10-CM diagnosis code Z00.6 or when there is expanded access use of immunotherapy. As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49080), providers should include the relevant billing notes or condition code indicated in the scenarios below.

Scenario 1: CAR-T or Other Immunotherapy Product Purchased in Cases Involving Clinical Trial of a Different Product:

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, the payment adjustment will not be applied in calculating the payment for the case. To notify the MAC of a case where 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 (and ICD-10-CM diagnosis code Z00.6 is on the claim), the provider may enter a Billing Note NTE02 "Diff Prod Clin Trial" on the electronic claim 837I or a remark "Diff Prod Clin Trial" on a paper claim, and MACs shall add payer-only condition code "ZC" so that the Pricer will not apply the payment adjustment in calculating the payment for the case.

Scenario 2: Expanded Access Use of CAR-T or Other Immunotherapy Product:

In a case where there was expanded access use of CAR T-cell therapy or other immunotherapy products, the provider may submit condition code "90" on the claim so that the Pricer will apply the payment adjustment in calculating the payment for the case.

Scenario 3: CAR-T or Other Immunotherapy Product Received at No Cost:

In a case where the CAR T-cell therapy or other immunotherapy product is not purchased in the usual manner, such as obtained at no cost, the provider shall include Billing Note "Prod No Cost" on the electronic claim 837I or a remark "Prod No Cost" on a paper or Direct Data Entry (DDE) claim, and MACs shall add payer-only condition code "ZD" so that the Pricer will apply the payment adjustment in calculating the payment for the case, effective for discharges occurring on or after October 1, 2025.

Outpatient

The A/B MAC billing requirements will pay for CAR T-cell therapy when the services are submitted on the TOBs: 13X and 85x. Type of facility and setting determines the basis of payment:

For services performed in hospital outpatient departments (HOPDs), TOBs 13X, or inpatient ancillary TOB 12X, payment is based on OPPS.

For services performed in CAH OPDs, TOB 85X, payment is based on reasonable cost.

For services performed in CAH Method II with revenue code 096X, 097X, and 098X, TOB 85X, payment is based on the lesser of the actual charge or the Medicare Physician Fee Schedule (115% of the lesser of the fee schedule amount and submitted charge).

HOPDs may report CPT codes 0537T, 0538T, and 0539T (end date 12/31/24 replaced with 38225, 38226, and 38227 effective 01/01/25) to allow tracking of these services when furnished in the outpatient setting. Medicare will reject these lines as Medicare does not separately pay for these services under the OPPS.

These following scenarios present further clarification on how to report items and services related to CAR-T in various clinical scenarios.

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in HOPDs:

In instances when you administer the CAR-T drug in the HOPD setting, report CPT code 0540T (end date 12/31/24 and replaced with 38228 effective 01/01/25) for the administration and HCPCS Q2041, Q2042, Q2053 (effective April 1, 2021), C9073 (prior to April 1, 2021), C9076, or, if a more specific code is unavailable, the most appropriate unclassified drug code (e.g., C9399 for unclassified drugs or biologicals). NOTE: the drug codes will be denied as a Part A service even if billed with the administration.) For specific instructions on billing unclassified drug codes, refer to Chapter 26, Section 10.4 of the "Medicare Claims Processing Manual" on the CMS website at: Regulations-and-Guidance.Ch26. As discussed in the Calendar Year (CY) 2019 OPPS/Ambulatory Surgery Center final rule (83 FR 58904), the procedures described by CPT *0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) (*0537T, 0538T, and 0539T end date 12/31/24 and replaced with 38225, 38226, and 38227 effective 01/01/25) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the OPPS. However, you may report the charges for these various steps to collect and prepare the CAR T-cells separately and Medicare will reject them on the HOPD claim, or they may be included in the charge reported for the biological.

Note: When including the charges for collection and preparation of the CAR-T cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD facility, the hospital may not report the drug Q code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT *0537T, 0538T, and 0539T (as appropriate) and (*0537T, 0538T, and 0539T end date 12/31/24 and replaced with 38225, 38226, and 38227 effective 01/01/25) the charges associated with each code under the appropriate revenue code on the HOPD claim. Medicare will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the HOPD setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (TOB 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug

Administration) Approved Cell Therapy – Charges for Modified cell therapy.

Note: When the cells are collected in the HOPD setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Physician Office or Non-Hospital Clinic

The A/B MAC billing requirements will pay for CAR T-cell therapy when the services are submitted on the Form CMS-1500 or electronic 837P.

Scenario 1: CAR T-cell Dosing and Preparation Services and Viable T-cells Administered in Physician Office or Non-Hospital Clinic:

In instances when a physician or non-physician provider administers the CAR T-cells product in the physician office setting or other non-hospital clinic setting report CPT code 0540T *(*end date 12/31/24 and replaced with 38228 effective 01/01/25) for the administration and HCPCS code Q2041, Q2042, Q2053 (effective April 1, 2021), C9073 (prior to April 1, 2021), C9076, or, if a more specific code is unavailable, the most appropriate unclassified drug code (e.g., J3590 for unclassified biologics). For specific instructions on billing unclassified drug codes, refer to Chapter 26, Section 10.4 of the "Medicare Claims Processing Manual" on the CMS website at: *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf*

The procedures described by CPT codes *0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the MPFS. However, you may report them separately, and Medicare will deny them on the professional claim as Medicare does not pay separately for this service. (*0537T, 0538T, and 0539T end date 12/31/24 and replaced with 38225, 38226, and 38227 effective 01/01/25.)

Note: Practitioners shall code the CAR T-cell product service on the date that the CAR T-cells administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in Physician Office or Non-Hospital Clinic, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the physician office or other non-hospital clinic facility, the practitioner may not report the drug HCPCS code (which only applies when the T-cells are administered in the setting). The practitioner may report CPT 0537T, 0538T, and 0539T. (0537T, 0538T, and 0539T end date 12/31/24 and replaced with 38225, 38226, and 38227 effective 01/01/25.)

Scenario 3: CAR T-cells Dosing and Preparation Services in Physician Office or Non-Hospital Clinic, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the physician office or other non-hospital clinic setting, but the CAR T-cells are administered in the hospital inpatient setting, the practitioner may not report the drug HCPCS code (which only applies when viable T-cells are administered in the setting). The hospital that administers the T-cells will report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (TOB 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.

Note: When the cells are collected in the physician office setting and the CAR T-cell is administered in the hospital inpatient setting, inpatient providers shall report the date that the CAR T-cell administration took place and not the date the cells were collected.