CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 13432	**Date: December 9, 2025**
	Change Request 14204

SUBJECT: 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

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to amend the claims processing instructions (Claims Processing Manual 100-04, Chapter 32, Section 400) for Chimeric Antigen Receptor (CAR) T-cell therapy and clarify that the Risk Evaluation and Mitigation Strategy (REMS) requirement in the National Coverage Determination (NCD) 110.24 for Chimeric Antigen Receptor (CAR) T-cell Part A and Part B requirements have been updated.

EFFECTIVE DATE: June 26, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: February 6, 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	32/400/400.1/Coverage Requirements
R	32/400/400.2 Billing Requirements
R	32/400/400.2.4/A/B MAC Diagnosis and Procedure Code Requirements
R	32/400/400.2.5/Billing Information for Professional Claims
R	32/400/400.3/Payment Requirements
R	32/400/400.4/Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages

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: 13432	Date: December 9, 2025	Change Request: 14204

SUBJECT: 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

EFFECTIVE DATE: June 26, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: February 6, 2026

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to amend the claims processing instructions (Claims Processing Manual 100-04, Chapter 32, Section 400) for Chimeric Antigen Receptor (CAR) T-cell therapy and clarify that the Risk Evaluation and Mitigation Strategy (REMS) requirement in the National Coverage Determination (NCD) 110.24 for Chimeric Antigen Receptor (CAR) T-cell Part A and Part B requirements have been updated.

II. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to amend the claims processing instructions (Claims Processing Manual 100-04, Chapter 32, Section 400) for Chimeric Antigen Receptor (CAR) T-cell therapy and clarify that the Risk Evaluation and Mitigation Strategy (REMS) requirement in the National Coverage Determination (NCD) 110.24 for Chimeric Antigen Receptor (CAR) T-cell Therapy no longer applies because the FDA eliminated REMS for all CAR T-cell products. MACs shall not require modifier KX to be appended to those claims.

As background, on August 7, 2019, the Centers for Medicare & Medicaid Services (CMS) finalized NCD 110.24. Among other criteria, CMS required CAR T-cell therapy to be administered at a healthcare facility enrolled in the Food and Drug Administration (FDA) REMS. For many years, the REMS was part of the FDA-approved indications for use for these therapies. The KX modifier was used on claims to acknowledge the service was performed in an FDA REMS participating facility.

On June 26, 2025, the FDA issued a communication that announced the elimination of REMS and updated product labeling for CAR T-cell therapies. The FDA communication is available at: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor

B. Policy: The implementation date for this CR as it pertains to the KX modifier on claims is 60 days from issuance. The Part B MACs only shall no longer require the KX modifier 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. The effective date for this CR is June 26, 2025. The Medicare Claims processing manual, Publication 100-04, Chapter 32, Section 400 has been updated.

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	
14204.1	Contractors shall no longer require the 'KX' modifier for CAR-T cell therapy claims, effective with Date of Service (DOS) on and after June 26, 2025		X							
14204.2	Contractors shall end date all editing and messaging requirements effective June 25, 2025 related to 'KX' modifier for CAR-T claims.		X							
14204.3	Contractors shall note the applicable changes outlined in the Medicare Claims Processing Manual, Publication 100-04, Chapter 32, Section 400.		X							
14204.4	Contractors shall disregard the 'KX' modifier on claims for CAR-T cell therapy effective with DOS on and after June 26, 2025.		X							
14204.5	Contractors shall no longer require CAR-T cell therapy services to be submitted by or performed in an FDA REMS approved facility, effective with DOS on and after June 26, 2025.	X								
14204.6	Contractors shall not search claims, but may adjust claims that are brought to their attention.	X	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, A/B MAC Part B

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: 1

400.1 - Coverage Requirements

(Rev. 13432; Issued: 12-09-25; Effective: 06-26-25; Implementation: 02-06-26)

Effective for services performed on or after August 7, 2019, the Centers for Medicare & Medicaid Services (CMS) covers autologous treatment for cancer with T-cells expressing at least one CAR when administered at healthcare facilities enrolled in the Food and Drug Administration (FDA) risk evaluation and mitigation strategies (REMS) and used for a medically accepted indication as defined at Social Security Act (the Act) section 1861(t)(2), i.e., is used for either an FDA-approved indication (according to the FDA-approved label for that product), or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia. See Publication 100-03, National Coverage Determination (NCD) Manual 110.24 for complete coverage criteria. See the following websites for specific REMS facility information:

Kymriah® https://www.us.kymriah.com/treatment-center-locator
Yescarta® https://www.yescarta.com/find-a-treatment-center
Tecartus™ https://www.tecartus.com/hcp/treatment-center-locator
Breyanzi® https://www.celltherapy360.com/locations
ABECMA® https://www.celltherapy360.com/locations
CARVYKTI™ https://www.carvyktihcp.com/treatment-centers

Effective for claims with dates of Service (DOS) on and after June 26, 2025, Medicare coverage for autologous treatment for cancer with T-cells expressing at least one CAR is allowed without being administered at healthcare facilities enrolled in the Food and Drug Administration (FDA) risk evaluation and mitigation strategies (REMS).

400.2 - Billing Requirements

(Rev. 13432; Issued: 12-09-25; Effective: 06-26-25; Implementation: 02-06-26)

Effective for dates of service on or after August 7, 2019, contractors shall pay for line-item professional claims for the administration of autologous treatment for cancer with T-cells expressing at least one CAR with Current Procedural Terminology (CPT) code 0540T end date 12/31/24 replaced with 38228 effective 01/01/25.

Contractors shall not require the NCD 110.24 -KX modifier and diagnosis codes for clinical trials under NCD 310.1. These claims shall bill with the NCT number for the specific trial, the -Q0 clinical trial modifier, and the Z00.6 clinical trial diagnosis code on the *0540T claim line effective for dates of service on or after August 7, 2019. (*0540T end date 12/31/24 and replaced with 38228 effective 01/01/25.)

For Part A Outpatient (OPPS) contractors shall not require NCD 110.24 REMS facility and diagnosis codes for CAR T-cell therapy CPT code *0540T in clinical trials under NCD 310.1 billed with the NCT number for the specific trial, the -Q0 clinical trial modifier, condition code 30, value code D4, and the Z00.6 clinical trial diagnosis code effective for dates of service on or after August 7, 2019. (*0540T end date 12/31/24 and replaced with 38228 effective 01/01/25.)

400.2.4 - A/B MAC Diagnosis and Procedure Code Requirements

(Rev. 13432; Issued: 12-09-25; Effective: 06-26-25; Implementation: 02-06-26)

Please see NCD spreadsheet for the applicable International Classification of Disease (ICD)-10-CM diagnosis codes for CAR T-cell therapy coverage.

The following are the applicable ICD-10-PCS procedure codes for CAR T-cell therapy coverage for inpatient claims:

For dates of service on or after October 1, 2021:

CARVYKTI™ - XW033A7: Introduction of Ciltacabtagene Autoleucel into Peripheral Vein, Percutaneous Approach, New Technology Group 7

CARVYKTI™ - XW043A7: Introduction of Ciltacabtagene Autoleucel into Central Vein, Percutaneous Approach, New Technology Group 7

When other CAR T-cell therapy obtains FDA approval but has not yet received a specific PCS code, and for use in clinical trials FDA-approved under NCD 310.1 – XW033C7: Introduction of Autologous Engineered Chimeric Antigen Receptor T-cell Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

When other CAR T-cell therapy obtains FDA approval but has not yet received a specific PCS code, and for use in clinical trials FDA-approved under NCD 310.1 – XW043C7: Introduction of Autologous Engineered Chimeric Antigen Receptor T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

Yescarta® - XW033H7: Introduction of Axicabtagene Ciloleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

Yescarta® - XW043H7: Introduction of Axicabtagene Ciloleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

Kymriah® - XW033J7: Introduction of Tisagenlecleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

Kymriah® - XW043J7: Introduction of Tisagenlecleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

ABECMA® - XW033K7: Introduction of Idecabtagene Vicleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

ABECMA® - XW043K7: Introduction of Idecabtagene Vicleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

Tecartus™ - XW033M7: Introduction of Brexucabtagene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

Tecartus™ - XW043M7: Introduction of Brexucabtagene Autoleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

Breyanzi® - XW033N7: Introduction of Lisocabtagene Maraleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

Breyanzi® - XW043N7: Introduction of Lisocabtagene Maraleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

Aucatzyl® - XW0338A: Introduction of Obecabtagene Autoleucel into Peripheral Vein, Percutaneous Approach, New Technology Group 10 (FDA Approval date of November 8, 2024). This code is covered in a clinical trial, see below.

Aucatzyl® - XW0438A: Introduction of Obecabtagene Autoleucel into Central Vein, Percutaneous Approach, New Technology Group 10 (FDA Approval date of November 8, 2024). This code is covered in a clinical trial, see below.

For dates of service prior to October 1, 2021:

Yescarta®, ABECMA®, Kymriah® - XW033C3: Introduction of Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 3

Yescarta®, ABECMA®, Kymriah® - XW043C3: Introduction of Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 3

Tecartus™ - XW23346 - Transfusion of Brexucabtagene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 6

Tecartus™ - XW24346 - Transfusion of Brexucabtagene Autoleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 6

Breyanzi® - XW23376 – Transfusion of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 6

Breyanzi®- XW24376 – Transfusion of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology 6

NOTE: Since allogenic T-cells are by definition not autologous CAR T-cells, it is inappropriate to use any of the above autologous CAR T-cell ICD-10 PCS procedure codes for allogenic T-cell treatments.

For Part A Inpatient contractors shall not require NCD 110.*24* diagnosis codes for autologous CAR T-cell therapy ICD-10-PCS codes XW033A7/XW043A7, XW033H7/XW043H7, XW033J7/XW043J7, XW033K7/XW043K7, XW033M7/XW043M7, XW033N7/XW043N7, and XW0338A/XW0438A in clinical trials under NCD 310.1 billed with the NCT number for the specific trial, condition code 30, value code D4, and the Z00.6 clinical trial diagnosis code effective for dates of service on or after August 7, 2019.

400.2.5 – Billing Information for Professional Claims

(Rev. 13432; Issued: 12-09-25; Effective: 06-26-25; Implementation: 02-06-26)

Professional claims for CAR T-cell therapy and related services are billed using the Form CMS-1500 or 837P following instructions in chapter 12 of this manual (www.cms.hhs.gov/manuals/104_claims/clm104index.asp).

Contractors shall use the CMS HCPCS Website for current HCPCS codes,

Contractors shall create an edit that only allows CAR T-cell therapy services when the line item has a -LU modifier appended. **Note:** When a provider submits an -LU modifier on a CAR T-cell claim, it informs the MAC that the service is fractionated. The total units shall not exceed 1 unit.

Contractors shall set up their systems to allow fractionated units on multiple claims for CAR T-cell products on the same DOS. These claims should suspend for proper adjudication of payment.

The total payment will be divided by 10 and the provider will need to bill in 0.1 unit fractions. The provider will need to bill a total of 10 fractional units to reach the total Medicare allowed payment amount.

Example: CAR T-cell product allowed payment $445,000:

0.2 units = $89,000.06
0.2 units = $89,000.00
0.2 units = $88,999.99
0.2 units = $88,999.98
0.2 units = $88,999.97

Note: Contractors shall only pay up to 1 unit, anything exceeding 1 unit must be denied.

For CAR T-cell products when the dose exceeds the code descriptor, use HCPCS code J3490, J3590, or J9999 for the exceeded dosage. Include the CAR T-cell product name and the exceeded dosage in Block 19 of the 1500 claim form or its electronic equivalent.

Example: CAR T-cell product with dose exceeded allowed payment $150,000:

0.5 units = $74,999.00
0.5 units = $75,001.00

For CAR T-cell products when the dose exceeds the code descriptor, the provider would bill a total of 1 unit of the Q code plus a total of 1 unit of the J code.
For example, Q2041 Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR positive T-cells. If the provider gives 300 million cells, they will bill:

Q2041 for 0.1 fraction $42,294.00 x10 for 200 million cells (total $422,940.00)
J9999 for 0.2 fractions $42,294.00 x5 for 100 million cells (total $211,470.00)

NOTE: The FDA labels for CAR T-cell products state the maximum number of cells that are to be infused. The HCPCS code descriptors for Q2041, Q2042, Q2053, Q2054, Q2055, and Q2056 all align with the FDA label maximum number of cells that are to be infused. If a provider exceeds the HCPCS code descriptor number of cells, this is off label use. This should be extremely rare.

Contractors shall allow a -76 modifier (repeat procedure or service by same physician or other qualified healthcare professional) on subsequent claims billed on the same date of service to assist with preventing duplicate denials.

400.3 - Payment Requirements

(Rev. 13432; Issued: 12-09-25; Effective: 06-26-25; Implementation: 02-06-26)

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.

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.

400.4 - Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages

(Rev. 13432; Issued: 12-09-25; Effective: 06-26-25; Implementation: 02-06-26)

Contractors shall continue to use the appropriate existing messages that they have in place when denying claims submitted that do not meet the Medicare coverage criteria for CAR T-cell therapy.

--When denying claims for covered CAR T-cell therapy procedures because the appropriate ICD-10 coding was not used, use the following messages:

CARC 50 - These are **non-covered services** because this is not deemed a "medical necessity" by the payer. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code CO or PR dependent upon liability.

MSN 15.20 - “The following polices were used when we made this decision: NCD 110.24.”
Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 110.24.”

--When denying claims for covered CAR T-cell therapy procedures because they are not performed in POS 11 or 49, use the following messages:

CARC 58 Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code CO or PR (Patient Responsibility) dependent upon liability. (Use PR when the GA modifier is appended to the line item).

MSN 09.040 - This item or service was denied because information required to make payment was incorrect.

MSN 15.20 - “The following polices were used when we made this decision: NCD 110.24.”

Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 110.24.”

--When denying claims for covered CAR T-cell therapy procedures because they do not contain new modifier -LU, use the following messages:

CARC 4 - The procedure code is inconsistent with the modifier used. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is

available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code CO

MSN 15.20 - "The following polices were used when we made this decision: NCD 110.24."

Spanish Version – "Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 110.24."

--When denying claims for covered CAR T-cell therapy procedures because the fractional units exceed 1 unit, use the following messages:

CARC 151 - Payment adjusted because the payer deems the information submitted does not support this many/frequency of services.

Group Code CO

MSN 15.060 - The information provided does not support the need for this many services or items within this period of time.

Spanish Version - (La información proporcionada no confirma la necesidad de estos servicios o artículos en este periodo de tiempo.)

-- Contractors shall reject claims for <u>allogeneic</u> CAR T-cell therapy ICD-10-PCS codes XW033G7 and XW043G7 and <u>autologous</u> CAR T-cell therapy ICD-10-PCS codes XW033C7 and XW043C7 when not billed for clinical trials under NCD 310.1 with the NCT number for the specific trial, condition code 30, value code D4, and the Z00.6 clinical trial diagnosis code effective for dates of service on or after October 1, 2021, using the following messages:

CARC 55: Procedure/treatment/drug is deemed experimental/investigational by the payor.

Group Code: CO

MSN 16.77 – This service/item was not covered because it was not provided as part of a qualifying trial/study.

Spanish Version – (Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo clínico/estudio calificado.)

In addition to the codes listed above, contractors shall afford appeal rights to all denied parties.