

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 11721</b>	<b>Date: November 28, 2022</b>
	<b>Change Request 12928</b>

**SUBJECT: National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to provide updated instructions on how to process claims in the Part B physician office and independent clinics for Chimeric Antigen Receptor (CAR) T Cell Therapy.

**EFFECTIVE DATE: January 1, 2022**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: January 3, 2023**

**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.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	TOC
R	32/400/Chimeric Antigen Receptor (CAR) T-cell Therapy
R	32/400/1/ Coverage Requirements
R	32/400/2/Billing Requirements
R	32/400/2/2/ A/B MAC (A) Revenue Code
R	32/400/2/3/ A/B MAC Billing HCPCS/CPT Codes
N	32/400/2/3/1/ A/B MAC (B) Places of Service (POS)
R	32/400/2/4/ A/B MAC Diagnosis and Procedure Code Requirements
R	32/400/2/5/ Billing Information for Professional Claims
R	32/400/3/Payment Requirements
R	32/400/4/Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages
R	32/400/5/Claims Editing

### **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: 11721	Date: November 28, 2022	Change Request: 12928
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**SUBJECT: National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy**

**EFFECTIVE DATE: January 1, 2022**

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**IMPLEMENTATION DATE: January 3, 2023**

## I. GENERAL INFORMATION

**A. Background:** Implementing CR 12177 did not allow for processing CAR T-cell claims in the Part B physician office and independent clinics. CR 12177 only allowed CAR T-cell claims in Part A inpatient and hospital-affiliated places of service that were Risk Evaluation and Mitigation Strategies (REMS)-approved. This CR implements POS 11 and 49 as valid POS for CAR T-cell claims.

The CAR T-cell related HCPCS codes can't be processed in the current MCS system because the field length for the dollar amount is only 7 digits (line item or total maximum is 99999.99). The CAR T-cell products need to bill as 1 unit with a dollar amount of 8 digits (999999.99). This isn't a problem when a single HCPCS code can be billed for multiple units or when the provider is billing multiple HCPCS codes. The reason CAR T-cell codes are an issue is because, based on the code description, they are billed as a single unit of one therapeutic dose. For example, Q2041 = 1 unit = \$448,316.40.

The total payment for the CAR T-cell HCPCS 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. Depending on the Medicare allowed payment for the CAR T-cell HCPCS, some providers will be able to submit 5 separate claims for 0.2 units on each claim.

Providers will need to utilize the new modifier -LU, fractionated payment CAR T-cell therapy, modifier -76, repeat procedure or service by same physician or other qualified healthcare professional, and modifier -KX, requirements specified in the medical policy have been met, to attest they are a REMS-approved facility. So, 3 modifiers will be needed on any CAR T-cell claim.

NOTE: Part A OPPS providers do not need to change their billing in FISS; they will continue to bill 1 unit for the CAR T-cell product.

**See the following websites:**

Kymriah® <https://www.us.kymriah.com/treatment-center-locator>

Inpatient hospital (IP) = XW033J7/XW043J7

Part A Outpatient (OP), Critical Access Hospitals (CAHs), and Part B = Q2042

Yescarta® <https://www.yescarta.com/find-a-treatment-center>

IP = XW033H7/XW043H7

Part A OP/CAHs and Part B = Q2041

Tecartus™ <https://www.tecartus.com/hcp/treatment-center-locator>

IP = XW033M7/XW043M7

Part A OP/CAHs and Part B = Q2053

Breyanzi® <https://www.celltherapy360.com/locations>

IP = XW033N7/XW043N7

Part A OP/CAHs and Part B = Q2054

ABECMA® <https://www.celltherapy360.com/locations>

IP = XW033K7/XW043K7

Part A OP/CAHs and Part B effective January 1, 2022 = Q2055

Part A OP/CAHs effective October 1-December 31, 2021 = C9081

CARVYKTI™ <https://www.carvyktihcp.com/treatment-centers>

IP = XW033A7/XW043A7

Part A OP/CAHs and Part B effective October 1, 2022 = Q2056

Part A OP/CAHs effective July 1-September 30, 2022 = C9098

Part A OP/CAHs effective February 28-June 30, 2022 = C9399

Part B effective February 28-September 30, 2022 = J3490, J3590, and J9999

The use of non-FDA-approved autologous T-cells expressing at least one CAR is non-covered. Autologous treatment for cancer with T-cells expressing at least one CAR is non-covered when the NCD criteria are not met. Routine costs in clinical trials that use CAR T-cell therapy as an investigational agent that meet the requirements listed in NCD 310.1 will be covered effective August 7, 2019.

NOTE: The use of allogenic T-cells from healthy donors are not autologous CAR T-cell treatments and shall not be billed as autologous CAR T-cell treatments.

NOTE: As specific codes are created for current and future FDA-approved CAR T-cell therapies, the MACs will update their local systems and above websites accordingly. Also see the CMS HCPCS Website:<https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>.

NOTE: See CR 12177 for initial implementing instructions not being revised in this CR as this CR is directed at Part B MACs and CWF.

NOTE: New HCPCS modifier -LU is included in the January 2023 HCPCS Update and is effective retroactively for use on claims with DOS January 1, 2022, forward.

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.

**B. Policy:** The Centers for Medicare & Medicaid Services (CMS) reviewed the evidence for CAR T-cell therapy in patients with cancer, and will cover Food and Drug Administration (FDA)-approved CAR T-cell therapy under the conditions specified in Publication 100-03, National Coverage Determination (NCD) Manual, section 110.24. Effective for claims with dates of service on or after August 7, 2019, CMS covers autologous treatment for cancer with T-cells expressing at least one CAR when administered at healthcare facilities enrolled in the FDA REMS and used for a medically accepted indication as defined at Social Security 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 CR 12177 for initial implementing instructions that have not been changed as a result of this CR.

## II. BUSINESS REQUIREMENTS TABLE

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



Number	Requirement	Responsibility									
		A/B MAC			D M E	Shared- System Maintainers				Other	
		A	B	H H H		F M V C	M C M S	V M S S	C W F		
	<p>Information REF), if present.</p> <p>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 <a href="http://www.cms.gov/mcd/search.asp">www.cms.gov/mcd/search.asp</a>. If you do not have web access, you may contact the contractor to request a copy of the NCD.</p> <p>Group Code CO (Contractual Obligations).</p> <p>MSN 16.2 – This service cannot be paid when provided in this location/facility.</p> <p>Spanish Version – Este servicio no se puede pagar cuando es suministrado en esta sitio/facilidad.</p> <p>In addition to the codes listed above, contractors shall afford appeal rights to all denied parties.</p>										
12928.3.1	<p>Contractors shall deny claims that are not submitted by or performed in an FDA REM approved facility using the following codes:</p> <p>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.</p> <p>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 <a href="http://www.cms.gov/mcd/search.asp">www.cms.gov/mcd/search.asp</a>. If you do not have web access, you may contact the contractor to request a copy of the NCD.</p> <p>Group Code CO (Contractual Obligations).</p> <p>MSN 16.2 – This service cannot be paid when provided in this location/facility.</p> <p>Spanish Version – Este servicio no se puede pagar cuando es suministrado en esta sitio/facilidad.</p>		X								





Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared-System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
12928.5.1	<p>Part B MACs shall deny claims for covered CAR T-cell therapy procedures that are not performed in POS 11 or 49 using the following messages:</p> <p>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.</p> <p>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 <a href="http://www.cms.gov/mcd/search.asp">www.cms.gov/mcd/search.asp</a>. If you do not have web access, you may contact the contractor to request a copy of the NCD.</p> <p>Group Code CO or PR (Patient Responsibility) dependent upon liability. (Use PR when the GA modifier is appended to the line item).</p> <p>MSN 09.040 - This item or service was denied because information required to make payment was incorrect.</p>		X								
12928.5.1.1	<p>(Continuation of BR 12928.5.1)</p> <p>MSN 15.20 - “The following polices were used when we made this decision: NCD 110.24.”</p> <p>Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 110.24.”</p> <p>In addition to the codes listed above, contractors shall afford appeal rights to all denied parties.</p>		X								
12928.6	Part B MACs shall allow modifier -76 (repeat procedure or service by same physician or other		X								

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared-System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
	<p>qualified healthcare professional) on subsequent claims for HCPCS codes Q2041, Q2042, Q2053, Q2054, Q2055, Q2056, J3490, J3590, and J9999 billed on the same date service (DOS).</p> <p>Note: This modifier will assist with preventing duplicate denials.</p>										
12928.7	<p>Effective for claims with DOS on and after January 1, 2022, Part B MACs shall require new modifier -LU (fractionated payment CAR T-cell therapy) when billing HCPCS codes Q2041, Q2042, Q2053, Q2054, Q2055, Q2056, J3490, J3590, and J9999.</p> <p>Note: When a provider submits a -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.</p> <p>Note: See January 2023 HCPCS Update</p>		X								
12928.7.1	<p>Part B MACs shall deny CAR T-cell HCPCS Q2041, Q2042, Q2053, Q2054, Q2055, Q2056, J3490, J3590, and J9999 when billed without modifier -LU from BR 12928.7 using the following messages:</p> <p>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.</p> <p>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 <a href="http://www.cms.gov/mcd/search.asp">www.cms.gov/mcd/search.asp</a>. If you do not have web access, you may contact the contractor to request a copy of the NCD.</p> <p>Group Code CO</p>		X								
12928.7.1.1	(Continuation of BR 12928.7.1)		X								

Number	Requirement	Responsibility									
		A/B MAC		H H H	D M E M A C	Shared- System Maintainers				Other	
		A	B			F I S S	M C S	V M S	C W F		
	<p>MSN 15.20 - “The following polices were used when we made this decision: NCD 110.24.”</p> <p>Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 110.24.”</p> <p>In addition to the codes listed above, contractors shall afford appeal rights to all denied parties.</p> <p>Note: For Unclassified/Not Otherwise Classified codes, modifier -LU is only required if there is an indication of a CAR T-cell product.</p>										
12928.8	<p>Part B MACs 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.</p> <p>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.</p> <p>Example: CAR T-cell product allowed payment \$445,000:</p> <p>0.2 units = \$89,000.06</p> <p>0.2 units = \$89,000.00</p> <p>0.2 units = \$88,999.99</p> <p>0.2 units = \$88,999.98</p> <p>0.2 units = \$88,999.97</p> <p>Note: Contractors shall only pay up to 1 unit, anything exceeding 1 unit must be denied.</p> <p>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.</p>		X								

Number	Requirement	Responsibility									
		A/B MAC		D M E	Shared- System Maintainers				Other		
		A	B		H H H	M A C	F I S S	M C S		V M S	C W F
	<p>Example: CAR T-cell product with dose exceeded allowed payment \$150,000:</p> <p>0.5 units = \$74,999.00</p> <p>0.5 units = \$75,001.00</p> <p>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:</p> <p>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).</p>										
12928.8.1	<p>Part B MACs shall deny fractional units that exceed 1 unit for CAR T-cell HCPCS Q2041, Q2042, Q2053, Q2054, Q2055, Q2056, J3490, J3590, and J9999 using the following messages:</p> <p>CARC 151 - Payment adjusted because the payer deems the information submitted does not support this many/frequency of services.</p> <p>Group Code CO.</p> <p>MSN 15.060 - The information provided does not support the need for this many services or items within this period of time.</p> <p>Spanish Version - (La información proporcionada no confirma la necesidad de estos servicios o artículos en este periodo de tiempo.)</p>	X	X								
12928.9	<p>Contractors shall end-date current denial editing (created with CR 12177-04.4, 12399.3, 12480.10, and 12822.2.1 to deny as a Part A service) for HCPCS codes Q2041, Q2042, Q2053, Q2054, Q2055, Q2056, C9098, C9399, J3490, J3590, and J9999, effective for dates of service on or after January 1, 2022.</p>		X								



Number	Requirement	Responsibility									
		A/B MAC		H H H	D M E M A C	Shared- System Maintainers				Other	
		A	B			F I S S	M C S	V M S	C W F		
	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.)										
12928.13	Contractors shall provide targeted education over and above their normal process to ensure the fractionated payment and multiple billings is adequately understood by the providers.	X	X								

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility									
		A/B MAC		H H H	D M E M A C	C E D I					
		A	B								
12928.14	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the “MLN Connects” listserv to get MLN content notifications. You don’t need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X	X								

### IV. SUPPORTING INFORMATION

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

*"Should" denotes a recommendation.*

<b>X-Ref Requirement Number</b>	<b>Recommendations or other supporting information:</b>
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**Section B: All other recommendations and supporting information:** N/A

**V. CONTACTS**

**Pre-Implementation Contact(s):** Patricia Brocato-Simons, patricia.brocato@cms.hhs.gov (Coverage and Analysis) , Wanda Belle, wanda.belle@cms.hhs.gov (Coverage and Analysis) , Lisa Davis, Lisa.Davis@cms.hhs.gov (Coverage and Analysis) , Eric Coulson, Eric.Coulson@cms.hhs.gov (Suppliers Claim Processing) , Yvette Cousar, Yvette.Cousar@cms.hhs.gov (Professional Claims Billing) , William Ruiz, William.Ruiz@cms.hhs.gov (Insitutional Claims Billing)

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

**VI. 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**

**Medicare Claims Processing Manual**  
**Chapter 32 – Billing Requirements for Special Services**  
**Table of Contents**  
*(Rev. 11721; Issued: 11-28-22)*

**400 - Chimeric Antigen Receptor (CAR) T-*cell Therapy***

***400.2.3.1 – A/B MAC (B) Places of Service (POS)***



## **400 - Chimeric Antigen Receptor (CAR) T-cell Therapy**

*(Rev. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)*

T-cells employ a number of mechanisms to fight abnormal cells such as cancer. One type of therapy that leverages the immune system, immunotherapy, is Chimeric Antigen Receptor (CAR) T-cell therapy. CAR T-cells have been genetically altered in order to improve the ability of the T-cells to fight cancer.

### **400.1 - Coverage Requirements**

*(Rev. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)*

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>

**NOTE:** The use of allogenic T-cells from healthy donors are not autologous *CAR T-cell* treatments and shall not be billed as autologous *CAR T-cell* treatments.

### **400.2 - Billing Requirements**

*(Rev. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)*

Effective for dates of service on or after August 7, 2019, contractors shall pay for line-item professional claims from approved providers for the administration of autologous treatment for cancer with T-cells expressing at least one CAR with *Current Procedural Terminology (CPT) code* 0540T.

*Contractors shall not require the NCD 110.24 -KX modifier and diagnosis codes for clinical trials under NCD 310.1. These claims shall be billed 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.*

*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.*

#### **400.2.2 - A/B MAC (A) Revenue Code**

***(Rev. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)***

The following Revenue Codes are used for billing inpatient and outpatient CAR T-cell therapy services:

0871 – Cell Collection w/*CPT* code 0537T

0872 – Specialized Biologic Processing and Storage – Prior to Transport w/*CPT code* 0538T

0873 – Storage and Processing after Receipt of Cells from Manufacturer w/*CPT code* 0539T

0874 – Infusion of Modified Cells w/*CPT code* 0540T

0891 – Special Processed Drugs – FDA Approved Cell Therapy w/ *Healthcare Common Procedure Coding System* (HCPCS) *codes* Q2041, Q2042, C9073 (replaced with Q2053 April 1, 2021), C9076 (*replaced with Q2054 October 1, 2021*), C9081 (*replaced with Q2055 January 1, 2022*), C9098 (*replaced with Q2056 October 1, 2022*), or C9399

#### **400.2.3 - A/B MAC Billing HCPCS/CPT Codes**

***(Rev. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)***

The following HCPCS/*CPT* procedure codes are used for billing outpatient CAR T-cell therapy services:

*HCPCS Code Q2041 for Axicabtagene Ciloleucel*

HCPCS Code Q2042 for Tisagenlecleucel

HCPCS *Code* Q2053 for Brexucabtagene Autoleucel (effective April 1, 2021)

*HCPCS Code Q2054 for Lisocabtagene Maraleucel (effective October 1, 2021)*

*HCPCS Code Q2055 for Idecabtagene Vicleucel (effective January 1, 2022)*

*HCPCS Code Q2056 for Ciltacabtagene Autoleucel (effective October 1, 2022)*

HCPCS Code C9073 for Brexucabtagene Autoleucel (prior to April 1, 2021)

HCPCS *Code* C9076 for Lisocabtagene maraleucel (*prior to October 1, 2021*)

*HCPCS Code C9081 for Idecabtagene Vicleucel (prior to January 1, 2022)*

*HCPCS Code C9098 for Ciltacabtagene Autoleucel (prior to October 1, 2022)*

HCPCS Code C9399, J3490, J3590, or J9999 for unclassified drugs or biologicals when dose of CAR T-cell therapy exceeds code descriptor or *when other CAR T-cell therapy obtains FDA approval but has not yet received a specific HCPCS code*

*CPT Code 0537T collection/handling\**

*CPT Code 0538T preparation for transport\**

*CPT Code 0539T receipt and preparation\**

*CPT Code 0540T the provider (physician/NPP) procedure to administer CAR T-cells*

\* Procedure represents the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the Outpatient Prospective Payment System (OPPS)/*Medicare Physician Fee Schedule (MPFS)*.

#### ***400.2.3.1 – A/B MAC (B) Places of Service (POS)***

***(Rev. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)***

*The following places of service (POS) are covered for CAR T-cells product HCPCS codes (Q2041, Q2042, Q2053-Q2056, J3490, J3590, and J9999):*

*11 (Office)*

*49 (Independent clinic)*

*Professional claims for the procedure to administer CAR T-cells (0540T) may include (but are not necessarily limited to):*

*11 (Office)*

*19 (Off Campus-Outpatient Hospital)*

*21 (Inpatient Hospital)*

*22 (On Campus-Outpatient Hospital)*

*49 (Independent Clinic)*

#### **400.2.4 - A/B MAC Diagnosis and Procedure Code Requirements**

***(Rev. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)***

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 Autoleucl into Peripheral Vein, Percutaneous Approach, New Technology Group 7*

*CARVYKTI™ - XW043A7: Introduction of Ciltacabtagene Autoleucl 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*

***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 Autoleucl Immunotherapy into Peripheral Vein,  
Percutaneous Approach, New Technology Group 6

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

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

Breyanzi®- XW24376 – Transfusion of lisocabtagene maraleucl 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 REMS facility and diagnosis codes for autologous CAR T-cell therapy ICD-10-PCS codes XW033A7/XW043A7, XW033H7/XW043H7, XW033J7/XW043J7, XW033K7/XW043K7, XW033M7/XW043M7, and XW033N7/XW043N7 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. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)***

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](http://www.cms.hhs.gov/manuals/104_claims/clm104index.asp)).

Contractors shall pay professional claims for CAR T-cell therapy when the service is administered at a healthcare facility that is enrolled in the REMS program as a REMS participating site. Contractors shall use the CMS HCPCS Website for current HCPCS codes, <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>, and the individual REMS facility websites noted at section 400.1.

Contractors shall create an edit that only allows CAR T-cell therapy services to be submitted by, or performed in, an FDA REMS approved facility when the line item has a -KX modifier appended. **Note:** When a provider submits a -KX modifier on CAR T-cell therapy services, they are acknowledging that the service is being submitted by or performed in an FDA REMS approved facility.

*Contractors shall create an edit that only allows CAR T-cell therapy services when the line item has a -LU modifier appended in addition to a -KX modifier. 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. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)*

#### 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 OPSS.

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 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 OPSS.

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

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

In instances when *a physician or non-physician provider* administers the CAR T-*cell product* in the HOPD setting, report CPT code 0540T for the administration. *The HOPD reports CAR T-*



*cell product HCPCS code* Q2041, Q2042, Q2053 (effective April 1, 2021), C9073 (prior to April 1, 2021), *Q2054 (effective October 1, 2021)*, C9076 (prior to October 1, 2021), *Q2055 (effective January 1, 2022)*, C9081 (prior to January 1, 2022), *Q2056 (effective October 1, 2022)*, C9098 (prior to October 1, 2022), or, if a more specific code is unavailable, the most appropriate unclassified drug code (e.g., C9399 for unclassified drugs or biologicals). 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 OPSS/Ambulatory Surgery Center final rule (83 FR 58904), 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 OPSS. 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-*cell* product, outpatient providers *should* code the *CAR T-cell* product service on the date that the CAR T-*cell* administration took place and not on the date when the cells were collected.

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

In instances when the CAR T-*cell product* is not ultimately administered to the beneficiary, but the CAR T-*cell* preparation services are initiated or performed in the HOPD facility, the hospital *shall* not report the *CAR T-cell product HCPCS* code (which only applies when *viable* T-cells are administered). HOPDs may report CPT *codes* 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Medicare will reject these codes.

### **Scenario 3: CAR T-*cell* Dosing and Preparation Services 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 *shall* not report the *CAR T-cell product HCPCS* code (which only applies when *viable* T-cells are administered in the *outpatient* 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-*cell product* 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.



## Physician Office or Non-Hospital Clinic

*The A/B MAC billing requirements will pay for CAR T-cell therapy products when the services are submitted in places of service 11 or 49. Proper adjudication of payment is based on fractionated units.*

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 that is enrolled in the REMS program as a REMS participating site, report CPT code 0540T for the administration and *CAR T-cell product* HCPCS code Q2041, Q2042, Q2053 (effective April 1, 2021), *Q2054 (effective October 1, 2021)*, *Q2055 (effective January 1, 2022)*, *Q2056 (effective October 1, 2022)*, 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: Regulations-and-Guidance.Ch26.

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*.

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

In instances when the *CAR T-cell product* is not ultimately administered to the beneficiary, but the CAR T-cells preparation services are initiated or performed in the physician office or other non-hospital clinic facility, the practitioner *shall* not report the *CAR T-cell product* HCPCS code (which only applies when *viable* T-cells are administered). The practitioner may report CPT *codes* 0537T, 0538T, and 0539T (as appropriate) on the professional claim. Medicare will *deny* these codes *as Medicare does not pay separately for this service*.

### **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 *shall* not report the *CAR T-cells product* HCPCS code (which only applies when *viable* T-cells are administered in the *outpatient* 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 product* 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.

***Scenario 4: CAR T-cells Dosing and Preparation Services in Physician Office or Non-Hospital Clinic, but Viable T-cells Administered in the HOPD 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 HOPD setting, the practitioner shall not report the CAR T-cell product HCPCS code (which only applies when the viable T-cells are administered). The HOPD that administers the T-cells may report CPT codes 0537T, 0538T, and 0539T (as appropriate) and the charges associated with each code under the appropriate revenue code on the HOPD claim. Medicare will reject these codes.*

**Note:** *When the cells are collected in the physician office setting and the CAR T-cell product is administered in the HOPD setting, HOPD 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. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)***

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.

**--Contractors shall deny claims for CAR T-cell therapy when the service is not administered through healthcare facilities that are enrolled in the FDA REMS requirements using 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](http://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 (Contractual Obligations).

MSN 16.2 – This service cannot be paid when provided in this location/facility.

Spanish Version – Este servicio no se puede pagar cuando es suministrado en esta sitio/facilidad.

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

**--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](http://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](http://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](http://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 allogeneic CAR T-cell therapy ICD-10-PCS codes XW033G7 and XW043G7 and autologous 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.

## **400.5 - Claims Editing**

*(Rev. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)*

### **A. Fee-For-Service Medicare**

Medicare edits CAR T-cell therapy claims based on requirements found in NCD 110.24.

### **B. Beneficiaries enrolled in Medicare Advantage (MA) plans**

Effective for claims with dates of service on and after August 7, 2019, CMS *determined* that the NCD requiring coverage of CAR T-cell therapy for cancer is a significant cost under section 422.109(a)(2) of title 42 of the Code of Federal Regulations. As a result, for CYs 2019 (beginning August 7, 2019) and 2020 only, original fee-for-service Medicare will pay for CAR T-cell therapy for cancer obtained by beneficiaries enrolled in Medicare Advantage (MA) plans when the coverage criteria outlined in the NCD are met. Plans should account for CAR T-cell therapy for cancer items and services in their contract year 2021 bids.

Consistent with §1862 (t)(2) of the Act, MACs will pay for CAR T-cell therapy for cancer for Medicare beneficiaries enrolled in MA plans in CYs 2019 (beginning August 7, 2019) and 2020.