CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11774	**Date: December 30, 2022**
	Change Request 12928

Transmittal 11721 issued November 28, 2022, is being rescinded and replaced by Transmittal 11774, dated, December 30, 2022 to revise the implementation date and to (1) remove duplicate Business Requirement (BR) 12928.3 and replace with the intended language, (2) clarify 1 unit per HCPCS code in BRs 12928.7, 12928.8, 12928.8.1, (3) clarify modifier -Q1 not -Q0 in BRs 12928.10, 12928.11, (4) change date to October 1, 2021 in BR 12928.11, (5) remove Part A from BR 12928.8.1, (6) where discussing NCD 310.1 replace 'FDA-approved' with 'qualifying clinical trial'. This correction also revises the IOM, the background section of the requirements, and the NCD excel file. All other information remains the same.

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 31, 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.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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: 11774	Date: December 30, 2022	Change Request: 12928

Transmittal 11721 issued November 28, 2022, is being rescinded and replaced by Transmittal 11774, dated, December 30, 2022 to revise the implementation date and to (1) remove duplicate Business Requirement (BR) 12928.3 and replace with the intended language, (2) clarify 1 unit per HCPCS code in BRs 12928.7, 12928.8, 12928.8.1, (3) clarify modifier -Q1 not -Q0 in BRs 12928.10, 12928.11, (4) change date to October 1, 2021 in BR 12928.11, (5) remove Part A from BR 12928.8.1, (6) where discussing NCD 310.1 replace 'FDA-approved' with 'qualifying clinical trial'. This correction also revises the IOM, the background section of the requirements, and the NCD excel file. All other information remains the same.

SUBJECT: National Coverage Determination (NCD 110.24): 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 31, 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 mainly directed at Part B MACs and CWF (see 11, 12, and 13 for Part A MACs).

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			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12928.1	Effective for Dates of Service (DOS) on or after January 1, 2022, contractors shall process CAR T-cell therapy claims consistent with the updated Claims Processing Manual, Publication 100-04, Chapter 32, Section 400.		X							
12928.2	Effective for line-items on claims with DOS on or after January 1, 2022, contractors shall recognize the updates to the following HCPCS codes as covered services under NCD 110.24. Q2041 (Yescarta) Q2042 (Kymriah) Q2053 (Tecartus) Q2054 (Breyanzi) Q2055 (Abecma) Q2056 (Carvykti) [effective 10/01/2022] J3490 (Unclassified drug), J3590 (Unclassified biologics), and J9999 (Not otherwise classified, antineoplastic drugs) to be used when (1) the dose of CAR T-cell therapy exceeds code descriptor, (2) when other CAR T-cell therapy obtains FDA approval but has not yet received a specific HCPCS code (such as with Carvykti effective 02/28/2022).		X							
12928.3	Contractors shall update the existing editing created in CR 12177 to include all other CAR T-cell therapy services to only be allowed and submitted by or performed in an FDA REM approved facility when the		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	line item has a -KX modifier appended. The additional services are listed in BR 12928.2 Note: When a provider submits a -KX modifier on a CAR T-cell therapy service, they are acknowledging that the service is being submitted by or performed in an FDA REM approved facility.									
12928.3.1	Contractors shall deny claims that are not submitted by or performed in an FDA REM approved facility using the following codes: 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 (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.		X							
12928.4	Contractors shall recognize the ICD-10 diagnoses codes necessary for coverage of CAR T-cell products in the NCD spreadsheet for services provided in BR 12928.2.		X							
12928.4.1	Contractors shall deny claims for covered CAR T-cell therapy procedures that do not contain the coding referenced in BR 12928.4 and the NCD spreadsheet using the following messages:		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	CARC 50 - These are non-covered services because this is not deemed a "medical necessity" by the payer. 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 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." In addition to the codes listed above, contractors shall afford appeal rights to all denied parties.									
12928.5	Part B MACs shall only allow places of service (POS) 11 (office) or 49 (independent clinic) for CAR T-cell products in BR 12928.2. (Note: CAR T-cell therapy is not allowed in an Ambulatory Surgical Center ASC)		X							
12928.5.1	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: 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		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	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.									
12928.5.1.1	(Continuation of BR 12928.5.1) 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." In addition to the codes listed above, contractors shall afford appeal rights to all denied parties.		X							
12928.6	Part B MACs shall allow modifier -76 (repeat procedure or service by same physician or other 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). Note: This modifier will assist with preventing duplicate denials.		X							
12928.7	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,		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Q2055, Q2056, J3490, J3590, and J9999. 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 per HCPCS code. Note: See January 2023 HCPCS Update									
12928.7.1	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: 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		X							
12928.7.1.1	(Continuation of BR 12928.7.1) 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." In addition to the codes listed above, contractors shall afford appeal rights to all denied parties. Note: For Unclassified/Not Otherwise Classified codes, modifier -LU is only required if there is an indication of a CAR T-cell product.		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12928.8	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. 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 per HCPCS code, 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		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	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).									
12928.8.1	Part B MACs shall deny fractional units that exceed 1 unit per HCPCS code for CAR T-cell HCPCS Q2041, Q2042, Q2053, Q2054, Q2055, Q2056, J3490, J3590, and J9999 using 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.)		X							
12928.9	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.		X							
12928.10	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 -Q1 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.		X							
12928.11	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,	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	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 October 1, 2021. 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 -Q1 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.									
12928.12	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.)	X								
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							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12928.14	Contractors shall adjust any claims that are brought to their attention.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12928.15	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.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s): Patricia Brocato-Simons, patricia.brocatosimons@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

NCD:	110.24
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA
ICD-10 CM	**ICD-10 CM Description**
	CMS reserves the right to add or remove diagnosis codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.
	FDA approved for Yescarta® (Axicabtagene Ciloleucel): **Yescarta® OP/CAHs=Q2041** **IP=XW033H7/XW043H7**
C82.01	Follicular lymphoma grade I, lymph nodes of head, face, and neck
C82.02	Follicular lymphoma grade I, intrathoracic lymph nodes
C82.03	Follicular lymphoma grade I, intra-abdominal lymph nodes
C82.04	Follicular lymphoma grade I, lymph nodes of axilla and upper limb
C82.05	Follicular lymphoma grade I, lymph nodes of inguinal region and lower limb
C82.06	Follicular lymphoma grade I, intrapelvic lymph nodes
C82.07	Follicular lymphoma grade I, spleen
C82.08	Follicular lymphoma grade I, lymph nodes of multiple sites
C82.09	Follicular lymphoma grade I, extranodal and solid organ sites
C82.11	Follicular lymphoma grade II, lymph nodes of head, face, and neck
C82.12	Follicular lymphoma grade II, intrathoracic lymph nodes
C82.13	Follicular lymphoma grade II, intra-abdominal lymph nodes
C82.14	Follicular lymphoma grade II, lymph nodes of axilla and upper limb
C82.15	Follicular lymphoma grade II, lymph nodes of inguinal region and lower limb
C82.16	Follicular lymphoma grade II, intrapelvic lymph nodes
C82.17	Follicular lymphoma grade II, spleen
C82.18	Follicular lymphoma grade II, lymph nodes of multiple sites
C82.19	Follicular lymphoma grade II, extranodal and solid organ sites
C82.31	Follicular lymphoma grade IIIa, lymph nodes of head, face, and neck
C82.32	Follicular lymphoma grade IIIa, intrathoracic lymph nodes
C82.33	Follicular lymphoma grade IIIa, intra-abdominal lymph nodes
C82.34	Follicular lymphoma grade IIIa, lymph nodes of axilla and upper limb
C82.35	Follicular lymphoma grade IIIa, lymph nodes of inguinal region and lower limb
C82.36	Follicular lymphoma grade IIIa, intrapelvic lymph nodes
C82.37	Follicular lymphoma grade IIIa, spleen
C82.38	Follicular lymphoma grade IIIa, lymph nodes of multiple sites
C82.39	Follicular lymphoma grade IIIa, extranodal and solid organ sites
C82.41	Follicular lymphoma grade IIIb, lymph nodes of head, face, and neck
C82.42	Follicular lymphoma grade IIIb, intrathoracic lymph nodes
C82.43	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes

C82.44	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb, intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb, spleen
C82.48	Follicular lymphoma grade IIIb, lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb, extranodal and solid organ sites
C82.51	Diffuse follicle center lymphoma, lymph nodes of head, face, and neck
C82.52	Diffuse follicle center lymphoma, intrathoracic lymph nodes
C82.53	Diffuse follicle center lymphoma, intra-abdominal lymph nodes
C82.54	Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb
C82.55	Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.56	Diffuse follicle center lymphoma, intrapelvic lymph nodes
C82.57	Diffuse follicle center lymphoma, spleen
C82.58	Diffuse follicle center lymphoma, lymph nodes of multiple sites
C82.59	Diffuse follicle center lymphoma, extranodal and solid organ sites
C82.61	Cutaneous follicle center lymphoma, lymph nodes of head, face, and neck
C82.62	Cutaneous follicle center lymphoma, intrathoracic lymph nodes
C82.63	Cutaneous follicle center lymphoma, intra-abdominal lymph nodes
C82.64	Cutaneous follicle center lymphoma, lymph nodes of axilla and upper limb
C82.65	Cutaneous follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.66	Cutaneous follicle center lymphoma, intrapelvic lymph nodes
C82.67	Cutaneous follicle center lymphoma, spleen
C82.68	Cutaneous follicle center lymphoma, lymph nodes of multiple sites
C82.69	Cutaneous follicle center lymphoma, extranodal and solid organ sites
C82.81	Other types of follicular lymphoma, lymph nodes of head, face, and neck
C82.82	Other types of follicular lymphoma, intrathoracic lymph nodes
C82.83	Other types of follicular lymphoma, intra-abdominal lymph nodes
C82.84	Other types of follicular lymphoma, lymph nodes of axilla and upper limb
C82.85	Other types of follicular lymphoma, lymph nodes of inguinal region and lower limb
C82.86	Other types of follicular lymphoma, intrapelvic lymph nodes
C82.87	Other types of follicular lymphoma, spleen
C82.88	Other types of follicular lymphoma, lymph nodes of multiple sites
C82.89	Other types of follicular lymphoma, extranodal and solid organ sites
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen

C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C85.11	Unspecified B-cell lymphoma, lymph nodes of head, face, and neck
C85.12	Unspecified B-cell lymphoma, intrathoracic lymph nodes
C85.13	Unspecified B-cell lymphoma, intra-abdominal lymph nodes
C85.14	Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb
C85.15	Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.16	Unspecified B-cell lymphoma, intrapelvic lymph nodes
C85.17	Unspecified B-cell lymphoma, spleen
C85.18	Unspecified B-cell lymphoma, lymph nodes of multiple sites
C85.19	Unspecified B-cell lymphoma, extranodal and solid organ sites
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face, and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face, and neck
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C85.86	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87	Other specified types of non-Hodgkin lymphoma, spleen
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites

NCD:	110.24
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA
ICD-10 CM	**ICD-10 CM Description**
	CMS reserves the right to add or remove diagnosis codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.
	FDA approved for Kymriah® (Tisagenlecleucel): **Kymriah® Part A OP and CAHs=Q2042** **IP=XW033J7/XW043J7** **R/R Diffuse Large B-cell Lymphoma (DLBCL), R/R Acute Lymphoblastic Leukemia (ALL) DOS 8/7/19,** **R/R Follicular Lymphoma (FL) DOS 5/27/22**
C82.01	Follicular lymphoma grade I, lymph nodes of head, face, and neck
C82.02	Follicular lymphoma grade I, intrathoracic lymph nodes
C82.03	Follicular lymphoma grade I, intra-abdominal lymph nodes
C82.04	Follicular lymphoma grade I, lymph nodes of axilla and upper limb
C82.05	Follicular lymphoma grade I, lymph nodes of inguinal region and lower limb
C82.06	Follicular lymphoma grade I, intrapelvic lymph nodes
C82.07	Follicular lymphoma grade I, spleen
C82.08	Follicular lymphoma grade I, lymph nodes of multiple sites
C82.09	Follicular lymphoma grade I, extranodal and solid organ sites
C82.11	Follicular lymphoma grade II, lymph nodes of head, face, and neck
C82.12	Follicular lymphoma grade II, intrathoracic lymph nodes
C82.13	Follicular lymphoma grade II, intra-abdominal lymph nodes
C82.14	Follicular lymphoma grade II, lymph nodes of axilla and upper limb
C82.15	Follicular lymphoma grade II, lymph nodes of inguinal region and lower limb
C82.16	Follicular lymphoma grade II, intrapelvic lymph nodes
C82.17	Follicular lymphoma grade II, spleen
C82.18	Follicular lymphoma grade II, lymph nodes of multiple sites
C82.19	Follicular lymphoma grade II, extranodal and solid organ sites
C82.31	Follicular lymphoma grade IIIa, lymph nodes of head, face, and neck
C82.32	Follicular lymphoma grade IIIa, intrathoracic lymph nodes
C82.33	Follicular lymphoma grade IIIa, intra-abdominal lymph nodes
C82.34	Follicular lymphoma grade IIIa, lymph nodes of axilla and upper limb
C82.35	Follicular lymphoma grade IIIa, lymph nodes of inguinal region and lower limb
C82.36	Follicular lymphoma grade IIIa, intrapelvic lymph nodes
C82.37	Follicular lymphoma grade IIIa, spleen
C82.38	Follicular lymphoma grade IIIa, lymph nodes of multiple sites
C82.39	Follicular lymphoma grade IIIa, extranodal and solid organ sites
C82.41	Follicular lymphoma grade IIIb, lymph nodes of head, face, and neck

C82.42	Follicular lymphoma grade IIIb, intrathoracic lymph nodes
C82.43	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes
C82.44	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb, intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb, spleen
C82.48	Follicular lymphoma grade IIIb, lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb, extranodal and solid organ sites
C82.51	Diffuse follicle center lymphoma, lymph nodes of head, face, and neck
C82.52	Diffuse follicle center lymphoma, intrathoracic lymph nodes
C82.53	Diffuse follicle center lymphoma, intra-abdominal lymph nodes
C82.54	Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb
C82.55	Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.56	Diffuse follicle center lymphoma, intrapelvic lymph nodes
C82.57	Diffuse follicle center lymphoma, spleen
C82.58	Diffuse follicle center lymphoma, lymph nodes of multiple sites
C82.59	Diffuse follicle center lymphoma, extranodal and solid organ sites
C82.61	Cutaneous follicle center lymphoma, lymph nodes of head, face, and neck
C82.62	Cutaneous follicle center lymphoma, intrathoracic lymph nodes
C82.63	Cutaneous follicle center lymphoma, intra-abdominal lymph nodes
C82.64	Cutaneous follicle center lymphoma, lymph nodes of axilla and upper limb
C82.65	Cutaneous follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.66	Cutaneous follicle center lymphoma, intrapelvic lymph nodes
C82.67	Cutaneous follicle center lymphoma, spleen
C82.68	Cutaneous follicle center lymphoma, lymph nodes of multiple sites
C82.69	Cutaneous follicle center lymphoma, extranodal and solid organ sites
C82.81	Other types of follicular lymphoma, lymph nodes of head, face, and neck
C82.82	Other types of follicular lymphoma, intrathoracic lymph nodes
C82.83	Other types of follicular lymphoma, intra-abdominal lymph nodes
C82.84	Other types of follicular lymphoma, lymph nodes of axilla and upper limb
C82.85	Other types of follicular lymphoma, lymph nodes of inguinal region and lower limb
C82.86	Other types of follicular lymphoma, intrapelvic lymph nodes
C82.87	Other types of follicular lymphoma, spleen
C82.88	Other types of follicular lymphoma, lymph nodes of multiple sites
C82.89	Other types of follicular lymphoma, extranodal and solid organ sites
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb

C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C85.11	Unspecified B-cell lymphoma, lymph nodes of head, face, and neck
C85.12	Unspecified B-cell lymphoma, intrathoracic lymph nodes
C85.13	Unspecified B-cell lymphoma, intra-abdominal lymph nodes
C85.14	Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb
C85.15	Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.16	Unspecified B-cell lymphoma, intrapelvic lymph nodes
C85.17	Unspecified B-cell lymphoma, spleen
C85.18	Unspecified B-cell lymphoma, lymph nodes of multiple sites
C85.19	Unspecified B-cell lymphoma, extranodal and solid organ sites
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face, and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face, and neck
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C85.86	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87	Other specified types of non-Hodgkin lymphoma, spleen
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C91.00	Acute lymphoblastic leukemia, not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse

NCD:	110.24
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA
ICD-10 CM	**ICD-10 CM Description**
	CMS reserves the right to add or remove diagnosis codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.
	FDA approved for Tecartus™ (Brexucabtagene Autoleucel): **Tecartus™ OP/CAHs=Q2053** **IP=XW033M7/XW043M7**
C83.11	Mantle cell lymphoma, lymph nodes of head, face, and neck
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83:14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse

NCD:	110.24
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA
ICD-10 CM	**ICD-10 CM Description**
	CMS reserves the right to add or remove diagnosis codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.
	FDA approved for Breyanzi® (Lisocabtagene Maraleucel; Liso-Cel): **Breyanzi® OP/CAHs=Q2054** **IP=XW033N7/XW043N7**
C82.41	Follicular lymphoma grade IIIb, lymph nodes of head, face, and neck
C82.42	Follicular lymphoma grade IIIb, intrathoracic lymph nodes
C82.43	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes
C82.44	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb, intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb, spleen
C82.48	Follicular lymphoma grade IIIb, lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb, extranodal and solid organ sites
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C85.11	Unspecified B-cell lymphoma, lymph nodes of head, face, and neck
C85.12	Unspecified B-cell lymphoma, intrathoracic lymph nodes
C85.13	Unspecified B-cell lymphoma, intra-abdominal lymph nodes
C85.14	Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb
C85.15	Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.16	Unspecified B-cell lymphoma, intrapelvic lymph nodes
C85.17	Unspecified B-cell lymphoma, spleen
C85.18	Unspecified B-cell lymphoma, lymph nodes of multiple sites
C85.19	Unspecified B-cell lymphoma, extranodal and solid organ sites
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face, and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes

C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face, and neck
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C85.86	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87	Other specified types of non-Hodgkin lymphoma, spleen
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites

NCD:	110.24
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA

ICD-10 CM	ICD-10 CM Description
	CMS reserves the right to add or remove diagnosis codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.
	FDA approved for ABECMA® (Idecabtagene Vicleucel): **ABECMA® OP/CAHs=Q2055 (use HCPCS C9081 10/1/21-12/30/2021)** **IP=XW033K7/XW043K7**
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

NCD:	110.24
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA

ICD-10 CM	ICD-10 CM Description
	CMS reserves the right to add or remove diagnosis codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.
	FDA approved Carvykti™(ciltacabtagene autoleucel) for Multiple myeloma effective 2/28/22: **Carvykti™ OP/CAHs=HCPCS Q2056 effective 10/1/22 (use HCPCS C9399 2/28/22-6/30/22, C9098 7/1/22-9/30/22, Q2056 10/1/22 forward)** **IP=XW033A7/XW043A7** **Part B effective February 28-September 30, 2022 = J3490, J3590, and J9999**
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

NCD:	110.24
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA

ICD-10 PCS	ICD-10 PCS Description	
	CMS reserves the right to add or remove diagnosis codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.	
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	Carvykti™
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	Yescarta®
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	Kymriah®
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	Abecma®
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	Tecartus™
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	Breyanzi®
	NOTE: Since allogenic T-cells are by definition not autologous CAR-T, it is inappropriate to use any of the above autologous CAR T-cell ICD-10 PCS procedure codes for allogenic T-cell treatments.	
	Only for new/future CAR T-cell products FDA-approved while awaiting their own 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	Autologous
XW043C7	Introduction of Autologous Engineered Chimeric Antigen Receptor T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7	Autologous
XW033G7	Introduction of Allogeneic Engineered Chimeric Antigen Receptor T-cell Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7	Allogeneic
XW043G7	Introduction of Allogeneic Engineered Chimeric Antigen Receptor T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7	Allogeneic

NCD:	110.24
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy (CR12177, CR12399, CR12480, CR12606, CR12822, CR12928)
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA

	Rule Description	Proposed HCPCS/CPT	Frequency Limitations	TOB (Part A) / POS (Part B)	Revenue Code (Part A only)	Modifier	Provider Specialty	Proposed MSN Message	Proposed CARC Message	Proposed RARC Message
Part A	**HISTORY OF ALL CODES APPEAR IN REVISION HISTORY BELOW AND IN CR 12177** **A/MACs**: Effective for Dates of Service (DOS) on or after 1/1/22, shall process CAR T-cell therapy claims consistent with the updated Claims Processing Manual, Publication 100-04, Chapter 32, Section 400.									
Part A	**A/MACs** shall create an ECPS event that only allows CAR T-cell therapy services to be submitted by or performed in an FDA REM-approved facility.							16.2	58	N386
Part A	**A/MACs**: Effective for DOS 8/7/19, shall recognize the most current CAR T-cell therapy ICD-10-PCS codes and their corresponding ICD-10 dx. **NOTE**: Since allogenic T-cells are by definition not autologous CAR-T, it is inappropriate to use any of the 1st 10 specific autologous CAR T-cell ICD-10 PCS procedure codes for allogenic T-cell treatments. **NOTE:** Only Use the latter 4 ICD-10 PCS codes for new/future CAR-T cell products either awaiting dedicated PCS codes or under NCD 310.1 clinical trials.	XW033A7 XW043A7 XW033H7 XW043H7 XW033J7 XW043J7 XW033K7 XW043K7 XW033M7 XW043M7 XW033N7 XW043N7 XW033C7 XW034C7 XW033G7 XW034G7						15.19 15.20	50	N386
Part A	**A/MACs**: Effective for line-items on claims with DOS 8/7/19 (depending on FDA approval of each therapy), A/MACs shall recognize the following coding necessary for coverage of CAR-T IP or OP facility claims for the corresponding ICD-10 dx: HCPCS Q2041 (Yescarta ®), DOS 8/7/19, HCPCS Q2042 (Kymriah®), DOS 8/7/19, FL DOS 5/27/22 HCPCS Q2053 (Tecartus™), DOS 7/24/20, HCPCS Q2054 (Breyanzi®) DOS 2/5/21, HCPCS Q2055 (Abecma®), DOS 3/27/21, HCPCS Q2056 (Carvykti™) DOS 2/28/22 and, HCPCS Code C9399 (Unclassified drugs or biologicals) to be used (1) when the dose of CAR T□cell therapy exceeds code descriptor, (2) when other CAR T-cell therapy obtains FDA approval but has not yet received a specific HCPCS code, along with: Revenue Code 0891 (for institutional claims only).	C9399 Q2041 Q2042 Q2053 Q2054 Q2055 Q2056			0891			15.19 15.20	50	N386

NCD:	110.24										
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy (CR12177, CR12399, CR12480, CR12606, CR12822, CR12928)										
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf										
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA										
Part A	**A/MACs**: Effective for line-items on claims with DOS 8/7/19, shall recognize for CAR T-cell therapy IP or OP facility claims: CPT codes 0537T, 0538T, and 0539T as not separately payable services under NCD 110.24 (they are tracking codes only), along with: Revenue code 0871, 0872, and 0873, respectively (for institutional claims only). Note: CPT codes 0537T, 0538T, and 0539T have a OPPS status indicator "B" (Code not recognized by OPPS) for Part A and a status indicator "B" (Bundled) for Part B, therefore, no additional system editing is required.	0537T 0538T 0539T			0871 0872 0873						
Part A	**A/MACs**: Effective for line-items on claims with DOS 8/7/19, shall recognize for CAR T-cell therapy IP or OP facility claims: HCPCS code 0540T as a covered service for the corresponding ICD-10 dx under NCD 110.24 when used for administering a CAR-T biological service. Along with: Revenue Code 0874 (for institutional claims only).	0540T			0874			15.19 15.20	50	N386	
Part A	**A/MACs**: Effective for claims with DOS 8/7/19, shall pay for professional services provided in a Method II CAH, for the administration of treatment for cancer with T-cells expressing at least one CAR in a facility that is enrolled in the REMS program as a REMS participating site, with HCPCS 0540T with Revenue Codes 096X, 097X, and 098X	0540T			096X 097X 098X						
Part A	**A/MACs: Part A Inpatient:** Contractors shall **not require** NCD 110.24 REMS facility and dx 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 dx effective DOS on or after 10/1/21. **Part A Outpatient (OPPS):** Contractors shall **not require** NCD 110.24 REMS facility and dx 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 -Q1 clinical trial modifier for routine clinical services, condition code 30, value code D4, and the Z00.6 clinical trial dx effective DOS on or after 8/7/19. **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.	IP: XW033A7 XW043A7 XW033H7 XW043H7 XW033J7 XW043J7 XW033K7 XW043K7 XW033M7 XW043M7 XW033N7 XW043N7 OPPS: 0540T				Q1					

NCD:	110.24									
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy (CR12177, CR12399, CR12480, CR12606, CR12822, CR12928)									
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf									
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA									
Part A	**A/MACs:** 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 dx effective DOS on or after 10/1/21, using the following messages:	XW033G7 XW043G7 XW033C7 XW043C7						16.77	55	Group: CO
Part A	**A/MACs:** shall allow Risk Medicare Advantage beneficiaries/providers to bill Medicare Fee-for-Service (FFS) for CAR-T services covered under NCD 110.24 for DOS 8/7/19-12/31/20, based on significant cost threshold requirements. **A/MACs** shall not search for CAR T-cell therapy claims with DOS 8/7/19, but shall adjust claims brought to their attention as appropriate.									

NCD:	110.24
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy (CR12177, CR12399, CR12480, CR12606, CR12822, CR12928)
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA

	Rule Description Part B	Proposed HCPCS/CPT Part B	Frequency Limitations	POS (Part B)	n/a	Modifier Part B	Provider Specialty	Proposed MSN Message Part B	Proposed CARC Message Part B	Proposed RARC Message Part B
Part B	**B/MACs**: Effective for DOS on or after 1/1/2022, shall process CAR T-cell therapy claims consistent with the updated Claims Processing Manual, Publication 100-04, Chapter 32, Section 400.									
Part B	**B/MACs**: Effective for line-items on claims with DOS on or after January 1, 2022, contractors shall recognize the updates to the following HCPCS codes as covered services under NCD 110.24. Q2041 (Yescarta) Q2042 (Kymriah) Q2053 (Tecartus) Q2054 (Breyanzi) Q2055 (Abecma) Q2056 (Carvykti) [effective 10/01/2022] J3490 (Unclassified drug), J3590 (Unclassified biologics), and J9999 (Not otherwise classified, antineoplastic drugs) to be used (1) when the dose of CAR T-cell therapy exceeds code descriptor, (2) when other CAR T-cell therapy obtains FDA approval but has not yet received a specific HCPCS code (such as with Carvykti effective 02/28/2022).	Q2041 Q2042 Q2053 Q2054 Q2055 Q2056 J3490 J3590 J9999								
Part B	**B/MACs** shall create an edit that only allows CAR T-cell therapy services to be submitted by or performed in an FDA REM-approved facility when the line item has a -KX modifier appended. **Note:** When a provider submits a -KX modifier on a CAR T-cell therapy Part B claim, they are acknowledging that the service is being submitted by or performed in an FDA REM-approved facility. NOTE: Contractors shall update the existing editing created in CR 12177 to include all other CAR T-cell therapy services to only be allowed and submitted by or performed in an FDA REM-approved facility when the line item has a -KX modifier appended. The additional services are listed in CR 12928.2. Note: When a provider submits a -KX modifier on a CAR T-cell therapy service, they are acknowledging that the service is being submitted by or performed in an FDA REM-approved facility.					KX		16.2	58	N386 Group CO

NCD:	110.24									
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy (CR12177, CR12399, CR12480, CR12606, CR12822, CR12928)									
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf									
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA									
Part B	**B/MACs**: Contractors shall recognize the ICD-10 dx necessary for coverage of CAR T-cell products in the NCD spreadsheet for services provided in CR 12928.2. Contractors shall deny claims for covered CAR T-cell therapy procedures that do not contain the coding referenced in BR CR 12928.4 and the NCD spreadsheet.							15.20	50	N386 Goup CO or PR
Part B	**B/MACs** shall only allow places of service (POS) 11 (office) or 49 (independent clinic) for CAR T-cell products in CR 12928.2. **NOTE:** CAR T-cell therapy is not allowed in an Ambulatory Surgical Center ASC.			11 49				09.040 15.20	58	N386 Group CO or PR
Part B	**B/MACs** shall allow modifier -76 (repeat procedure or service by same physician or other 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). Note: This modifier will assist with preventing duplicate denials.	Q2041 Q2042 Q2053 Q2054 Q2055 Q2056 J3490 J3590 J9999				76				
Part B	**B/MACs**: Effective for claims with DOS on and after 1/1/22, 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. **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 per HCPCS code. **NOTE:** See 1/23 HCPCS Update **NOTE:** For Unclassified/Not Otherwise Classified codes, modifier -LU is only required if there is an indication of a CAR T-cell product.	Q2041 Q2042 Q2053 Q2054 Q2055 Q2056 J3490 J3590 J9999				LU		15.20	4	N386 Group CO

NCD:	110.24									
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy (CR12177, CR12399, CR12480, CR12606, CR12822, CR12928)									
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf									
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA									
Part B	**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. 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. **NOTE:** Contractors shall only pay up to 1 unit per HCPCS code 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. 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. Refer to CR 12928.8 for examples. **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 descriptor number of cells, this is off label use. This should be extremely rare.	Q2041 Q2042 Q2053 Q2054 Q2055 Q2056 J3490 J3590 J9999						15.060	151	Group CO
Part B	**B/MACs:** 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 1/1/22.	C9399 J3490 J3590 J9999 Q2041 Q2042 Q2053 Q2054 Q2055 Q2056								
Part B	**B/MACs**: 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 -Q1 clinical trial modifier for routine clinical services, and the Z00.6 clinical trial dx on the 0540T claim line effective for DOS on or after 10/1/21.	0540T				Q1				

NCD:	110.24									
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy (CR12177, CR12399, CR12480, CR12606, CR12822, CR12928)									
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf									
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA									
Part B	**B/MACs**: Effective for claims with DOS on or after 8/7/19, shall recognize for CAR T-cell therapy IP or OP facility claims: Current Procedural Terminology (CPT) codes 0537T, 0538T, and 0539T as not separately payable services under NCD 110.24 (they are tracking codes only), along with: Revenue code 0871, 0872, and 0873, respectively (for institutional claims only). Note: CPT codes 0537T, 0538T, and 0539T have a OPPS status indicator "B" (Code not recognized by OPPS) for Part A and a status indicator "B" (Bundled) for Part B, therefore, no additional system editing is required.	0537T 0538T 0539T			0871 0872 0873					
Part B	**B/MACs**: Effective for claims with DOS on or after 8/7/19, shall pay for line-items professional claims from approved providers, for the administration of treatment for cancer with T-cells expressing at least one CAR in a facility that is enrolled in the REMS program as a REMS participating site, with HCPCS 0540T.	0540T						15.20		
Part B	**B/MACs** shall not search for CAR T-cell therapy claims with DOS on and after 8/7/19, but shall adjust claims brought to their attention as appropriate.									
REVISION HISTORY										
	CR12399: End-date HCPCS C9076 for Breyanzi® effective 9/30/21. Add HCPCS Q2054 for Breyanzi® effective 10/1/21. Delete HCPCS C9399 for ABECMA® effective 9/30/21. Add HCPCS C9081 for ABECMA® effective 10/1/21. New spreadsheet created based on CR12177 plus updates.									
	CR12480: End-date HCPCS C9081 for ABECMA® effective 12/31/21. Add HCPCS Q2055 for ABECMA® effective 1/1/22. End date ICD-10 PCS codes effective 9/30/2021: XW033C3, XW043C3 for Yescarta®, Kymriah®, ABECMA®, XW23346, XW24346 for Tecartus™, XW23376, XW24376 for Breyanzi®. Add ICD-10 PCS codes effective 10/01/2021: XW033H7, XW043H7 for Yescarta®, XW033J7, XW043J7 for Kymriah®, XW033K7, XW043K7 for ABECMA®, XW033M7, XW043M7 for Tecartus™, XW043N7, XW033N7 for Breyanzi®. Add ICD-10 dx for Tecartus™ effective 10/1/21 (FDA approval): C91.00, C91.02. Add ICD-10 dx for Yescarta®, effective 3/5/21 (FDA approval): C82.01-C82.09, C82.11-C82.19, C82.31-C82.39, C82.41-C82.49, C82.51-C82.59, C82.61-C82.69, C82.81-C82.89. Autologous codes to be used for new/future CAR T-cell products FDA-approved under NCD 110.24 while awaiting their own PCS code, and for use in qualifying clinical trials under NCD 310.1: XW033C7 Introduction of Autologous Engineered Chimeric Antigen Receptor T-cell Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7 XW043C7 Introduction of Autologous Engineered Chimeric Antigen Receptor T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7 Allogenic codes to be used for new/future FDA-approved CAR T-cell products awaiting their own PCS code, and for use in qualifying clinical trials under NCD 310.1: XW033G7 Introduction of Allogeneic Engineered Chimeric Antigen Receptor T-cell Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7 XW043G7 Introduction of Allogeneic Engineered Chimeric Antigen Receptor T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7									

NCD:	110.24
NCD Title:	Chimeric Antigen Receptor (CAR) T-cell Therapy (CR12177, CR12399, CR12480, CR12606, CR12822, CR12928)
IOM:	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf
MCD:	https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=374&bc=CAAAAAAAAAAA
	CR12606: FISS and A/MACs shall allow revenue code 0891 to be billed on TOB 85X and ensure that FISS RC 32979 allows TOB 85X with revenue code 0891 when billed with HCPCS C9399 for claims with DOS on and after 8/7/19.
	CR12822: Add ICD-10 dx related to relapsed, refractory follicular lymphoma for Kymriah® effective FDA approval 5/27/22: C82.01,C82.02,C82.03,C82.04,C82.05,C82.06,C82.07,C82.08,C82.09,C82.11,C82.12,C82.13,C82.14,C82.15,C82.16,C82.17,C82.18,C82.19,C82.31,C82.32,C82.33,C82.34,C82.35,C82.36,C82.37, C82.38,C82.39,C82.41,C82.42,C82.43,C82.44,C82.45,C82.46,C82.47,C82.48,C82.49,C82.51,C82.52,C82.53,C82.54,C82.55,C82.56,C82.57,C82.58,C82.59,C82.61,C82.62,C82.63,C82.64,C82.65, C82.66,C82.67,C82.68,C82.69,C82.81,C82.82,C82.83,C82.84,C82.85,C82.86,C82.87,C82.88,C82.89. Add CARVYKTI™ HCPCS Q2056 effective 10/1/22, ICD-10 PCS XW033A7/XW043A7, and ICD-10 dx C90.00, C90.02 - FDA approval of multiple myeloma dx effective 2/28/2022. For Part A OPPS use HCPCS C9399 2/28/22-6/30/22, HCPCS C9098 7/1/22-9/30/22, HCPCS Q2056 10/1/22 forward. For Part B physicians use J3490, J3590, J9999 2/28/22-9/30/22, Q2056 10/1/22 forward.
	CR12928: Add POS 11 and 49 as valid POS for CAR-T claims. For clinical trial services, REMs approval and dx criteria for Part A and B are removed. Add new claim processing instructions and modifier requirements for Part B. Remove Part B rule created with CR 12177-04.4, 12399.3, 12480.10, and 12822.2.1 that denied as a Part A service. Add new modifier -LU to denote fractionated billing effective 1/1/22.

Medicare Claims Processing Manual
Chapter 32 – Billing Requirements for Special Services
Table of Contents

(Rev. 11774, 12-22)

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

(Rev. 11774, Issued: 12-30-22; Effective: 01-01-23, Implementation: 01-31-23)

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. 11774, Issued: 12-30-22; Effective: 01-01-23, Implementation: 01-31-23)

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. 11774, Issued: 12-30-22; Effective: 01-01-23, Implementation: 01-31-23)

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 -Q1 clinical trial modifier for routine clinical services, 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 -Q1 clinical trial modifier for routine clinical services, 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. 11774, Issued: 12-30-22; Effective: 01-01-23, Implementation: 01-31-23)

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. 11774, Issued: 12-30-22; Effective: 01-01-23, Implementation: 01-31-23)

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. 11774, Issued: 12-30-22; Effective: 01-01-23, Implementation: 01-31-23)

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. 11774, Issued: 12-30-22; Effective: 01-01-23, Implementation: 01-31-23)

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 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 qualifying clinical trials 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 qualifying clinical trials 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 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 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 October 1, 2021.

400.2.5 – Billing Information for Professional Claims

(Rev. 11774, Issued: 12-30-22; Effective: 01-01-23, Implementation: 01-31-23)

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).

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 REM*S* 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 REM*S* 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 REM*S* 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 per HCPCS code.

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 per HCPCS code, 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. 11774, Issued: 12-30-22; Effective: 01-01-23, Implementation: 01-31-23)

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 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 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-*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* administer*s* 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 OPPS/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 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-*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* administer*s* 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.

cenario 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. 11774, Issued: 12-30-22; Effective: 01-01-23, Implementation: 01-31-23)

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. 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. 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 per HCPCS code, 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. 11774, Issued: 12-30-22; Effective: 01-01-23, Implementation: 01-31-23)

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 clams with dates of service on and after August 7, 2019, CMS *determine*d 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.