CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10891	**Date: July 20, 2021**
	Change Request 12177

Transmittal 10796, dated May 20, 2021, is being rescinded and replaced by Transmittal 10891, dated, July 20, 2021 to add CPT code C9076 for Breyanzi and the HCPCS website for reference to the policy section and in the 100-04 manual attachment. This correction also updates the implementation date and updates business requirements 12177-04.1, 12177-04.3, 12177-04.4 and 12177-04.8. This correction only revises publication 100-04, there are no changes to publication 100-03. All other information remains the same.

SUBJECT: National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy - This CR Rescinds and Fully Replaces CR 11783.

I. SUMMARY OF CHANGES: The purpose of the Change Request (CR) is to inform MACs that 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 Risk Evaluation and Mitigation Strategies (REMS),and meets specifiied FDA conditions.

EFFECTIVE DATE: August 7, 2019
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: September 20, 2021

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
N	Table of Contents/32/400/Chimeric Antigen Receptor (CAR) T-cell therapy
N	32/400.1/Coverage Requirements
N	32/400.2/Billing Requirements
N	32/400/2.1/A/B Medicare Administrative Contractor (MAC) (A) Bill Types
N	32/400/2.2/A/B MAC (A) Revenue Codes
N	32/400/2.3/ A/B MAC Billing Healthcare Common Procedural Coding System (HCPCS) Codes
N	32/400/2.4/A/B MAC Diagnosis Requirements
N	32/400/3/Payment Requirements
N	32/400/4/Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages
N	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: 10891	Date: July 20, 2021	Change Request: 12177

Transmittal 10796, dated May 20, 2021, is being rescinded and replaced by Transmittal 10891, dated, July 20, 2021 to add CPT code C9076 for Breyanzi and the HCPCS website for reference to the policy section and in the 100-04 manual attachment. This correction also updates the implementation date and updates business requirements 12177-04.1, 12177-04.3, 12177-04.4 and 12177-04.8. This correction only revises publication 100-04, there are no changes to publication 100-03. All other information remains the same.

SUBJECT: National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy - This CR Rescinds and Fully Replaces CR 11783.

EFFECTIVE DATE: August 7, 2019
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: September 20, 2021

I. GENERAL INFORMATION

A. Background: A person's immune system contains cells to help fight substances that are foreign to the body, including cancer. These cells are called white blood cells, most of which are lymphocytes. The two main types of lymphocytes are B lymphocytes (B-cells) and T lymphocytes (T-cells). B-cells generate and release antibodies to fight infection, especially bacterial infections, while T-cells employ a number of other 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. The genetic modification creating a CAR can enhance the ability of the T-cell to recognize and attach to a specific protein, called an antigen, on the surface of a cancer cell.

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.

B. Policy: 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 Risk Evaluation and Mitigation Strategies (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 the following websites:

Kymriah® https:/www.us.kymriah.com/treatment-center-locator
Part A Outpatient (OP) and Critical Access Hospitals (CAHs)=Q2042 Inpatient hospital (IP)=XW033C3/XW043C3

Yescarta® https:/www.yescarta.com/find-a-treatment-center
OP/CAHs=Q2041 IP=XW033C3/XW043C3

Tecartus™ https:/www.tecartus.com/hcp/treatment-center-locator
OP/CAHs=Q2053 IP=XW23346/XW24346

Breyanzi® https:/www.breyanzihcp.com/treatment-centers

OP/CAHs=C9076 IP=XW23376/XW24376

ABECMA® https:/www.abecmahcp.com/treatment-centers

OP/CAHs=C9399 IP=XW033C3/XW043C3

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 requirements noted above 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 NCD is the formal policy. Unless otherwise specified in the NCD, coverage determinations are be made by the Medicare Administrative Contractors (MACs).

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

NOTE: This NCD 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.

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.

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	
12177 - 04.1	Effective for Dates of Service (DOS) on or after August 7, 2019, contractors shall process CAR T-cell therapy claims consistent with the Claims Processing Manual, Publication 100-04, Chapter 32, Section 400. That is, CMS covers autologous treatment for cancer	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	with T-cells expressing at least one CAR when administered at healthcare facilities enrolled in the FDA Risk Evaluation and Mitigation Strategies (REMS), and meets specified FDA conditions. MACs shall consult the CMS HCPCS Website for updated FDA approvals at: https:/www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update									
12177 - 04.1.1	Contractors 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.	X								
12177 - 04.1.2	Contractors 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 services, they are acknowledging that the service is being submitted by or performed in an FDA REM approved facility.		X							
12177 - 04.1.3	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.	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	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.									
12177 - 04.2	Effective for on claims with DOS on or after August 7, 2019, contractors shall recognize for Inpatient claims: CAR T-cell therapy International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS): XW033C3, XW043C3, XW23346, XW24346, XW23376, and XW24376. NOTE: Since allogenic T-cells are by definition not autologous CAR-T, it is inappropriate to use any of the above autologous CAR-T ICD-10 PCS procedure codes for allogenic T-cell treatments.	X								
12177 - 04.3	Effective for line-items on claims with DOS on or after August 7, 2019, contractors shall recognize the following coding necessary for coverage of CAR-T for Outpatient hospital and CAH claims: Healthcare Common Procedure Coding System Code (HCPCS) Q2041 (Yescarta ®) HCPCS Code Q2042 (Kymriah®) HCPCS C9073 (Tecartus™) (effective April 1, 2021, C9073 is replaced with HCPCS Q2053), and, HCPCS C9076 (Breyanzi®) (effective July 1, 2021, the use of C9399 NOC code for Breyanzi claims effective February 5, 2021, is replaced with HCPCS C9076), and, HCPCS Code C9399 (Unclassified drugs or biologicals) to be used (1) when the dose of CAR T-	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	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 ABECMA effective March 27, 2021) along with: Revenue Code 0891 (for institutional claims only).									
12177 - 04.4	Effective for line-items on claims with DOS on or after August 7, 2019, contractors shall deny, as a Part A service, CAR T-cell therapy Healthcare Common Procedure Coding System (HCPCS) code Q2041 (Yescarta ®) (Type of Service [TOS] 1), Q2042 (Kymriah®) (TOS 1), Q2053 (Tecartus™) (TOS 1) (effective April 1, 2021 C9073 is replaced with HCPCS Q2053), and, C9076 (Breyanzi®) (TOS 1) (effective July 1, 2021, the use of C9399 for Breyanzi claims effective February 5, 2021, is replaced with C9076), and, C9399, J3490, J3590, or J9999 (Unclassified drugs or biologicals) (TOS F or 1) when (1) the dose of CAR T-cell therapy exceeds the code descriptor, or, (2) for administration of ABECMA®, and other CAR T-cell therapy that may obtain FDA approval but have not yet received a specific HCPCS code. Note: HCPCS codes Q2041, Q2042, and C9073 (TOS F) have an Ambulatory Surgical Center (ASC) payment indicator "B5" (Alternative code may be available, no payment made); therefore, no additional system editing is required. Note: HCPCS codes C9076 and Q2053 are invalid codes in the ASC setting. 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 109 - Claim/service not covered by this payer/contractor. You must send the claim/service to the correct payer/contractor. Group Code CO MSN 17.9 - Medicare Part A pays for this service. The provider must bill the correct Medicare contractor. Spanish Version - Este servicio es pagado por Medicare (Parte A/Parte B). El proveedor debe enviar la factura al contratista de Medicare correcto. In addition to the codes listed above, contractors shall afford appeal rights to all denied parties.									
12177 - 04.5	Effective for line-items on claims with DOS on or after August 7, 2019, contractors shall recognize for CAR T-cell therapy outpatient hospital and CAH 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.	X	X							
12177 - 04.6	Effective for line-items on claims with DOS on or after August 7, 2019, contractors shall recognize for CAR T-cell therapy outpatient hospital and CAH claims: HCPCS code 0540T as a covered service under NCD 110.24 when used for administering a	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	CAR-T biological service. Along with: Revenue Code 0874 (for institutional claims only).									
12177 - 04.6.1	Effective for claims with DOS on or after August 7, 2019, contractors shall pay for professional services provided in a Method II CAH, for the administration of autologous 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.	X								
12177 - 04.7	Effective for claims with DOS on or after August 7, 2019, contractors shall pay for line-items professional claims from approved providers, for the administration of autologous 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.		X							
12177 - 04.8	Contractors shall recognize the ICD-10 diagnoses codes necessary for coverage of CAR-T in Attachment 1 for services provided in Business Requirements 04.2, 04.3, 04.6, and 04.7.	X	X							
12177 - 04.9	Contractors shall deny claims for covered CAR T-cell therapy procedures that do not contain the coding referenced in BR 04.8 above: Using the following messages: 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	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	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).									
12177 - 04.9.1	Continuation of Business Requirement (BR) 12177-04.9) MSN 15.19: “We used a Local Coverage Determination (LCD) to decide coverage for your claim. To appeal, get a copy of the LCD at www.cms.gov/medicare-coverage-database (use the MSN Billing Code for the CPT/HCPCS Code) and send with information from your doctor." (for Part A only) Spanish Version - Usamos una Determinación de Cobertura Local (LCD) para decidir la cobertura de su reclamo. Para apelar, obtenga una copia del LCD en www.cms.gov/medicare-coverage-database (use el código de facturación de MSN para el código "CPT/HCPCS") y envíela con la información de su médico. 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.” NOTE: Due to system requirement, the Fiscal Intermediary Shared System (FISS) has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	In addition to the codes listed above, contractors shall afford appeal rights to all denied parties.									
12177 - 04.10	Contractors shall allow Risk Medicare Advantage beneficiaries/providers to bill Medicare Fee-for-Service (FFS) for CAR-T services covered under NCD 110.24 for dates of service beginning August 7, 2019, through December 31, 2020, based on significant cost threshold requirements. Contractors shall not search for CAR T-cell therapy claims with DOS on and after August 7, 2019, but shall adjust claims brought to their attention as appropriate.	X								
12177 - 04.11	Contractors shall not search for CAR T-cell therapy claims with DOS on and after August 7, 2019, but shall adjust claims brought to their attention as appropriate.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12177 - 04.12	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	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, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov , Cami DiGiacono, 410-786-5888 or Cami.DiGiacomo@cms.hhs.gov , David Dolan, 410-786-3365 or David.Dolan@cms.hhs.gov , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov , Yvette Cousar, 410-786-2160 or Yvette.Cousar@cms.hhs.gov , Fred Rooke, 404-562-7205 or Fred.Rooke@cms.hhs.gov

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

Attachment 1

FDA approved for Tecartus™ (Brexucabtagene Autoleucel):
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

FDA approved for Yescarta® (Axicabtagene Ciloleucel) and Kymriah® (Tisagenlecleucel):
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

FDA approved for Kymriah® (Tisagenlecleucel):
C91.00: Acute lymphoblastic leukemia, not having achieved remission
C91.02: Acute lymphoblastic leukemia, in relapse

FDA approved for Breyanzi® (Lisocabtagene Maraleucel; Liso-Cel):
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

FDA approved for ABECMA® (Idecabtagene Vicleucel):
C90.00: Multiple myeloma not having achieved remission
C90.02: Multiple myeloma in relapse

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents
(Rev. 10891, Issued: 07-20-19)

400 Chimeric Antigen Receptor (CAR) T-cell therapy

(Rev. 10891, Issued: 07-20-21, Effective: 08-07-19, Implementation: 09-20-21)

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. 10891, Issued: 07-20-21, Effective: 08-07-19, Implementation: 09-20-21)

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 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 REM 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.breyanzihcp.com/treatment-centers
ABECMA® https://www.abecmahcp.com/treatment-centers

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

400.2 - Billing Requirements

(Rev. 10891, Issued: 07-20-21, Effective: 08-07-19, Implementation: 09-20-21)

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 Healthcare Common Procedure Coding System (HCPCS) 0540T.

400.2.1 - A/B Medicare Administrative Contractor (MAC) (A) Bill Types

(Rev. 10891, Issued: 07-20-21, Effective: 08-07-19, Implementation: 09-20-21)

Valid type of bills (TOBs) for billing inpatient CAR T-cell therapy services may include (but are not necessarily limited to):

011x – Inpatient Hospital
012x – Inpatient Ancillary Hospital

Valid TOBs for billing outpatient CAR T-cell therapy services may include (but are not necessarily limited to):

013x – Outpatient Hospital
085x – Critical Access Hospital

400.2.2 - A/B MAC (A) Revenue Code
(Rev. 10891, Issued: 07-20-21, Effective: 08-07-19, Implementation: 09-20-21)

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

0871 – Cell Collection w/Current Procedural Technology (CPT) code 0537T
0872 – Specialized Biologic Processing and Storage – Prior to Transport w/CPT 0538T
0873 – Storage and Processing after Receipt of Cells from Manufacturer w/CPT 0539T
0874 – Infusion of Modified Cells w/CPT 0540T
0891 – Special Processed Drugs – FDA Approved Cell Therapy w/ HCPCS Q2041, Q2042, C9073 (replaced with Q2053 April 1, 2021), C9076, or C9399

400.2.3 - A/B MAC Billing HCPCS Codes
(Rev. 10891, Issued: 07-20-21, Effective: 08-07-19, Implementation: 09-20-21)

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

HCPCS Code Q2042 for Tisagenlecleucel,
HCPCS Code Q2041 for Axicabtagene Ciloleucel,
HCPCS Q2053 for Brexucabtagene Autoleucel (effective April 1, 2021)
HCPCS Code C9073 for Brexucabtagene Autoleucel (prior to April 1, 2021)
HCPCS C9076 for Lisocabtagene maraleucel (effective July 1, 2021)
HCPCS Code C9399 for unclassified drugs or biologicals when dose of CAR T-cell therapy exceeds code descriptor or when a more specific code is unavailable
*HCPCS Code 0537T collection/handling**
*HCPCS Code 0538T preparation for transport**
*HCPCS Code 0539T receipt and preparation**
HCPCS Code 0540T the administration

** 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).*

400.2.4 A/B MAC Diagnosis and Procedure Code Requirements
(Rev. 10891, Issued: 07-20-21, Effective: 08-07-19, Implementation: 09-20-21)

Please see attachment 1 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:

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, it is inappropriate to use any of the above autologous CAR T-cell ICD-10 PCS procedure codes for allogenic T-cell treatments.*

400.2.5 – Billing Information for Professional Claims
(Rev. 10891, Issued: 07-20-21, Effective: 08-07-19, Implementation: 09-20-21)

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 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 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 approved facility.*

400.3 - Payment Requirements

(Rev. 10891, Issued: 07-20-21, Effective: 08-07-19, Implementation: 09-20-21)

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 in various clinical scenarios.

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

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

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

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

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

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

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

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

Physician Office or Non-Hospital Clinic

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

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

In instances when you administer the CAR-T drug 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 HCPCS Q2041, Q2042, Q2053 (effective April 1, 2021), C9073 (prior to April 1, 2021), C9076, or, if a more specific code is unavailable, the most appropriate unclassified drug code (e.g., 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 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 reject them on the professional claim.

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

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

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the physician office or other non-hospital clinic facility, the practitioner may not report the drug HCPCS code (which only applies when the T-cells are administered in the setting). The practitioner may report CPT 0537T, 0538T, and 0539T (as appropriate) on the professional claim. Medicare will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered 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 inpatient setting, the practitioner may not report the drug HCPCS code (which only applies when the T-cells are administered in the setting). The hospital that administers the T-cells will report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (TOB 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration)

Approved Cell Therapy – Charges for Modified cell therapy.

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

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

(Rev. 10891, Issued: 07-20-21, Effective: 08-07-19, Implementation: 09-20-21)

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 Chimeric Antigen Receptor (CAR) T-cell therapy procedures because the appropriate ICD-10 coding was not used:

*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."

MSN 15.19: "We used a Local Coverage Determination (LCD) to decide coverage for your claim. To appeal, get a copy of the LCD at www.cms.gov/medicare-coverage-database (use the MSN Billing Code for the CPT/HCPCS Code) and send with information from your doctor".

Spanish Version - Usamos una Determinación de Cobertura Local (LCD) para decidir la cobertura de su reclamo. Para apelar, obtenga una copia del LCD en www.cms.gov/medicare-coverage-database (use el código de facturación de MSN para el código "CPT/HCPCS") y envíela con la información de su médico

NOTE: Due to system requirement, the Fiscal Intermediary Standard System has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.

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

400.5 - Claims Editing

(Rev. 10891, Issued: 07-20-21, Effective: 08-07-19, Implementation: 09-20-21)

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 announces 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 Social Security 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.