

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10454	Date: November 13, 2020
	Change Request 11783

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

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 specified FDA conditions.

EFFECTIVE DATE: August 7, 2019

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

IMPLEMENTATION DATE: February 16, 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: 10454	Date: November 13, 2020	Change Request: 11783
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SUBJECT: National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy

EFFECTIVE DATE: August 7, 2019

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

IMPLEMENTATION DATE: February 16, 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.

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: 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.

Number	Requirement	Responsibility									
		A/B MAC		D M E	Shared- System Maintainers				Other		
		A	B		H H H	M A C	F I S S	M C S		V M S	C W F
	<p>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.</p> <p>MSN 15.20 - “The following polices were used when we made this decision: NCD 110.24.”</p> <p>Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 110.24.”</p> <p>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.</p> <p>In addition to the codes listed above, contractors shall afford appeal rights to all denied parties.</p>										
11783 - 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.	X									
11783 - 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			D M E D I C A N A C T O R	C O N T R A C T I N G O F F I C E R
		A	B	H H H		
11783 - 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): David Dolan, 410-786-3365 or David.Dolan@cms.hhs.gov (Coverage and Analysis) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis) , Yvette Cousar, 410-786-2160 or Yvette.Cousar@cms.hhs.gov (Professional Claims Processing) , Fred Rooke, 404-562-7205 or Fred.Rooke@cms.hhs.gov (Institutional Claims Processing) , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis) , Cami DiGiacono, 410-786-5888 or Cami.DiGiacomo@cms.hhs.gov (Institutional Claims Processing)

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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

ATTACHMENTS: 1

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

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- 400 Chimeric Antigen Receptor (CAR) T-cell therapy*
 - 400.1 - Coverage Requirements*
 - 400.2 - Billing Requirements*
 - 400.2.1- A/B Medicare Administrative Contractor (MAC) (A) Bill Types*
 - 400.2.2 - A/B MAC (A) Revenue Codes*
 - 400.2.3 - A/B MAC Billing Healthcare Common Procedural Coding System (HCPCS) Codes*
 - 400.2.4 - A/B MAC Diagnosis Requirements*
 - 400.3 - Payment Requirements*
 - 400.4 - Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages*
 - 400.5 - Claims Editing*

400 Chimeric Antigen Receptor (CAR) T-cell therapy

(Rev. 10454, Issued: 11-13-20, Effective: 08-07-19, Implementation: 02-16-21)

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. 10454, Issued: 11-13-20, Effective: 08-07-19, Implementation: 02-16-21)

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). See Publication 100-03, National Coverage Determination (NCD) Manual 110.24 for complete coverage criteria.

400.2 - Billing Requirements

(Rev. 10454, Issued: 11-13-20, Effective: 08-07-19, Implementation: 02-16-21)

Effective for dates of service 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 with Healthcare Common Procedure Coding System (HCPCS) 0540T.

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

(Rev. 10454, Issued: 11-13-20, Effective: 08-07-19, Implementation: 02-16-21)

The following type of bills (TOBs) are used for billing inpatient CAR T-cell therapy services:

011x – Inpatient Hospital

012x – Inpatient Ancillary Hospital

The following TOBs are used for billing outpatient CAR T-cell therapy services:

013x – Outpatient Hospital

085x – Critical Access Hospital

400.2.2 - A/B MAC (A) Revenue Code

(Rev. 10454, Issued: 11-13-20, Effective: 08-07-19, Implementation: 02-16-21)

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, or C9399

400.2.3 - A/B MAC Billing HCPCS Codes

(Rev. 10454, Issued: 11-13-20, Effective: 08-07-19, Implementation: 02-16-21)

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 Code C9399 for unclassified drugs or biologicals when dose of CAR T-cell therapy exceeds
code descriptor
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 Requirements

(Rev. 10454, Issued: 11-13-20, Effective: 08-07-19, Implementation: 02-16-21)

*The following are the applicable International Classification of Disease (ICD)-10-CM diagnosis codes for CAR
T-cell therapy coverage:*

*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
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

NOTE: Acute Lymphoblastic Leukemia diagnosis dx codes C91.00-C91.02 are only FDA-approved for Kymriah®.

Mantle Cell Lymphoma dx codes C83.11-C83.19 are only valid for Tecartus™

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

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

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

400.3 - Payment Requirements

(Rev. 10454, Issued: 11-13-20, Effective: 08-07-19, Implementation: 02-16-21)

Inpatient

The A/MAC billing requirements will allow for CAR T-cell therapy only 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/MAC billing requirements will pay for CAR T-cell therapy only 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 OPSS.

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 or Q2042 for the drug/biological. As discussed in the Calendar Year (CY) 2019 OPSS/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 OPSS. However, you may report the charges for these various steps to collect and prepare the CAR T-cells separately and Medicare will reject them on the HOPD claim, or they may be included in the charge reported for the biological.

Note: *When including the charges for collection and preparation of the CAR T-cells in the charge for the CAR-T 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.*

400.4 - Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages (Rev. 10454, Issued: 11-13-20, Effective: 08-07-19, Implementation: 02-16-21)

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 coverage.

Medicare coverage for CAR T-cell therapy is restricted to the hospital inpatient or HOPD settings.

Contractors shall deny claims for CAR T-cell therapy when the service is not rendered to an inpatient or outpatient of a hospital, including CAHs using the following codes:

CARC 171 – Payment is denied when performed/billed by this type of provider in this type of facility.

NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

Remittance Advice Remark Code (RARC) N428 – Not covered when performed in this place of service.

Group Code CO (Contractual Obligations) or PR (Patient Responsibility) dependent on liability.

When rejecting/denying claims for covered Chimeric Antigen Receptor (CAR) T-cell therapy procedures because the appropriate coding was not used:

CARC 16 - Claim/service lacks information or has submission/billing error(s) which is needed for adjudication. Do not use this code for claims attachment(s)/other documentation. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC M76 - Missing/incomplete/invalid diagnosis or condition.

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.”

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. 10454, Issued: 11-13-20, Effective: 08-07-19, Implementation: 02-16-21)

A. Fee-For-Service Medicare

Nationwide claims processing edits for pre- or post-payment review of claim(s) for CAR-T are not being required at this time. Contractors shall develop local medical review policy and edits for such claim(s).

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

B. Beneficiaries enrolled in Medicare Advantage (MA) plans

Effective for claims 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.

Attachment 1

- 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
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- C83.16: Mantle cell lymphoma, intrapelvic lymph nodes
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- 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
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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

NOTE: Acute Lymphoblastic Leukemia diagnosis dx codes C91.00-C91.02 are only FDA approved for Kymriah®.

Mantle Cell Lymphoma dx codes C83.11-C83.19 are only valid for Tecartus™.