CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-03 Medicare National Coverage Determinations	**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.

The Federal government creates NCDs that are binding on the MACs who review and/or adjudicate claims, make coverage determinations, and/or payment decisions, and also binds quality improvement organizations, qualified independent contractors, the Medicare appeals council, and Administrative Law Judges (ALJs) (see 42 Code of Federal Regulations (CFR) section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

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
R	Table of Contents/Chapter1/Part 2
N	1/110.24/Chimeric Antigen Receptor (CAR) T-cell therapy

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. 100-03	Transmittal: 10454	Date: November 13, 2020	Change Request: 11783

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

EFFECTIVE DATE: August 7, 2019
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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 shall 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.

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	
11783 - 03.1	Effective for dates of service on or after August 7, 2019, contractors shall cover CAR T-cell therapy consistent with the NCD Manual, Publication 100.3, Chapter 1, Part 2, Section 110.24.	X	X							
11783 - 03.2	Contractors shall use default Council for Affordable Quality Health (CAQH) Committee on Operating Rules for Information Exchange (CORE) messages where appropriate: Remittance Advice Remark Code (RARC) N386 with Claims Adjustment. Reason Code (CARC) 50, 96, and/or 119. See latest CAQH CORE update. When denying claims associated with the attached NCDs, except where otherwise indicated, A/B MACs shall use: Group Code PR (Patient Responsibility) assigning financial responsibility to the beneficiary Group Code CO (Contractual Obligation) assigning financial liability to the provider NOTE: This replicates the note under the Policy section.	X	X							
11783 - 03.3	A/B MACs shall work together collaboratively from a clinical aspect to ensure consistent national editing across jurisdictions.	X	X							
11783 - 03.3.1	Contractors shall attend up to four (4) 1-hour calls to discuss feedback regarding implementation of coding for this policy and how to ensure consistent national editing across MACS. NOTE: CMS shall schedule the calls at a later date.	X	X							
11783 - 03.3.2	Contractors shall be responsible for taking meeting notes on a rotating basis and submit notes to E-Chimp within three (3) business days of meeting. Contractors shall appoint appropriate points-of-contact for staffing meetings within 14 business days of the date of this CR to: Wanda.Belle@cms.hhs.gov	X	X							
11783 - 03.4	Contractors shall provide consensus recommendations to CMS in a final report uploaded into ECHIMP, under the Post Issued tab, Analysis Call Documents	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	sub-tab, no later than 30 business days following the final meeting.									
11783 - 03.5	A/B MACs shall implement local edits in each respective jurisdiction until such time as CMS may determine shared edits to be appropriate, which will be relayed via a subsequent CR.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11783 - 03.6	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): 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) , Cami DiGiacomo, 410-786-5888 or Cami.DiGiacomo@cms.hhs.gov (Institutional Claims Processing) , Fred Rooke, 404-562-7205 or Fred.Rooke@cms.hhs.gov (Institutional Claims Processing) , Lori Ashby, 410-786-6322 or Lori.Ashby@cms.hhs.gov (Coverage and Analysis) , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis)

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: 0

Medicare National Coverage Determinations Manual Chapter 1, Part 2(Sections 90-160.26)

Table of Contents
(Rev. 10454, Issued: 11-13-20)

110.24 Chimeric Antigen Receptor (CAR) T-cell therapy

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

A. General

Cancer is a collection of related diseases of dividing cells that can start almost anywhere in or on the body, evade the immune system, and invade nearby tissues. Categories of cancer are typically organized by the location in the body and specific type of cell. These categories may include carcinoma, sarcoma, leukemia, lymphoma, multiple myeloma, melanoma, and brain and spinal cord tumors. There are also changes to these cells that are not considered cancer. These changes include hyperplasia—when a cell divides faster than normal—and dysplasia—a buildup of extra cells with abnormal shape and disorganization.

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.

B. Nationally Covered Indications

A. 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 chimeric antigen receptor (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.

C. Nationally Non-Covered

Effective for services performed on or after August 7, 2019, 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 in Section A are not met.

D. Other

Effective for services performed on or after August 7, 2019, 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.

(This NCD last reviewed August 2019.)