

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	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Transmittal 10796, dated May 20, 2021, is being rescinded and replaced by Transmittal 10891, dated, July 20, 2021 to add CPT code C9076 for Breyanzi and the HCPCS website for reference to the policy section and in the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 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: 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/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: 10891	Date: July 20, 2021	Change Request: 12177
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EFFECTIVE DATE: August 7, 2019

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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 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.

See the following websites:

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>

Number	Requirement	Responsibility									
		A/B MAC		H H H	M A C	D M E	Shared-System Maintainers				Other
		A	B				F I S S	M C S	V M S	C W F	
	across jurisdictions.										
12177 - 03.3	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		H H H	M A C	D M E	C E D I				
		A	B								
12177 - 03.4	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:
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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 , Yvette Cousar, 410-786-2160 or Yvette.Cousar@cms.hhs.gov , Cami DiGiacomo, 410-786-5888 or Cami.DiGiacomo@cms.hhs.gov , Fred Rooke, 404-562-7205 or Fred.Rooke@cms.hhs.gov , Lori Ashby, 410-786-6322 or Lori.Ashby@cms.hhs.gov , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@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: 0

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

Table of Contents
(Rev. 10891; Issued: 07-20-21)

110.24 Chimeric Antigen Receptor (CAR) T-cell therapy

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

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.)