



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

MLN Matters Number: MM12177 **Revised**

Related Change Request (CR) Number: 12177

Related CR Release Date: July 20, 2021

Effective Date: August 7, 2019

Related CR Transmittal Number: R10891CP  
and R10891NCD

Implementation Date: September 20, 2021

**Note: We revised the Article to add information on the use of the KX modifier on professional claims. You'll find the substantive content update in dark red font on page 4. All other information is the same.**

### Provider Types Affected

This MLN Matters Article is for physicians, hospitals, other providers, and suppliers billing Medicare Administrative Contractors (MACs) for Chimeric Antigen Receptor (CAR) T-cell Therapy services provided to Medicare patients.

### What You Need to Know

This Article tells you 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 1 CAR when administered at healthcare facilities:

- Enrolled in the FDA Risk Evaluation and Mitigation Strategies (REMS)
- Meets specified CMS/FDA criteria

### Background

We reviewed the evidence for CAR T-cell therapy in patients with cancer and will cover FDA-approved CAR T-cell therapy under the conditions specified in [Publication 100-03, National Coverage Determination \(NCD\) Manual, Section 110.24](#).

### Coverage and Diagnosis Requirements:

Effective for claims with dates of service on or after August 7, 2019, we cover autologous treatment for cancer with T-cells expressing at least 1 CAR when administered at healthcare facilities enrolled in the FDA REMS and used for a medically accepted indication as defined at Social Security Act, [Section 1861\(t\)\(2\)](#) (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 1 or more CMS-approved compendia.

The use of non-FDA-approved autologous T-cells expressing at least 1 CAR is non-covered. Autologous treatment for cancer with T-cells expressing at least 1 CAR is non-covered when the requirements noted above aren't met. The use of allogenic T-cells from healthy donors aren't autologous CAR-T treatments and you shouldn't bill those as autologous CAR-T treatments.

We will cover routine costs in clinical trials that use CAR T-cell therapy as an investigational agent that meet the requirements listed in NCD 310.1 effective August 7, 2019.

### See the following websites for specific REMS facility information:

- [Kymriah®](#)
- [Yescarta®](#)
- [Tecartus™](#)
- [Breyanzi®](#)
- [ABECMA®](#)

### 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
- XW23346: Transfusion of Brexucabtagene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 6
- XW24346: Transfusion of Brexucabtagene Autoleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 6
- XW23376 – Transfusion of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 6
- XW24376 – Transfusion of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology 6

See Attachment 1 of the [Transmittal R10796CP](#) for a list of the primary ICD-10 diagnosis codes.

### Payment Information for hospitals:

#### Inpatient

Billing requirements will allow for CAR T-cell therapy when you bill the services on Type of Bill (TOB) 11X.

#### Outpatient

We will pay for CAR T-cell therapy when you bill the services on TOBs 12X, 13X, or 85X. Type

of facility and setting determines the basis of payment. HOPDs may report CPT codes 0537T, 0538T, and 0539T to allow tracking of these services furnished in the outpatient setting. Medicare will reject these lines as Medicare doesn't separately pay for these services under the OPFS.

**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.

### Revenue Code:

Use the following Revenue Codes for billing inpatient and outpatient CAR T-cell therapy services:

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

We provide [several HOPD scenarios](#) to further show how to report items and services related to CAR-T in various clinical scenarios for institutional providers.

### Physician Office or Non-Hospital Clinic

Physicians and non-hospital clinics bill for CAR T-cell therapy using the Form [CMS-1500](#).

We supply [several scenarios](#) for you on billing for CAR-T cell therapy services.

### Billing HCPCS Codes:

Use the following HCPCS procedure codes 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 Code 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
- HCPCS code 0537T for collection/handling\*
- HCPCS code 0538T for preparation for transport\*
- HCPCS code 0539T for receipt and preparation\*
- HCPCS code 0540T for the administration

\*Procedure represents the various steps required to collect and prepare the genetically modified T-cells, and these steps aren't paid separately under the OPPS.

Make sure you use the KX modifier when you send claims for CAR T-cell therapy services. This tells your MAC that you did that service in an FDA REM approved facility. Your MAC only allows CAR T-cell therapy services when the line item contains the KX modifier.

## Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), and Group Codes

MACs will continue to use the appropriate existing messages that are in place when denying claims that don't meet the Medicare coverage criteria for CAR T-cell therapy.

### More Information

We issued CR 12177 to your MAC in 2 transmittals. [Transmittal R10891CP](#) updates the Medicare Claims Processing Manual. [Transmittal R10891NCD](#) updates the Medicare National coverage Determinations Manual. These transmittals include the updates to the manuals.

For more information, contact your [MAC](#).

### Document History

Date of Change	Description
October 6, 2021	We revised the Article to add information on the use of the KX modifier on professional claims. You'll find the substantive content update in dark red font on page 4. All other information is the same.
July 21, 2021	We revised the Article to reflect a revised CR that added CPT code C9076 (Breyanzi). You'll find the substantive content update in dark red font on page 3. We also revised the implementation date. We revised the CR release date, transmittal number, and the web address of the transmittal. All other information is the same.
July 14, 2021	We revised the Article to give information for HCPCS code Q2053. You'll find substantive content updates in dark red font on page 3. All other information is the same.
May 24, 2021	Initial article released.

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