



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

MLN Matters Number: MM11783

Related Change Request (CR) Number: 11783

Related CR Release Date: November 13, 2020

Effective Date: August 7, 2019

Related CR Transmittal Number: R10454CP
and R10454NCD

Implementation Date: February 16, 2021

PROVIDER TYPES AFFECTED

This MLN Matters Article is for physicians and hospitals billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article informs you that effective for claims with dates of service 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 Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies (REMS) and meets specified FDA conditions.

Make sure your billing staffs are aware of these changes.

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 CAR T-cell therapy.

CMS 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 the National Coverage Determinations (NCD) Manual, Section 110.24, which is part of Change Request (CR) 11783.

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 REMS and used for a medically accepted indication as defined at Social

Security Act Section 1861(t)(2), that 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.

Billing Requirements

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 HCPCS 0540T.

Bill Types

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

Revenue Code

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

Billing HCPCS Codes

The following HCPCS 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). They are tracking codes only.

Diagnosis Requirements

See attachment 1 of [CR 11783](#) 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:

- 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.

Payment Requirements

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 Outpatient Prospective Payment System (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.

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

MACs will 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.
- 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

NOTE: 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.

ADDITIONAL INFORMATION

The official instruction, CR 11783, issued to your MAC regarding this change consists of two transmittals. The first updates the Medicare Claims Processing Manual and it is available at <https://www.cms.gov/files/document/r10454cp.pdf>. The manual attachment of this transmittal contains several scenarios for billing CAR-T cell therapy. The second transmittal updates the NCD Manual and it is available at <https://www.cms.gov/files/document/r10454ncd.pdf>.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

DOCUMENT HISTORY

Date of Change	Description
November 17, 2020	Initial article released.

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