



## Billing Instructions for Beneficiaries Enrolled in Medicare Advantage (MA) Plans for Services Covered by Decision Memo CAG-00451N

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### PROVIDER TYPE AFFECTED

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This MLN Matters Special Edition Article is for Hospital providers.

### WHAT YOU NEED TO KNOW

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This article conveys information on the National Coverage Determination (NCD) requiring coverage of Chimeric Antigen Receptor (CAR) T-cell therapy for cancer. For more information on the National Coverage Determination, see the decision memorandum at <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=291>.

The Centers for Medicare & Medicaid Services (CMS) is providing this information for hospitals providing CAR T-cell therapy to beneficiaries enrolled in Medicare Advantage (MA) plans. Make sure your billing staff is aware of these instructions.

### BACKGROUND

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#### 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 several 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 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**

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 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) - 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 Indications**

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**

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.

### **E. Beneficiaries enrolled in Medicare Advantage (MA) plans**

CMS announces that the National Coverage Determination requiring coverage of Chimeric Antigen Receptor (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 Calendar Years (CYs) 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 decision memorandum is met. This policy is effective as of August 7, 2019. Plans should account for CAR T-cell therapy for cancer items and services in their contract year 2021 bids.

Consistent with Section 1862 (t)(2) of the Social Security Act, Medicare Administrative Contractors will pay for CAR T-cell therapy for cancer for Medicare beneficiaries enrolled in MA plans in CYs 2019 and 2020.

#### **F. Medicare Advantage Beneficiary Billing Instructions**

For claims submitted on or after August 7, 2019, hospitals may report for Medicare Advantage Beneficiaries temporarily being paid under Fee-For-Service Medicare the CAR T-cell-related revenue codes 087X (Cell/Gene Therapy) and 089X (Pharmacy) established by the National Uniform Billing Committee (NUBC). When billing charges separately for tracking these services when furnished in the outpatient setting, providers must submit:

- HCPCS 0537T with revenue code 0871
- HCPCS 0538T with revenue code 0872
- HCPCS 0539T with revenue code 0873

***The above codes will appropriately receive Reason Code W7111.***

Remember that Medicare pays for the administration of CAR T-cells in the hospital outpatient setting separately under CPT code 0540T with Revenue Code 0874, which is assigned to status indicator “S”. Medicare payment for the various steps required to collect and prepare CAR-T is included in payment for the biological. You may choose to include the charges for these various steps in the charge submitted for the biological or report these charges separately for tracking purposes.

**Note:** Do not report the same charge(s) twice. Providers should choose one option listed above. You **must not** include charges for pre-infusion steps in both the drug revenue code (0891) and separately listed for the pre-infusion revenue codes (0871, 0872, and 0873).

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 Hospital Outpatient Setting:**

In instances when you administer the CAR-T drug in the hospital outpatient setting, report CPT code 0540T for the administration and HCPCS Q-code Q2041 or Q2042 for the drug/biological. As discussed in the CY 2019 OPPTS/ASC final rule (83 FR 58904), the procedures described by CPT codes 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 OPPTS.

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 outpatient 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 Hospital Outpatient 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 codes 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 Hospital Outpatient Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:**

When CAR T-cell preparation services are initiated and furnished in the hospital outpatient 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 (Type of Bill 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 hospital outpatient 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.

## **ADDITIONAL INFORMATION**

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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
October 24, 2019	Initial article released.

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