

**Payment Policy | Chimeric Antigen Receptor (CAR)
T-cell Therapy for Cancers**



EFFECTIVE DATE: 08|07|2019
POLICY LAST UPDATED: 12|21|2022

OVERVIEW

This documents the coverage and payment guidelines for Medicare Advantage Plan members requiring chimeric antigen receptor (CAR) T-cell therapy for cancer.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

To ensure reimbursement for this service, providers must submit claims for chimeric antigen receptor (CAR) T-cell therapy for cancer procedures to CMS for authorization/reimbursement.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable physician administered drug covered benefits/coverage.

BACKGROUND

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.

Commented [LO1]: Replacing to match the current NCD exactly.

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.

RELATED POLICIES

New Technology

CODING

Medicare Advantage Plans

In addition to the HCPCS code for the CAR T – cell therapy, the following codes are required to be submitted to CMS claims processing.

- 0537T** Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
- 0538T** Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
- 0539T** Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
- 0540T** Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous

Providers should use the following modifiers when submitting claims for CAR T-cell therapy services:

- KX: acknowledging that the service is being submitted by or performed in an FDA REMS approved facility
- LU: informs the Medicare Administrative Contractor that the service is fractionated

REFERENCES

1. CMS.gov; Decision Memo for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N); retrieved November 2019. <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=291>.
2. <https://www.cms.gov/files/document/r11391otn.pdf> updated July 5, 2022
3. <https://www.cms.gov/files/document/mm12177-national-coverage-determination-ncd-11024-chimeric-antigen-receptor-car-t-cell-therapy-cr.pdf> Implementation Date: September 20, 2021
4. CMS Manual System, Transmittal 11721 <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/R11721CP.pdf>

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