

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



EFFECTIVE DATE: 08|07|2019

POLICY LAST UPDATED: 12|17|2019

OVERVIEW

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

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

Effective for services rendered in 2019 and 2020, Centers for Medicare & Medicaid Services (CMS) has announced that due to the significant cost for CAR T-cell therapy for cancer, original fee-for-service Medicare will provide reimbursement for this service.

To ensure reimbursement for this services 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).

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 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.

RELATED POLICIES

New Technology

CODING

BlueCHiP for Medicare

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
- Q2042** Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose
- Q2041** Axicabtagene Ciloleucel, up to 200 Million Autologous Anti-CD19 CAR T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Infusion

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>.

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