



**World Trade Center (WTC) Health Program Medical Coverage Determination
Chimeric Antigen Receptor T-cell (CAR-T) Therapy
Final Medical Coverage Determination**
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I. Coverage Overview

This Medical Coverage Determination (MCD) outlines the coverage of medically necessary¹ CAR-T therapy for WTC Health Program members.

CAR-T therapy is a type of cancer treatment that is used when standard cancer treatments have failed or cancer has relapsed. In CAR-T therapy, a type of immune system cell called a T-cell is taken from a patient's blood and altered in the laboratory so it will attack cancer cells. Large numbers of CAR-T cells are grown in the laboratory and given to the patient by infusion.² CAR-T therapy may be covered by the WTC Health Program when the services are medically necessary for the member's certified WTC-related cancer, or health condition medically associated with a certified WTC-related cancer.

Members may receive medically necessary CAR-T therapy when they meet certain criteria for authorization. CAR-T therapy must be administered at a healthcare facility enrolled in the FDA Risk Evaluation and Mitigation Strategies (REMS)³ compliance program; the therapy must be used for either an FDA-approved indication or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia.⁴ Coverage of CAR-T therapy services is permitted only when in accordance with other Program guidelines.⁵

II. Covered CAR-T Therapy Services

A Prior Authorization Level 3 (PA3) is required for all CAR-T therapy services. CAR-T therapy services available for coverage under the WTC Health Program include autologous treatment of cancer with T-cells expressing at least one CAR. Autologous treatment consists of harvesting the patient's own T-cells for transplant.⁶

¹ The WTC Health Program defines medically necessary treatment as the provision of healthcare services to manage, ameliorate, or cure a WTC-related health condition or health condition medically associated with a WTC-related health condition. See 42 C.F.R. § 88.1 at <https://www.cdc.gov/wtc/regulations2.html>.

² See CAR T-cell therapy, NIH, at <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/car-t-cell-therapy>

³ See FDA "REMS Compliance Program" at <https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/rems-compliance-program>.

⁴ Social Security Act, Section 1861(t)(2), at https://www.ssa.gov/OP_Home/ssact/title18/1861.htm.

⁵ See generally WTC Health Program Administrative Manual for a full description of Program guidelines, policies, and procedures, at <https://www.cdc.gov/wtc/ppm.html>.

⁶ See Chimeric Antigen Receptors (CAR) T-cell Therapy for Cancers, Centers for Medicare and Medicaid Services (CMS) Medical Coverage Database, at <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=291>.

The WTC Health Program may cover CAR-T therapy beyond those referenced in this MCD only on a limited case-by-case basis and where supported by the clinical evidence base. Refer to the WTC Health Program Codebook for a full list of covered medical services, procedures, and diagnosis codes.

A. CAR-T Therapy Services

In order to determine whether the member is a candidate for CAR-T therapy, the member may require diagnostic testing and/or medical consultations for pretreatment evaluation. Pretreatment evaluation may vary based on individual member needs. The CCE/NPN Clinical Director will authorize such evaluative services based on the prior authorization requirements in the WTC Health Program Codebook.⁷

If the member is determined to be a candidate for CAR-T therapy after their pretreatment evaluation, the following services may be provided if the member meets all PA3 requirements outlined in Section III below:

1. Cell Collection and Alteration

White blood cells are removed from the blood, then T-cells are separated and sent to the laboratory for genetic alteration with specific CAR.⁸

2. Administration of CAR-T

CAR-T cell therapy is administered by infusion as a one-time regimen⁹ in a hospital setting or CAR-T outpatient center to allow for monitoring of potential side effects.¹⁰

3. Treatment of Potential Side Effects

CAR-T therapy may result in serious side effects as the CAR-T cells multiply in the body to fight the cancer, including two potentially dangerous syndromes: Cytokine Release Syndrome (CRS)¹¹ and Immune Cell-Associated Neurotoxicity Syndrome (ICANS).¹² Treatment of these and other potential side effects as a result of CAR-T therapy will be covered under the approved CAR-T therapy PA3 when they meet the definition of a medically associated health condition.¹³

⁷ Please contact the WTC Health Program for questions regarding coverage of non-medical expenses related to pre-treatment evaluation, including reimbursement for travel, meals, and accommodations.

⁸ See CAR T-cell Therapy and Its Side Effects, American Cancer Society, at <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy/car-t-cell1.html>

⁹ A regimen consists of several steps that may expand over several weeks to include cell collection and modification, administration, and monitoring. See How CAR T-cell Therapy Works, University of Chicago Medicine, at <https://www.uchicagomedicine.org/cancer/types-treatments/car-t-cell-therapy/how-car-t-cell-therapy-works>

¹⁰ See Immunotherapy Side Effects: CAR T-Cell Therapy, National Comprehensive Cancer Network, at <https://www.nccn.org/patientresources/patient-resources/guidelines-for-patients/guidelines-for-patients-details?patientGuidelineId=45>

¹¹ See CAR T-cell Therapy and Its Side Effects, American Cancer Society, at <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy/car-t-cell1.html>

¹² See Neurotoxicity associated with CAR T-cell therapy, Cancer Institute of New South Wales, at <https://www.eviq.org.au/clinical-resources/bmt-cellular-therapies/3834-neurotoxicity-associated-with-car-t-cell-ther>

¹³ The WTC Health Program defines a health condition medically associated with a WTC-related health condition as a condition that results from treatment or progression of a certified WTC-related health condition. See WTC Health Program Policy & Procedure, "Health Conditions Medically Associated with World Trade Center-Related Health Conditions," at <https://www.cdc.gov/wtc/pdfs/policies/WTCHPMedicallyAssociatedHealthConditions7November2014-508.pdf>.

4. Acute Recovery Period

The first four weeks post-completion of CAR-T infusion is considered the Acute Recovery Period.¹⁴ To monitor for potential side effects and effectiveness of the treatment, it is recommended the recipient remain within close distance to the treating facility during this time.

III. Coverage Guidelines – General Eligibility Requirements for Medically Necessary CAR-T Therapy

All CAR-T therapy services must meet the criteria below.

A. Prior Authorization (PA) Level

1. Level 3 – Authorization by the WTC Health Program

A PA3 is required for all CAR-T therapy services. The WTC Health Program will review the medical justification provided by the CCE/NPN Clinical Director and determine whether the CAR-T therapy services are medically necessary to treat the member's certified WTC-related cancer, or health condition medically associated with a certified WTC-related cancer. The WTC Health Program will also ensure that the member meets the PA criteria listed below in Section III.B. and confirm that the criteria are appropriately documented in the member's medical record.

For detailed Prior Authorization procedures, see instructions found in the WTC Health Program's Administrative Manual.¹⁵

B. PA3 Criteria

1. Authorization Criteria for CAR-T Therapy Services

The CCE/NPN Clinical Director may request authorization from the WTC Health Program for CAR-T therapy services if **ALL** the criteria below (a. through f.) are met and clearly documented in the member's medical record. To request CAR-T therapy services, the CCE/NPN Clinical Director must submit a PA3 request to the WTC Health Program confirming that each of the following criteria is met:

- a. CAR-T therapy services are determined to be medically necessary to manage, ameliorate, or cure a certified WTC-related cancer, or health condition medically associated with a certified WTC-related cancer.¹⁶
- b. The services are provided while the member is under the care of a WTC Health Program-affiliated provider.

¹⁴ See Frequently Asked Questions About CAR T-Cell Therapy, Dana-Farber Cancer Institute, at <https://www.dana-farber.org/cellular-therapies-program/car-t-cell-therapy/faq-about-car-t-cell-therapy/>.

¹⁵ WTC Health Program Administrative Manual, [Chapter 4, Section 3.4], at https://www.cdc.gov/wtc/ppm.html#medical_prior.

¹⁶ The member may require pretreatment evaluation to determine whether they are a candidate for medically necessary CAR-T therapy services. Pretreatment evaluation may vary based on individual member needs. The CCE/NPN Clinical Director will include any pretreatment evaluation results in the member's record to support the determination of medical necessity for CAR-T therapy.

- c. The services are administered at a facility enrolled in the FDA REMS compliance program.
- d. The CAR-T product must be used for an FDA-approved indication (or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia).
- e. The member requires CAR-T therapy due to failure of prior standard cancer treatments or cancer recurrence.¹⁷ If the CAR-T therapy request is due to a failure of prior standard cancer treatments, the PA3 request must include narrative details describing the previous treatment failure.
- f. The treatment plan should align with NCCN treatment guidelines.¹⁸

2. Coverage Limitations

Once signed and authorized by the WTC Health Program, the PA3 for CAR-T services will cover only a single CAR-T regimen. The authorization period starts the day the member begins the cell collection period and ends when the Acute Recovery Period is completed.

The PA3 will only cover one instance of CAR-T therapy administration and the 30 days following administration for the Acute Recovery Period. If the Acute Recovery Period is extended for an individual because additional monitoring and/or treatment is indicated, a new PA3 is required. Additional new PA3s are required for each 14-calendar day interval after the initial 30-day Acute Recovery Period for any applicable extension.

IV. Prior Authorization Request Submission Requirements

The PA3 for CAR-T therapy services must be signed by the requesting CCE/NPN Clinical Director and submitted to the Third-Party Administrator (TPA) contractor securely following the Program's standard procedures. The WTC Health Program will decide whether to authorize the service and will inform the TPA contractor, who will subsequently inform the CCE/NPN of the decision. The CCE/NPN will maintain documentation that demonstrates MCD criteria has been met in the member's medical record, as well as documentation related to the PA3 Request. Incomplete or inaccurate requests will be returned to the requesting CCE/NPN for additional information.

Prior authorization must be obtained before initiating CAR-T therapy services. Retrospective PA3 requests for CAR-T therapy services are not permitted.

All documentation for completed CAR-T therapy service authorizations are subject to audit by the WTC Health Program.

V. Billing/Coding Guidelines

¹⁷ See CAR T Cell Therapy, MD Anderson Cancer Center, at <https://www.mdanderson.org/treatment-options/car-t-cell-therapy.html>.

¹⁸ See NCCN "Treatment by Cancer Type" for clinical practice guidelines for Lymphoma and Multiple Myeloma, at https://www.nccn.org/guidelines/category_1. Please note that the Program may consider a treatment regimen that does not align with NCCN guidelines if the member has a medical contraindication to one of the therapies recommended by NCCN. There may also be other reasonable explanations for case exceptions.

All applicable codes are listed in the WTC Health Program Codebook, located on the Centralized Accessible Real-time Enterprise (CARE) portal.

For consideration of codes that are not currently included in the WTC Health Program Codebook, please submit a WTC-5 Medical Code Request form to the TPA Contractor via the standard WTCMedCode@csra.com mailbox process.