# Clinical Policy: CAR T-Cell Therapy

Reference Number: WNC.CP.192
Last Review Date:

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Note:** When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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## Description[1]

Engineered T cell–based antitumor immunotherapy uses gene transfer of tumor antigen-specific T-cell receptors (TCR) or synthetic chimeric antigen receptors (CAR). CAR T-Cells are prepared from the patient's peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure. The blood is sent to the manufacturer where the mononuclear cells are enriched for T cells. The T cells are expanded in cell culture, washed, and formulated into a suspension, which then is cryopreserved. This process may take several weeks. The product is then infused into the Member. This technique has shown very encouraging results in clinical trials for treatment of types of leukemias and lymphomas.

## Definitions:

- **A Certified or Authorized Treatment Center** for CAR T-Cell Therapy is a healthcare facility approved to administer CAR T-cell treatments. These centers meet manufacturer and regulatory requirements, including having medical staff trained in the entire CAR T-cell therapy process, from administration to managing potential adverse effects. Certification requires compliance with FDA-mandated training and may be based on a facility's expertise, infrastructure, and ability to treat patients with hematologic malignancies. Only certified or authorized treatment centers can provide specific CAR T-cell therapies, ensuring safe and effective patient care.

- **Rescue Transplant** - A method of replacing blood-forming stem cells that were destroyed by treatment with high doses of anticancer drugs or radiation therapy. The stem cells help the bone marrow recover and make healthy blood cells. A rescue transplant may allow more chemotherapy or radiation therapy to be given so that more cancer cells are killed. It is usually done using the patient's own stem cells that were saved before treatment. Also called stem cell rescue.

- **United States Food & Drug Administration (U.S. FDA)** - the Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

## Policy/Criteria[1]

**I.** WellCare of North Carolina® shall cover CAR T-Cell Therapy when **all** of the following criteria are met:
- **A.** The CAR T-Cell Therapy has received approval from the United States Food & Drug Administration (U.S. FDA);
- **B.** The CAR T-Cell Therapy is administered per U.S. FDA approved guidelines regarding:
  1. Indications and usage;
  2. Dosage and administration;
  3. Dosage forms and strengths; **and**
  4. Warnings and precautions;
- **C.** The CAR T-Cell Therapy is administered at a certified or authorized treatment center. If the therapy is subject to a Risk Evaluation and Mitigation Strategies (REMS) program, the treatment center must be enrolled in the REMS, and providers must be trained on the management of cytokine release syndrome (CRS) and neurological toxicities.

**II.** WellCare of North Carolina shall **not** cover CAR T-Cell Therapy for any **one** of the following:
- **A.** The CAR T-Cell Therapy has not received approval from the U.S. FDA;
- **B.** The CAR T-Cell Therapy is being administered outside U.S. FDA guidelines regarding:
  1. Indications and usage;
  2. Dosage and administration; **or**
  3. Dosage forms and strengths;
- **C.** if a CAR T-Cell Therapy requires a Risk Evaluation and Mitigation Strategy (REMS), it is being administered at a facility that has not enrolled in that therapy's REMS;
- **D.** Repeat treatment in members who have received another CAR T-Cell Therapy previously;
- **E.** When the Member's psychosocial history limits the Member's ability to comply with pre- and post-infusion medical care; **or**
- **F.** When there is current Member or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

**III.** WellCare of North Carolina shall **not** cover concurrent rescue transplant with infusion of any CAR T-Cell Therapy as this is considered experimental.

## Background[1]

**I.** The provider shall obtain prior approval before rendering CAR T-Cell Therapy. Documentation required for prior authorization includes but is not limited to:

**A.** Letter of medical necessity **signed by the attending physician**, which documents past chemotherapy regimens and dates, the clinical and social history, and indications for treatment with CAR T-Cell therapy;
**B.** Verification that the administering facility a qualified or authorized treatment center for the requested CAR T-Cell therapy; If this information is publicly available, additional documentation is not required. Otherwise, the provider must submit a copy of the contract between the administering facility and the manufacturer of the requested CAR T-Cell Therapy as confirmation;
**C.** Serologies (less than three months old) to include Human Immunodeficiency Virus (HIV) and Hepatitis panel (*positive* serology results may be reported that are greater than three months old);
**D.** All diagnostic and procedure results, including bone marrow biopsy (not more than six months old);
**E.** Other diagnostic tests may be requested as appropriate; **and**
**F.** Complete psychological and social evaluation to include:
1. Member's medical compliance;
2. Member's support network
3. post-treatment care plan, with identification of primary and secondary care providers; **and**
4. history of mental health issues, substance use, or legal issues.

**Coding Implications**



- CAR T-Cell Therapy, when medical necessity criteria above is met, is covered in both hospital inpatient and hospital outpatient places of service.

- Provider(s) shall file outpatient claims for CAR T-Cell Therapy with **Revenue Code 0636** and the **product-specific** HCPCS code for the CAR T-Cell Therapy. If the CAR T-Cell Therapy has been approved by the U.S. FDA but has not yet been assigned a product-specific HCPCS code, the provider shall use HCPCS C9399 (UNCLASSIFIED DRUGS OR BIOLOGICALS).

- If the CAR T-Cell Therapy administered is **KYMRIAH (tisagenlecleucel)** for B-cell precursor acute lymphoblastic leukemia (ALL), provider(s) shall attach documentation with the claim regarding 30-day Member response.

| Reviews, Revisions, and Approvals | Reviewed Date | Approval Date |
|---|---|---|
| Original approval date | 04/21 | 05/21 |
| Removed descriptions of specific CAR T-Cell Therapies. Removed listing of specific CAR T-Cell Therapies. Added coverage statement for FDA approved CAR T-Cell Therapies when administered per FDA approved guidelines. Specific ICD-10 CM, ICD-10 PCS, and HCPCS codes removed.<br>Revised criteria on requirements to submit 30-day patient response to therapy with claim (for KYMRIAH for ALL). | 10/21 | 11/21 |
| Annual Review. Added verbiage regarding Revenue Code 0636 & HCPCS C9399, with no change to criteria. | 11/22 | 11/22 |
| NCHC verbiage removed from NC Guidance Verbiage | 04/23 | 04/23 |
| Annual Review. | 08/23 | 08/23 |
| Annual Review. Changed 'beneficiary' to 'member' Removed 'Medicaid and health choice' verbiage from References. | 08/24 | 08/24 |
| Annual Review. Moved 'engineered T-Cell based antitumor' text to Description, from Background I. Definitions added for Certified or Authorized Treatment Center & USFDA. Criteria I.C. Language updated to reflect that only CAR T-Cell Therapies with an FDA-required REMS will require facility participation in the REMS program. Criteria II.C. Language updated to reflect that only CAR T-Cell Therapies with an FDA-required REMS will require facility participation in the REMS program. Background I.B. Clarified that facility-manufacturer contracts are only required to verify certification or authorization as a treatment center if this information is not publicly available on the website. Moved Kymriah information from Background to under Coding Implications. Under NC Guidance/Claims related information, updated state web address. | | |

**References**

1. State of North Carolina Medicaid Clinical Coverage Policy No: 11A-17 CAR T-Cell Therapy. **Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov)**. Published April 1, 2025. Accessed April 4, 2025.

**North Carolina Guidance**

*Eligibility Requirements*

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

*EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age*

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]
Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**EPSDT and Prior Approval Requirements**

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:
   *NCTracks Provider Claims and Billing Assistance Guide*:
   https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
   *EPSDT provider page*: https://medicaid.ncdhhs.gov/

*Provider(s) Eligible to Bill for the Procedure, Product, or Service*
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

*Compliance*
Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state, and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

*Claims-Related Information*
Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

a. Claim Type - as applicable to the service provided:
   Professional (CMS-1500/837P transaction)
   Institutional (UB-04/837I transaction)
   Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.
   *Unlisted Procedure or Service*

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.
HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service

d. Modifiers - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
For Medicaid refer to Medicaid State Plan:
https://medicaid.ncdhhs.gov/meetingsnotices/medicaid-state-plan-public-notices

g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.