

Clinical Policy: CAR-T Cell Therapy

Reference Number: WNC.CP.192

Last Review Date: 08/22

[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.

Description¹

This policy outlines the medical necessity criteria for CAR-T Cell therapy.

Policy/Criteria¹

- 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 healthcare facility that has enrolled in the therapy's Risk Evaluation and Mitigation Strategies (REMS) and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities.
 - 1. Due to the risk of CRS and neurological toxicities, CAR-T Cell Therapies are only available through a restricted program under a REMS. A REMS is a program to manage known or potential serious risks associated with a drug product and is required by the U.S. FDA to ensure that the benefits of the drug outweigh its risks. The U.S. FDA has required a REMS for CAR-T Cell Therapies. Each CAR-T Cell Therapy has a respective REMS Program.
- 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. The CAR-T Cell Therapy is being administered at a facility that has not enrolled in that therapy's REMS;
 - D. Repeat treatment in beneficiaries who have received another CAR-T Cell Therapy previously;
 - E. When the beneficiary's psychosocial history limits the beneficiary's ability to comply with pre- and post-infusion medical care; **or**

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- F. When there is current beneficiary 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.

Background¹

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

- 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;
- Copy of contract between administering facility and manufacturer of the requested CAR-T Cell therapy;
- 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);
- All diagnostic and procedure results, including bone marrow biopsy (not more than six months old);
- Other diagnostic tests may be requested as appropriate; **and**
- Complete psychological and social evaluation to include:
 - beneficiary's medical compliance;
 - beneficiary's support network
 - post-treatment care plan, with identification of primary and secondary care providers; **and**
 - history of mental health issues, substance use, or legal issues.

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

Engineered T cell–based antitumor immunotherapy uses gene transfer of tumor antigen-specific T-cell receptors (TCR) or synthetic chimeric antigen receptors (CAR-T). 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 beneficiary. This technique has shown very encouraging results in clinical trials for treatment of types of leukemias and lymphomas.

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.

Coding Implications

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This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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).

Reviews, Revisions, and Approvals	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. Revised criteria on requirements to submit 30-day patient response to therapy with claim (for KYMRIA for ALL).	10/21	11/21
Annual Review. Added verbiage regarding Revenue Code 0636 & HCPCS C9399, with no change to criteria.	08/22	

References

1. State of North Carolina Medicaid. Medicaid and Health Choice Clinical Coverage Policy No: 11A-17 CAR-T Cell Therapy. <https://medicaid.ncdhhs.gov/providers/clinical-coverage-policies>. Published October 1, 2021. Accessed August 30, 2022.

North Carolina Guidance

Eligibility Requirements

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise); or
 2. the NC Health Choice (NCHC is NC Health Choice program, unless context clearly indicates otherwise) Program on the date of service and shall meet the criteria in this policy.
- b. Provider(s) shall verify each Medicaid or NCHC 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.

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- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

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:

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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/>

EPSDT does not apply to NCHC beneficiaries.

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 or NCHC 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 and NCHC:

- 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

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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/get-involved/nc-health-choice-state-plan>
For NCHC refer to NCHC State Plan:
<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>
- 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

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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.

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