TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Ciltacabtagene autoleucel (Carvykti®)	**CRITERIA ID:** TX.CC.PHAR.22
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 10/19/2022	**PRODUCT(S):** STAR, STAR Plus, STAR Kids, STAR Health, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 11/27/2023, 03/15/2024, 09/11/2024, 09/30/2024, 8/6/2025	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for ciltacabtagene autoleucel (Carvykti®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

Additionally, this medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage Precision Drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All Precision Drug requests or potential requests must be reported to the PDAC

for tracking, regardless of whether agents are carved out, passed through, etc. All Precision Drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

The procedure code Q2056 (used for Carvykti) will be limited to one approval per lifetime, by any provider. This includes if Carvykti was previously approved with any other code. If the code is updated in the future it will still be limited to once per lifetime.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
PDAC = Precision Drug Action Committee
UM = Utilization Management
CAR-T = chimeric antigen receptors T-cell

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of ciltacabtagene autoleucel (Carvykti®); procedure code: Q2056.

Description/Mechanism of Action:
Ciltacabtagene autoleucel (Carvykti®) is a B-cell maturation antigen-directed genetically modified autologous T-cell immunotherapy.

FDA Approved Indications:
Ciltacabtagene autoleucel (Carvykti®) is indicated to treat adult clients with relapsed or refractory multiple myeloma after one or more lines of therapy including a proteasome inhibitor, an immunomodulatory agent and are refractory to lenalidomide.

Formulations:
Ciltacabtagene autoleucel (Carvykti®) is a cell suspension for intravenous infusion. A single dose of Carvykti contains a cell suspension of 0.5-1.0×10^6 CAR-positive viable T cells per kg body weight in one infusion bag.

PROCEDURE:

I. Approval Criteria

A. Relapse or refractory multiple myeloma

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. Medical necessity determinations will be supported by PDAC UM recommendation. The pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the Medical Director but will not make the ultimate determination on any case.
3. The client is 18 years of age or older.
4. The client has a histologically confirmed diagnosis of relapsed or refractory multiple myeloma (diagnosis codes: C90.00, C90.02).
5. The client has relapsed or refractory disease, is refractory to lenalidomide, and has received at least one line of the following systemic therapies before treatment with Carvykti:
    - A proteasome inhibitor
    - An immunomodulatory agent
6. The client does not have primary central nervous system lymphoma/disease.
7. The client does not have an active infection or inflammatory disorder.
8. The client has not received prior CAR-T therapy.

Approval duration: Only 1 dose per lifetime will be provided on this drug regardless of Provider.

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document		10/19/2022
Ad Hoc Review	Added Centene Pharmacy Services (CPS) throughout document Updated language in header sections: PUPOSE, SCOPE Updated criteria step verbiage to “The client” throughout Split criteria step 5 into two separate criteria steps (5 and 6) to clarify language/criteria step intent	11/27/2023

	Added CHIP Perinate to Products	
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement	03/15/2024
Ad Hoc Review	Updated PURPOSE section to include NRB status effective 10/1/2024 Updated Carvykti criteria step to align with TMHP notification "Prior Authorization Criteria for CAR T-Cell Therapy to Change Effective August 1, 2024"	09/11/2024
Ad Hoc Review	Updated Carvykti *FDA Approved Indications* to align with TMHP CAD Manual updates (10/1/24)	09/30/2024
Annual Review	Font and format changes for 508 remediation Added CAR-T definition	8/6/2025