POLICY AND PROCEDURE

POLICY NAME: Ciltacabtagene autoleucel (Carvykti)	**POLICY ID:** TX.PHAR.107
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 10/19/2022	**PRODUCT(S):** STAR, STAR Plus, STAR Kids, STAR Health, CHIP
REVIEWED/REVISED DATE:	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
It is the policy of Superior HealthPlan (SHP) to follow state guidance for medical necessity review of ciltacabtagene autoleucel (Carvykti)

PURPOSE:
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.

In addition, Carvykti (Q2056) requests are limited to one approval per lifetime, by any provider. This includes if Carvykti was previously approved with any other code.

Description and Indication:
Carvykti (Ciltacabtagene autoleucel) is a B-cell maturation antigen-directed genetically modified autologous T cell immunotherapy indicated to treat adult clients with relapsed or refractory multiple myeloma after four or more lines of therapy including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

Formulations:
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.

SCOPE:
Superior HealthPlan Pharmacy Department, Medical Directors

DEFINITIONS:
PDAC = Precision Drug Action Committee
UM = Utilization Management

POLICY:
It is the policy of Superior HealthPlan (SHP) to follow state guidance for medical necessity review of ciltacabtagene autoleucel (Carvykti). All determinations will be performed by a Superior 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.

PROCEDURE:

I. Approval Criteria

A. Relapse or refractory multiple myeloma

1. All prior authorization approvals or denials will be determined by a SHP Medical Director.
2. Medical necessity determinations will be supported by PDAC UM recommendation. The SHP pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the SHP Medical Director but will not make the ultimate determination on any case.
3. Member age is 18 years of age or older.

4. Confirmed diagnosis of relapsed or refractory multiple myeloma (diagnosis code: C90.00, C90.02)
5. Member has relapsed or refractory disease and has received four or more lines of the following systemic therapies before treatment with citacabtagene autoleucel (Carvykti):
    a. A proteasome inhibitor
    b. An immunomodulatory agent
    c. An anti-CD38 monoclonal antibody
6. Member does not have primary central nervous system lymphoma/disease.
7. Member does not have an active infection or inflammatory disorder.
8. Member 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:

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document		10/19/2022

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.