10/17/2022

Prior Authorization Criteria for Carvykti Begins December 1, 2022

Background:

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. Procedure code Q2056 is limited to once per lifetime administration.

Certified healthcare facilities must enroll and comply with the Risk Evaluation and Mitigation Strategies (REMS) requirements for each drug administered under this policy.

Key Details:

Authorization requirements

HHSC will consider prior authorization approval of Carvykti (ciltacabtagene autoleucel) infusion therapy when a client meets the following criteria:

- Client is 18 years of age or older
- Client has histologically confirmed diagnosis of relapse or refractory multiple myeloma (diagnosis code: C90.00, C90.02)
- Clients has relapsed or refractory disease and has received four or more lines of the following systemic therapies before treatment with ciltacabtagene autoleucel:
    - A proteasome inhibitor
    - An immunomodulatory agent
    - An Anti-CD38 monoclonal antibody
    - Client does not have primary central nervous system lymphoma/disease
    - Client does not have an active infection or inflammatory disorder
    - Client has not received prior CAR-T therapy
- Client does not have primary central nervous system lymphoma/disease
- Client does not have an active infection or inflammatory disorder
- Client has not received prior CAR-T therapy

Ciltacabtagene autoleucel (Carvykti) (procedure code Q2056) is limited to once per lifetime.

Additional Information:

HHSC approved this updated clinical prior authorization for use by MCOs. While HHSC will implement these criteria for Medicaid fee-for-service on December 1, 2022, MCOs do not need to wait for publication in the TMPPM before implementation. MCOs may choose to implement the updated requirements but shall not make them more restrictive.

Resources:

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

Contact:

vdp-cad@hhsc.state.tx.us

Type: Informational

To: CHIP; STAR; STAR+PLUS; STARHEALTH; STAR_KIDS

From: VDP