| Ciltacabtagene autoleucel (Carvykti™) | Place of Service<br>Outpatient Facility Administration<br>Hospital Administration<br><br>HCPCS: **Q2056** up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose |
|---|---|

**Condition listed in policy (*see criteria for details*)**

- Multiple myeloma

**AHFS therapeutic class:** Antineoplastic Agents

**Mechanism of action**: B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy

## (1) Special Instructions and pertinent Information

**Covered under the Medical Benefit,** please submit clinical information for prior authorization review via fax.

## (2) Prior Authorization/Medical Review is required for the following condition(s)

**All requests for Carvykti™ (ciltacabtagene autoleucel) must be sent for clinical review and receive authorization for both ciltacabtagene autoleucel and for hospital admission prior to drug administration or claim payment.**

**Multiple myeloma**

1. Patient has received at least 4 prior therapies that include the use of all of the following:
    a. an immunomodulatory agent (e.g., Pomalyst, Revlimid, Thalomid), and
    b. a proteasome inhibitor (e.g., Kyprolis, Ninlaro, Velcade), and
    c. an anti-CD38 monoclonal antibody (e.g., Darzalex, Sarclisa),

    **AND**
2. Patient has not received prior treatment with CAR-T therapy, including Carvykti, **AND**
3. Being used as single-agent therapy

**Covered Doses**
One-time IV infusion. Recommended dose range per prescribing information is $0.5\text{-}1.0\times10^6$ CAR-positive viable T cells per kg of body weight, with a maximum dose of $1\times10^8$ CAR-positive viable T cells

**Coverage Period**
Single infusion per lifetime

**ICD-10:**
C90.00, C90.02, C90.10, C90.12, C90.20, C90.22, C90.30, C90.32, D47.2, Z85.79

## (3) The following condition(s) DO NOT require Prior Authorization/Preservice

**All requests for Carvykti™ (ciltacabtagene autoleucel) must be sent for clinical review and receive authorization for both ciltacabtagene autoleucel and for hospital admission prior to drug administration or claim payment.**

## (4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

## (5) Additional Information

How supplied:

- 30 mL infusion bag and metal cassette
- 70 mL infusion bag and metal cassette

## (6) References


- AHFS®. Available by subscription at http://www.lexi.com
- Carvykti™ (ciltacabtagene autoleucel) [Prescribing information]. Horsham, PA: Janssen Biotech, Inc.; 2023.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network. Multiple Myeloma (Version 4.2023). Available at: www.nccn.org


## (7) Policy Update

Date of last review: 4Q2023
Date of next review: 4Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity*
*Reviewed by P&T Committee*