

Ciltacabtagene autoleucel (Carvykti™)

Place of Service  
Outpatient Facility Administration  
Hospital Administration

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 0.5-1.0×10<sup>6</sup> CAR-positive viable T cells per kg of body weight, with a maximum dose of 1×10<sup>8</sup> 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**

Commercial

ciltacabtagene autoleucel (Carvykti™)

All requests for Carvykti™ (ciltacabtagene autoleucl) must be sent for clinical review and receive authorization for both ciltacabtagene autoleucl 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 autoleucl) [Prescribing information]. Janssen Biotech, Inc., Horsham, PA. 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](http://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*