

POLICY: Oncology (Injectable – CAR-T) – Carvykti Utilization Management Medical Policy

- Carvykti™ (ciltacabtagene autoleucel intravenous infusion – Janssen Biotech)

EFFECTIVE DATE: 6/1/2022

LAST REVISION DATE: 03/20/2024

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Carvykti, a B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy, is indicated for the treatment of relapsed or refractory **multiple myeloma** in adults after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.¹

Dosing Information

Carvykti is supplied in one infusion bag containing a frozen suspension of genetically modified autologous T-cells in 5% dimethyl sulfoxide.¹ The bag is stored in the vapor phase of liquid nitrogen (-184°F). The recommended dose is a single infusion of 0.5 to 1.0 x 10⁶ chimeric antigen receptor (CAR)-T cells per kg of body weight, to a maximum dose of 1 x 10⁸ CAR-T cells.

Guidelines

The National Comprehensive Cancer Network clinical practice guidelines for multiple myeloma (version 3.2024 – March 8, 2024) recommend Carvykti for the treatment of multiple myeloma in patients who have received four or more previous therapies.^{2,3} Patients should receive a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody before receiving Carvykti.

Safety

Carvykti has a Boxed Warning for cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, parkinsonism and Guillain-Barre syndrome, hemophagocytic lymphohistiocytosis/macrophage activation syndrome, prolonged and/or recurrent cytopenias, and secondary hematological malignancies.¹ Carvykti is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Carvykti REMS.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Carvykti. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Because of the specialized skills required for evaluation and diagnosis of patients treated with Carvykti as well as the monitoring required for adverse events and long-term efficacy, approval requires Carvykti to be prescribed by or in consultation with a physician who specializes in the condition being treated. The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Carvykti is recommended in those who meet the following criteria:

FDA-Approved Indication

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- 1. Multiple Myeloma.** Approve a single dose if the patient meets ALL of the following (A, B, C, D, and E):
- A) Patient is ≥ 18 years of age; AND
 - B) Patient has received four or more lines of systemic therapy, including one therapy from each of the following (i, ii, and iii):
 - i. Immunomodulatory agent; AND
Note: Immunomodulatory agents include Thalomid (thalidomide capsules), lenalidomide capsules, and Pomalyst (pomalidomide capsules).
 - ii. Proteasome inhibitor; AND
Note: Proteasome inhibitors include bortezomib injection, Kyprolis (carfilzomib intravenous infusion), and Ninlaro (ixazomib capsules).
 - iii. Anti-CD38 monoclonal antibody; AND
Note: Anti-CD38 monoclonal antibodies include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), and Sarclisa (isatuximab-irfc intravenous infusion).
 - C) Patient has received or plans to receive lymphodepleting chemotherapy prior to infusion of Carvykti; AND
 - D) Patient has not been previously treated with chimeric antigen receptor (CAR-T) therapy; AND
Note: Examples of CAR-T therapy includes Carvykti, Abecma (idecabtagene vicleucel intravenous infusion), Breyanzi (lisocabtagene maraleucel intravenous infusion), Kymriah (tisagenlecleucel intravenous infusion), Tecartus (brexucabtagene intravenous infusion), and Yescarta (axicabtagene intravenous infusion).
 - E) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 1×10^8 CAR-T cells administered intravenous as a single dose.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Carvykti is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Carvykti intravenous infusion [prescribing information]. Horsham, PA: Janssen Biotech; December 2023.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on March 11, 2024.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2024 – March 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on March 11, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/22/2023
Annual Revision	No criteria changes.	03/20/2024