UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – CAR-T) – Carvykti Utilization Management Medical Policy
- Carvykti® (ciltacabtagene autoleucel intravenous infusion – Janssen Biotech)

REVIEW DATE: 03/05/2025

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 at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide.[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 10^6 chimeric antigen receptor (CAR)-T cells per kg of body weight, to a maximum dose of 1 x 10^8 CAR-T cells.

Guidelines

The National Comprehensive Cancer Network clinical practice guidelines for multiple myeloma (version 1.2025 – September 17, 2024) recommend Carvykti as a "Preferred Regimen" for the treatment of multiple myeloma in patients who have received at least one prior therapy including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide.[2,3] Carvykti is also recommended as a "Preferred Regimen" for the treatment of multiple myeloma in patients who have received three or more previous therapies.

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 meets ONE of the following (i or ii):
  - **i.** Patient meets BOTH of the following (a and b):
    - **a)** Patient has received one or more lines of systemic therapy, including one therapy from BOTH of the following [(1) and (2)]:
      - **(1)** Immunomodulatory agent; AND
        Note: Immunomodulatory agents include Thalomid (thalidomide capsules), lenalidomide capsules, and Pomalyst (pomalidomide capsules).
      - **(2)** Proteasome inhibitor; AND
        Note: Proteasome inhibitors include bortezomib injection, Kyprolis (carfilzomib intravenous infusion), and Ninlaro (ixazomib capsules).
    - **b)** Patient is refractory to lenalidomide; OR
  - **ii.** Patient has received at least three prior lines of therapy; AND
- **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 x 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; April 2024.
2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 24, 2025.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 1.2025 – September 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 24, 2025.

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
Selected Revision	**Multiple Myeloma:** Changed patient has received four or more lines of systemic therapy from requirement to option for approval. New option for approval added that the patient has received one or more lines of systemic therapy including an immunomodulatory agent and a proteasome inhibitor, and is refractory to lenalidomide.	05/29/2024
Annual Revision	**Multiple Myeloma:** Removed patient has received four or more lines of systemic therapy, including one from each of the following as an option for approval. Added patient has received at least three prior lines of therapy as an option for approval.	03/05/2025