Medicare Advantage Medical Utilization Review Policy

Policy:	**Oncology (Injectable – CAR-T) – Carvykti Utilization Management Medical Policy** • Carvykti™ (ciltacabtagene autoleucel intravenous infusion – Janssen Biotech)
Date:	03/25/2025
Applicable Lines of Business:	Medicare Advantage - Medical
Applicable States:	All States
Applicable NCDs, LCDs, and/or LCAs	NCD 110.24

SUMMARY OF EVIDENCE

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.

ANALYSIS OF EVIDENCE

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

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. The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the Sources of Information section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Sources of Information section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

Indications with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.

Indications with a @ below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.

Indications with a # below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. Multiple Myeloma. ^

Criteria. Approve a single dose if the patient meets the following criteria (A, B, C, and D):

A) Patient is ≥ 18 years of age; [IC-COMP] 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)]: [IC-COMP]

(1) Immunomodulatory agent; [IC-COMP] AND

Note: Immunomodulatory agents include Thalomid (thalidomide capsules), lenalidomide capsules, and Pomalyst (pomalidomide capsules).

(2) Proteasome inhibitor; [IC-COMP] AND

Note: Proteasome inhibitors include bortezomib injection, Kyprolis (carfilzomib intravenous infusion), and Ninlaro (ixazomib capsules).

b) Patient is refractory to lenalidomide; [IC-COMP] OR

ii. Patient has received at least three prior lines of therapy; [IC-COMP] AND

C) Patient has received or plans to receive lymphodepleting chemotherapy prior to infusion of Carvykti; [IC-COMP] AND

D) Patient has not been previously treated with chimeric antigen receptor (CAR-T) therapy. [IC-COMP]

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).

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.

SOURCES OF INFORMATION

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.

4. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). Original effective date 8/7/2019. Implementation date 2/16/2021. Revision Date: 10/2024. Accessed March 25, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	03/10/2022
Policy revision	Added: "The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy." to the Policy Statement.	07/26/2023
Policy review	No criteria changes. Review based on commercial policy annual review	04/19/2024
Policy 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. Revision based on review of commercial policy updates	06/05/2024
Policy review	No criteria changes. Review based on NCD surveillance review.	01/06/2025
Policy revision	No criteria changes. Formatting and notation updates.	03/10/2025
Policy 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. Revision based on commercial policy update	03/25/2025