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: 09/16/2024

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 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 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. 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 References 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 Reference 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 also covered (and, if applicable, further detailed/referenced) in the corresponding Commercial Care Continuum (CC) Policy. Note: Additional criteria requirements for coverage of the same indication as outlined in the Commercial CC Policy and this Medicare Advantage CC Policy may NOT be the same.

Indications noted with eviCore are managed by eviCore healthcare for those clients who use eviCore for oncology and/or oncology-related reviews. For these indications, a prior authorization should be initiated through eviCore at www.eviCore.com.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. Multiple Myeloma. ^ *eviCore*

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

A) Patient is ≥ 18 years of age; AND

B) Patient has received four or more lines of systemic therapy, including one from each of the following (i, ii, and iii):

i. Patient has received an immunomodulatory agent; AND

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

ii. Patient has received a proteasome inhibitor; AND
Note: Proteasome inhibitors include bortezomib injection, Kyprolis (carfilzomib intravenous infusion), and Ninlaro (ixazomib capsules).

iii. Patient has received an 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.
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.

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.
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. Accessed April 19, 2024.

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
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024