Drug Coverage Policy

Effective Date 6/1/2025
Coverage Policy Number.....IP0414
Policy Title.....Carvykti

Oncology (Injectable – CAR-T) – Carvykti

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

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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.

Coverage Policy

Carvykti is considered medically necessary when the following are met:

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; AND
     - **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. Up to 1 x 10^8 CAR-T cells administered intravenous as a single dose.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Carvykti for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

Note:
1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
38225	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
38226	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
38227	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
38228	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous
0537T	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day (Code deleted 12/31/2024)
0538T	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage) (Code deleted 12/31/2024)
0539T	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration (Code deleted 12/31/2024)
0540T	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous (Code deleted 12/31/2024)

HCPCS Codes	Description
Q2056	Ciltacabtagene autoleucel, up to 100 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Multiple Myeloma.** Removed (1) 'Documentation of an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1', (2) 'Does not have central nervous system involvement with myeloma', (3) 'Does not have presence or history of plasma cell leukemia' for alignment **Conditions Not Covered.** **Removed** 'Repeat administration of ciltacabtagene autoleucel (Carvykti)' and moved to medical necessity criteria to state approve for single dose for alignment	6/15/2024
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 are refractory to lenalidomide.	8/1/2024
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. **Updated CPT/HCPCS Coding** **Added code deleted note to CPT Codes:** 0537T, 0538T, 0539T, 0540T (Codes deleted 12/31/2024) **Added CPT Codes:** 38225, 38226, 38227, 38228	6/1/2025

The policy effective date is in force until updated or retired.