Effective Date **2/15/2024**
Next Review Date… **2/15/2025**
Coverage Policy Number **IP0414**

Ciltacabtagene autoleucel

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Related Coverage Resources

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. 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

This policy supports medical necessity review for ciltacabtagene autoleucel (**Carvykti™**).

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

Medical Necessity Criteria

Ciltacabtagene autoleucel (Carvykti) is considered medically necessary when the following are met:

Multiple Myeloma, Relapsed or Refractory. Individual meets **ALL** of the following criteria:

A. Age 18 years or older
B. Documented diagnosis of multiple myeloma
C. Documentation of relapsed or refractory disease after **FOUR** or more lines of systemic therapy, including **ONE** from each of the following:
    i. An immunomodulatory agent

Immunomodulatory agents include Thalomid (thalidomide capsules), Revlimid® (lenalidomide capsules), and Pomalyst® (pomalidomide capsules)

ii. A proteasome inhibitor
Proteasome inhibitors include Velcade® (bortezomib injection), Kyprolis® (carfilzomib intravenous infusion), and Ninlaro® (ixazomib capsules).

iii. An anti-CD38 monoclonal antibody
Anti-CD38 monoclonal antibodies include Darzalex® (daratumumab intravenous infusion), Darzalex Faspro™ (daratumumab and hyaluronidase-fihj subcutaneous injection), and Sarclisa® (isatuximab-irfc intravenous infusion).

D. Has received or plans to receive lymphodepleting chemotherapy (for example, cyclophosphamide and fludarabine) prior to infusion of Carvykti
E. Documentation of an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1
F. Does not have central nervous system involvement with myeloma
G. Does not have presence or history of plasma cell leukemia
H. Documentation of no previous treatment with chimeric antigen receptor T-cell (CAR-T) therapy
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).
I. Medication is prescribed by, or in consultation with, a Hematologist or 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.

Authorization Duration

Authorization is for one-time approval, a single dose.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

Repeat administration of ciltacabtagene autoleucel (Carvykti).

Coding Information

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
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
0538T	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)

0539T	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
0540T	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous

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

Background

OVERVIEW

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

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).

Guidelines

The National Comprehensive Cancer Network clinical practice guidelines for multiple myeloma (version 3.2023 – December 8, 2022) 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, and prolonged and/or recurrent cytopenias.[1] Carvykti is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Carvykti REMS.

References

1. Carvykti intravenous infusion [prescribing information]. Horsham, PA: Janssen Biotech; February 2023.
2. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 8, 2023.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2023 – December 8, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 8, 2023.