CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines

Medical Benefit Drugs

Carvykti™ (ciltacabtagene autoleucel)

Effective: July 1, 2024

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956

☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Chimeric antigen receptor T-cell therapy (CAR-T cell therapy), a type of immunotherapy which may also be referred to as adoptive T-cell therapy, attempts to program patients' own immune systems to recognize and attack cancer cells. The first step in this therapy is to remove T-cells from the patient via apheresis, a process that removes blood from the body and removes one or more blood components (such as white blood cells, plasma, or platelets). The remaining blood is then returned to the body. The T-cells are then sent to a drug manufacturing facility or laboratory where they are genetically engineered to produce chimeric antigen receptors (CARs) on their surface. These CARs are what allow the T-cells to recognize an antigen on targeted tumor cells. The genetically modified T-cells are grown in the lab until there are enough of them (many millions) to freeze and return to the center treating the patient. There they are infused into the recipient with the expectation that the CAR T cells will recognize and kill cancerous cells that have the targeted antigen on their surface. Since the CART cells may remain in the body long after the infusion, it is possible the treatment can bring about long-term remission. CART cell therapy can be used to treat certain hematologic malignancies when the disease is relapsed or refractory to standard line(s) of treatment.

Food and Drug Administration (FDA) Approved Indications:

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

REMS Program: Carvykti is managed under a Risk Evaluation Mitigation Strategy (REMS) program per the Food and Drug Administration (FDA) to manage or reduce the incidence of known or potential serious risks associated with Carvykti therapy. The purpose of the CARVYKTI REMS is to mitigate the risks of cytokine release syndrome (CRS) and neurological toxicities by:

- Ensuring that Hospitals and their Associated Clinics that dispense CARVYKTI are specially certified and have on-site, immediate access to tocilizumab.
- Ensuring those who prescribe, dispense, or administer CARVYKTI are aware of how to manage the risks of CRS and neurological toxicities.

Hospitals and their Associated Clinics must be certified in the CARVYKTI REMS in order to treat patients with CARVYKTI. For additional information, go to https://www.carvyktirems.com/ or call 1-844-672-0067.

Care Partners of Connecticut uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Medicare Advantage plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations where available. For Care Partners of Connecticut Members, the following criteria is used: Chimeric Antigen Receptor (CAR) T- cell Therapy NCD 110.24

Clinical Guideline Coverage Criteria

The Plan may authorize coverage of Carvykti for Members when **all** the following criteria are met:

1. The Member has a documented diagnosis of relapsed* or refractory* multiple myeloma

AND

2. There is documentation to support that the Member has already been treated with one or more prior lines of therapy including a proteasome inhibitor, and an immunomodulatory age

AND

3. The Member is receiving treatment at a facility that is certified and enrolled in the Carvykti REMS Program

AND

4. The Member 18 years of age or older

*Relapsed/Refractory defined as disease progression after last the treatment regimen or refractory/suboptimal response to the most recent therapy

Note: Documentation submitted must list previous lines of treatment/systemic therapies and date of each therapy.

In addition to the above criteria, the Plan may cover Carvykti in an outpatient setting when all of the following criteria is met:

1. The provider attests that they have assessed the Member and determined that outpatient administration is clinically appropriate.
2. The provider attests that the Member meets and understands the requirements of safety and monitoring post infusion as described by the Carvykti REMS program[1].

Note: Prior authorization for Carvykti is required regardless of hospital inpatient or outpatient setting.

Limitations

- Authorization for Carvykti is limited to a one-time infusion
- Members who have had prior treatment with any form of CAR-T cell therapy, including therapies in clinical trial settings, will not be approved for additional CAR-T therapy
- All other indications other than those listed above are considered experimental/investigational and not medically necessary

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

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

Table 2: CPT Codes

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

References:

1. Janseen Oncology. (2022). Cavykti *Risk Evaluation and Mitigation Strategy (REMS)*. Carvykti Rems. https://www.carvyktirems.com/#Main
2. Carvykti™ (ciltacabtagene autoleucel). Horsham, PA: Janssen Biotech, Inc.; Last updated February 2022. Accessed at https://www.fda.gov/media/156560/download
3. Decision memo for chimeric antigen receptor (CAR) T-cell therapy for cancers (CAG-00451N). Centers for https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=291.
4. Center for Medicare and Medicaid National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24) last accessed May 31, 2022 at https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374&bc=CAAAAAAAAAAA.

5. Hansen, D. K., Liu, Y. H., Ranjan, S., Bhandari, H., Potluri, R., McFarland, L., De Braganca, K. C., & Huo, S. (2023). The Impact of Outpatient versus Inpatient Administration of CAR-T Therapies on Clinical, Economic, and Humanistic Outcomes in Patients with Hematological Cancer: A Systematic Literature Review. Cancers, 15(24), 5746. https://doi.org/10.3390/cancers15245746

Approval And Revision History

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
Subsequent endorsement date(s) and changes made:

- Originally approved at September 21, 2022 MPAC effective January 1, 2023
- Administrative update: November 2023 added Medical Benefit Drugs to title, updated CPCT logo, and clarified NCD language effective January 1, 2024
- October 18, 2023: Reviewed by MPAC, renewed without changes effective January 1, 2024
- December 1, 2023: Reviewed and approved by UM Committee effective January 1, 2024
- January 17, 2024: Reviewed by MPAC, added criteria for allow for outpatient administration and updated references effective March 1, 2024
- May 15, 2024: Reviewed by MPAC, moved from fourth line treatment to second line treatment effective July 1, 2024
- June 13, 2024: Reviewed and approved by UM Committee effective July 1, 2024

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.