

Effective: July 1, 2024

<p><b>Prior Authorization Required</b> If <u>REQUIRED</u>, submit supporting clinical documentation pertinent to service request.</p>	<p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p>
<p><b>Applies to:</b></p> <p><b>Commercial Products</b></p> <p><input type="checkbox"/> Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988</p> <p><input type="checkbox"/> Tufts Health Plan Commercial products; Fax 617-673-0988 CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</p> <p><b>Public Plans Products</b></p> <p><input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988</p> <p><input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939</p> <p><input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939</p> <p><input checked="" type="checkbox"/> Tufts Health One Care - A dual-eligible product; Fax 617-673-0956</p> <p><b>Senior Products</b></p> <p><input checked="" type="checkbox"/> Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956</p> <p><input checked="" type="checkbox"/> Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956</p> <p><input checked="" type="checkbox"/> Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956</p> <p><input checked="" type="checkbox"/> Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956</p>	

**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.

The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan members, and Centers for Medicare and Medicaid Services (CMS) 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 and MassHealth Medical Necessity Determinations are the basis for coverage determinations where available. For the Plan's members, the following criteria is used: [Chimeric Antigen Receptor \(CAR\) T- cell Therapy NCD 110.24](#)

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## Clinical Guideline Coverage Criteria

The Plan may cover Carvykti for Members when **all** the following clinical 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 (1) or more prior lines of therapy including a proteasome inhibitor, and an immunomodulatory agent
- 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<sup>1</sup>.

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

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## 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

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## 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). *Carvykti Risk Evaluation and Mitigation Strategy (REMS)*. Carvykti Rems. <https://www.carvyktirems.com/#Main>
2. Carvykti™ (ciltacabtagene autoleucl). 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 Medicare and Medicaid. <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=CAAAAAAAAAAAAA>
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 MATogether and RITogether fax numbers to 617-673-0939, changed Unify name to One Care, and clarified NCD language effective January 1, 2024
- November 16, 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.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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.