Medical Necessity Guidelines:
Carvykti™ (ciltacabtagene autoleucel)

Effective: January 1, 2023

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.

<table>
<thead>
<tr>
<th>Applies to:</th>
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<tbody>
<tr>
<td><strong>Commercial Products</strong></td>
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<tr>
<td>☑ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988</td>
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<tr>
<td>☑ Tufts Health Plan Commercial products; Fax 617-673-0988</td>
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<tr>
<td></td>
<td>CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</td>
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<tr>
<td><strong>Public Plans Products</strong></td>
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<tr>
<td>☑ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988</td>
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<tr>
<td>☑ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0988</td>
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<tr>
<td>☑ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988</td>
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<tr>
<td>☑ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956</td>
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*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

**Senior Products**

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<tr>
<td>☑ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956</td>
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<tr>
<td>☑ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956</td>
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<tr>
<td>☑ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956</td>
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<tr>
<td>☑ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956</td>
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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 CAR-T cells may remain in the body long after the infusion, it is possible the treatment can bring about long-term remission. CAR- T 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 four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

**CARVYKTI™ (ciltacabtagene autoleucel)** is not indicated for the treatment of patients with primary central nervous system lymphoma.
REMS Program: The FDA has determined that a REMS program is necessary to ensure that the benefits of CARVYKTI™ (ciltaclabtagene autoleucel) outweigh the risks of cytokine release syndrome (CRS) and neurological toxicities. The goal of the CARVYKTI REMS is to mitigate the risks of CRS and neurological toxicities by:

- Ensuring that hospitals and associated clinics that dispense CARVYKTI are specially certified and have on-site immediate access to tocilizumab.
- Ensuring that those who prescribe, dispense, or administer CARVYKTI are aware of how to manage the risks of CRS and neurologic toxicities

Hospitals and their Associated Clinics must be certified in the CARVYKTI REMS in order to treat patients with CARVYKTI. For more information about the Carvykti REMS program, contact Janssen Biotech, Inc at 1-800-Janssen or go to https://www.carvyktirems.com/

Clinical Guideline Coverage Criteria

The Plan may cover Carvykti™ (ciltaclabtagene autoleucel) for Members aged 18 years or over with relapsed or refractory multiple myeloma (defined as disease progression after last treatment regimen or refractory/suboptimal response to the most recent therapy) when all of the following clinical criteria are met:

1. The Member has been diagnosed with relapsed or refractory multiple myeloma
   AND
2. Documentation supports that the Member has relapsed or refractory multiple myeloma after four or more prior lines of therapy that have included but are not limited to ALL of the following:
   a. A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib)
   b. An immunomodulatory agent (e.g. lenalidomide, pomalidomide)
   c. An anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab)
   AND
3. The Member has adequate and stable kidney, liver, pulmonary and cardiac function
   AND
4. The Member does not have an active uncontrolled infection or inflammatory disorder
   AND
5. The Member does not have an active inflammatory disorder
   AND
6. For Members with a history of allogeneic stem cell transplantation, there is no indication of active graft vs. host disease (GVHD)
   AND
7. The Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2
   AND
8. The treating facility is certified under the Carvykti Risk Evaluation and Mitigation Strategy (REMS) System program.

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

Limitations

- Carvykti™ (ciltaclabtagene autoleucel) therapy is contraindicated in pregnancy.
- Members receiving immunosuppressive therapy for an autoimmune disorder will not be approved for Carvykti™ (ciltaclabtagene autoleucel) therapy.
- Members with a history of CNS disease (such as seizure or cerebrovascular ischemia) will not be approved for Carvykti™ (ciltaclabtagene autoleucel) therapy.
- Members with untreated underlying primary immunodeficiency syndromes will not be approved for Carvykti™ (ciltaclabtagene autoleucel) therapy.
- Members with active and/or metastatic malignancy that is unlikely to respond to treatment will not be approved for Carvykti™ (ciltaclabtagene autoleucel) therapy.
- Authorization of Carvykti™ (ciltaclabtagene autoleucel) therapy is limited to a single dose.
- 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.
• Carvykti™ (cilta-cel) will not be covered if the Member demonstrates clinical decompensation from time of authorization to time of infusion and no longer meets clinical coverage criteria.
• Any indications for Carvykti™ (cilta-cel) therapy other than those outlined above are considered investigational and will not be covered.

**ECOG Performance Status:**

- **0:** Fully active, no restrictions on activities. A performance status of 0 means no restrictions in the sense that someone is able to do everything they were able to do prior to their diagnosis.
- **1:** Unable to do strenuous activities, but able to carry out light housework and sedentary activities. This status basically means you can't do heavy work but can do anything else.
- **2:** Able to walk and manage self-care, but unable to work. Out of bed more than 50% of waking hours. In this category, people are usually unable to carry on any work activities, including light office work.
- **3:** Confined to bed or a chair more than 50 percent of waking hours. Capable of limited self-care.
- **4:** Completely disabled. Totally confined to a bed or chair. Unable to do any self-care.
- **5:** Death

**Codes**

The following code(s) require prior authorization:

**Table 1: HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>Q2056</td>
<td>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</td>
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**Table 2: CPT Codes**

<table>
<thead>
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<tr>
<td>0537T</td>
<td>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</td>
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<tr>
<td>0538T</td>
<td>Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)</td>
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<tr>
<td>0539T</td>
<td>Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration</td>
</tr>
<tr>
<td>0540T</td>
<td>Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous</td>
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**References:**


**Approval And Revision History**

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)
September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

**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.