Medical Necessity Guidelines:
Abecma® (idecabtagene vicleucel)

Effective: January 1, 2023

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>Yes ☒ No ☐</th>
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<tbody>
<tr>
<td>If REQUIRED, submit supporting clinical documentation pertinent to service request.</td>
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**Applies to:**

**Commercial Products**

- ☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
- ☐ Tufts Health Plan Commercial products; Fax 617-673-0988
  - CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Public Plans Products**

- ☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
- ☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0988
- ☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988
- ☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
  - *The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

**Senior Products**

- ☒ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
- ☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
- ☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
- ☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 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:**

- Abecma® (idecabtagene vicleucel) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

**REMS Program:** Abecma® (idecabtagene vicleucel) is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS. A REMS is a drug safety program to manage known or potential risks associated with a drug and is required by the United States (US) Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. ABECMA® (idecabtagene vicleucel) is only available under a restricted program called ABECMA REMS because of the serious risks of CRS and neurologic toxicities.
Abecma® (idecabtagene vicleucel)

- All hospitals and their associated clinic(s) must be certified and enrolled in the ABECMA REMS to be able to dispense ABECMA (idecabtagene vicleucel).
- All relevant staff involved in the prescribing, dispensing, or administering of ABECMA® (idecabtagene vicleucel) are trained on ABECMA REMS requirements and must successfully complete the Knowledge Assessment and submit it to the REMS Program.

For more information about the Abecma REMS program, go to https://www.abecmarems.com/.

NATIONAL COVERAGE DETERMINATION (NCD)

Nationally Covered Indication(s):
- Effective for services performed on or after August 7, 2019, the Centers for Medicare & Medicaid Services (CMS) covers autologous treatment for cancer with T-cells expressing at least one CHIMERIC antigen receptor (CAR) when administered at healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies (REMS) and used for a medically accepted indication as defined at Social Security Act section 1861(t)(2) - i.e., is used for either an FDA-approved indication (according to the FDA-approved label for that product), or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia.

Nationally Non-Covered:
- Effective for services performed on or after August 7, 2019, the use of non-FDA-approved autologous T-cells expressing at least one CAR is non-covered. Autologous treatment for cancer with T-cells expressing at least one CAR is non-covered when the requirements in Section A are not met.

Clinical Guideline Coverage Criteria

The Plan may cover Abecma® (idecabtagene vicleucel) when all the following clinical criteria is met:

1. The Member is 18 years of age or older and has been diagnosed with relapsed* or refractory* multiple myeloma
   AND
2. The Member has received treatment with four or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.
   AND
3. Treatment is administered at healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies (REMS) for Abecma®
   AND
4. The Member has not received prior treatment with a CAR-T therapy

*Relapsed/Refractory defined as disease progression after the last 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.

Note: Refer to Center for Medicare and Medicaid National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24) at https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374&bc=CAAAAAAAAAAA

Limitations

- Authorization for Abecma (idecabtagene vicleucel) 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

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>Q2055</td>
<td>Idecabtagene vicleucel, up to 460 million autologous B-cell maturation antigens (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose</td>
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## Table 2: CPT Codes

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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.