Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

# Abecma® (idecabtagene vicleucel)

*Effective: March 1, 2024*

| **Prior Authorization Required**<br>If REQUIRED, submit supporting clinical documentation pertinent to service request. | Yes ☒ No ☐ |
|---|---|

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – 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 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care-- A dual-eligible product; Fax 617-673-0956

**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 CAR-Ts 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:**

- Abecma (idecabtagene vicleucel) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four (4) or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

**REMS Program**: Abecma is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS program. 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 is only available under the ABECMA REMS program because of the serious risks of Cytokine Release Syndrome (CRS) and neurologic toxicities.

- All hospitals and their associated clinic(s) must be certified and enrolled in the ABECMA REMS to be able to dispense ABECMA.
- All relevant staff involved in the prescribing, dispensing, or administering of ABECMA 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/

## Clinical Guideline Coverage Criteria

The Plan may cover Abecma for Members aged 18 years or over when **All** of the following clinical criteria are met:

1. Documentation supports that the Member has a diagnosis of active, measurable multiple myeloma, relapsed or refractory after four (4) or more lines of therapy. This is defined as disease progression after last treatment regimen or refractory /suboptimal response to the most recent therapy

**AND**

2. The Member's previous treatments, unless contraindicated, must have included but are not limited to ALL of the following:
    a. an immunomodulatory agent (e.g., lenalidomide, pomalidomide)
    b. a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib)
    c. an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab)

**AND**

3. The Member must have undergone at least 2 consecutive cycles of treatment for each regimen, unless progressive disease was the best response to the regimen

**AND**

4. The Member has had no prior treatment with a CAR-T therapy

**AND**

5. The Member has adequate organ function including bone marrow, cardiac, pulmonary, , and neurological with no anticipated decline in organ function in close proximity to apheresis timeframe

**AND**

6. The Member has no active infection (e.g., viral, bacterial, fungal) including HIV, active hepatitis B or active hepatitis C. Screening must be completed at the time of leukapheresis

**AND**

7. For Members with a history of allogeneic stem cell transplantation, there is no indication of active graft vs. host disease (GVHD)

**AND**

8. The treating facility is certified under the Risk Evaluation and Mitigation Strategy (REMS) System program for Abecma

**AND**

9. The Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2

**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 Abecma 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 Abecma REMS program[1].

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

## Limitations

- Abecma therapy is contraindicated in pregnancy
- Members receiving immunosuppressive therapy for an autoimmune disorder will not be approved for Abecma therapy.
- Members with untreated underlying primary immunodeficiency syndromes will not be approved for Abecma therapy.

- Members with active and/or metastatic malignancy that is unlikely to respond to treatment will not be approved for Abecma therapy.
- Authorization of CAR-T therapy is limited to one single dose treatment.
- 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.
- Abecma 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 CAR-T cell 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. 5 Modified T-Cell Therapies

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 selfcare.

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: 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 |

**Table 2: HCPCS Codes**

| HCPCS Codes | Description |
|---|---|
| Q2055 | Idecabtagene vicleucel, up to 460 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose |

**References:**


1. Bristol Myers Squibb. (2021, April 1). *Risk Evaluation and Mitigation Strategy (REMS)*. Abecma Rems. https://www.abecmarems.com/index.html
2. Hayes, Inc. Medical Technology Directory Report. Adoptive Immunotherapy Using Genetically Modified Lymphocytes for Lymphoproliferative Disorders and Hematological Malignancies. September 7, 2017. Available at hayesinc.com. Last accessed October 26, 2017.
3. 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
4. United States Department of Health and Human Services, National Institutes of Health, National Cancer Institute. CAR-T Cells: Engineering Patients' Immune Cells to Treat Their Cancers. Available at cancer.gov. Last accessed October 24, 2017.

5. Munshi NC, Anderson LD Jr, Shah N, Madduri D, Berdeja J, Lonial S, Raje N, Lin Y, Siegel D, Oriol A, Moreau P, Yakoub-Agha I, Delforge M, Cavo M, Einsele H, Goldschmidt H, Weisel K, Rambaldi A, Reece D, Petrocca F, Massaro M, Connarn JN, Kaiser S, Patel P, Huang L, Campbell TB, Hege K, San-Miguel J. Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma. N Engl J Med. 2021 Feb 25;384(8):705-716. doi: 10.1056/NEJMoa2024850.
6. Abecma (idecabtagene vicleucel) [package insert]. Summit, New Jersey. Celgene Corporation. March 2021.
7. Center for Medicare and Medicaid National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24) last accessed June 28, 2021 at cms.gov/medicare-coverage- database/details/ncd-details.aspx?ncdid=374&ncdver=1&bc=CAAAAAAAAAAA.
8. Trando A, Ter-Zakarian A, Yeung P, et al. Outcomes of Chimeric Antigen Receptor (CAR) T-Cell Therapy in Patients with Large B-Cell Lymphoma (LBCL): A Single-Institution Experience. *Cancers (Basel)*. 2023;15(18):4671. Published 2023 Sep 21. doi:10.3390/cancers15184671

## Approval And Revision History

September 21, 2022, year: 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, and change Unify name to One Care
- October 18, 2023: Reviewed by MPAC, renewed without changes effective January 1, 2024
- January 17, 2024: Reviewed by MPAC, added language to allow for contraindication to previous treatment, updated organ function criteria question, added criteria for allow for outpatient administration, updated ECOG from 0-1 to 0-2, removed history of CNS disease limitation, and updated references effective March 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.