

Effective: July 1, 2024

<p>Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.</p>	<p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p>
<p>Applies to:</p> <p>Commercial Products</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 CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</p> <p>Public Plans Products</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>Senior Products</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:

- Abecma (idecabtagene vicleucel) is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after two 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. 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 a restricted program called ABECMA REMS because of the serious risks of 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/>.

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](#)

Clinical Guideline Coverage Criteria

The Plan may cover Abecma 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 two 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.

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.
AND
2. The provider attests that the Member meets and understands the requirements of safety and monitoring post infusion as described by the Abecma REMS program¹.

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

Limitations

- Authorization for Abecma 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
Q2055	Idecabtagene vicleucel, up to 460 million autologous B-cell maturation antigens (BCMA) directed CAR-

HCPCS Codes	Description
	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. Bristol Myers Squibb. (2021, April 1). *Risk Evaluation and Mitigation Strategy (REMS)*. Abecma Rems. <https://www.abecmarems.com/index.html>
2. Abecma [package insert]. Summit, NJ: Celgene Corporation; March 2021.
3. Center for Medicare and Medicaid National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374&bc=CAAAAAAAAAAAAA> .
4. 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. 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. Leukemia & Lymphoma Society. Chimeric Antigen Receptor (CAR) T-Cell Therapy Facts. Available at lls.org. Last accessed October 20, 2017.
6. 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, 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 third 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.