Medical Necessity Guidelines:
Abecma® (idecabtagene vicleucel)

Effective: January 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, 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.

- 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) for Members, when **all** the following criteria are 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 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.
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	Description
Q2055	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

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. Abecma [package insert]. Summit, NJ: Celgene Corporation; March 2021.
2. 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=CAAAAAAAAAAA
3. 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.
4. Leukemia & Lymphoma Society. Chimeric Antigen Receptor (CAR) T-Cell Therapy Facts. Available at lls.org. Last accessed October 20, 2017.

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.

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.