

Effective: January 1, 2025

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| <p>Prior Authorization Required If <u>REQUIRED</u>, submit supporting clinical documentation pertinent to service request.</p> | <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> |
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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:

TECARTUS (brexucabtagene autoleucel) is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

- Adult patients with relapsed or refractory mantle cell lymphoma (MCL). This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial
- Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

REMS Program:

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of TECARTUS outweigh the risks of cytokine release syndrome and neurologic toxicities. TECARTUS is available only through the YESCARTA and TECARTUS REMS Program.

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

For more information, call the Tecartus REMS Center at 1-844-454-KITE (5483) or go to <https://www.yescartatecartusrems.com/> online.

Care Partners of Connecticut uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth 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 are the basis for coverage determinations where available. For Care Partners of Connecticut members, the following criteria is used:

Clinical Guideline Coverage Criteria

The Plan may cover Tecartus for Members, when **all** the following clinical criteria are met:

1. The Member meets **ONE (1)** of the following criteria:
 - a. The Member is diagnosed with relapsed* or refractory* mantle cell lymphoma (MCL), **or**
 - b. The Member is diagnosed with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

AND

2. The Member is 18 years of age or older

AND

3. The Member is receiving treatment at a facility that is certified by the Tecartus REMS Program

*Relapsed/Refractory defined as disease progression after last the treatment regimen or refractory/suboptimal response to the most recent therapy

In addition to the above criteria, the Plan may cover Tecartus 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 Tecartus REMS program¹.

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

Limitations

- Tecartus 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 |
|-------------|---|
| Q2053 | Brexucabtagene autoleucl, up to 200 million autologous anti-CD19 CAR positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose |

Table 2: CPT Codes

| CPT Codes | Description |
|-----------|-------------|
| | none |

References:

1. Kite Pharma. (2023). *Risk Evaluation and Mitigation Strategy (REMS)*. Tecartus Rems. <https://www.yescartatecartusrems.com>
2. Center for Medicare and Medicaid National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24) last accessed January 25, 2022 at [cms.gov/medicarecoverage/database/details/ncddetails.aspx?ncdid=374&ncdver=1&bc=CAAAAAAAAAAAAA](https://www.cms.gov/medicarecoverage/database/details/ncddetails.aspx?ncdid=374&ncdver=1&bc=CAAAAAAAAAAAAA).
3. Decision memo for chimeric antigen receptor (CAR) T-cell therapy for cancers (CAG-00451N). Centers for Medicare & Medicaid Services (CMS). August 2019. <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=291>.
4. FDA Approves First Cell-Based Gene Therapy For Adult Patients with Relapsed or Refractory MCL. U.S. Food and Drug Administration. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-cellbased-gene-therapy-adult-patients-relapsed-or-refractory-mcl> Published 2020. Accessed November 2, 2021.

5. Tecartus [package insert]. Los Angeles, CA: Kite Pharma; October 2021. Accessed online June 2, 2022 at <https://www.gilead.com/-/media/files/pdfs/medicines/oncology/tecartus/tecartus-pi.pdf>.
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 CPCT logo, and clarified NCD language effective January 1, 2024
- October 18, 2023: Reviewed by MPAC, renewed without changes effective January 1, 2024
- January 17, 2024: Reviewed by MPAC, added criteria for allow for outpatient administration and updated references effective March 1, 2024
- November 21, 2024: Reviewed by MPAC, renewed without changes. Effective January 1, 2025.
- December 13, 2024: Reviewed by UM Committee; Coding updated: Removal of prior authorization from 0537T, 0538T, 0539T, and 0540T. Effective January 1, 2025.
- December 18, 2024: Reviewed by MPAC; Coding updated: Removal of prior authorization from 0537T, 0538T, 0539T, and 0540T. Effective January 1, 2025.

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.