CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines

Medical Benefit Drug

Yescarta® (axicabtagene ciloleucel)

Effective: January 1, 2025

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:

Yescarta (axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

- Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.
- Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. Limitations of use: YESCARTA is not indicated for the treatment of patients with primary central nervous system lymphoma.
- Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

REMS Program:

Yescarta is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (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. Yescarta is only available under a restricted program called Yescarta 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 Yescarta REMS to be able to dispense Yescarta. Relevant staff involved in the prescribing, dispensing, or administering of Yescarta are trained on Yescarta REMS requirements, and must successfully complete the Knowledge Assessment and submit it to the REMS Program.
For further information, go to https://www.yescartatecartusrems.com/ or call 1-844-454-KITE (5483).

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 authorize a one-time infusion of Yescarta when all of the following criteria is met:

1. The Member has a documented diagnosis of one of the following:
   a. Large B-cell lymphoma that is refractory* to first-line chemoimmunotherapy or that relapses* within 12 months of first line chemoimmunotherapy

   OR

   b. Relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including:
      i. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified,
      ii. Primary mediastinal large B-cell lymphoma,
      iii. High grade B-cell lymphoma,
      iv. DLBCL arising from follicular lymphoma

      AND

      v. The Member does not have central nervous system (CNS) lymphoma

      OR

   c. Relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

   AND

2. The Member is receiving treatment at a facility that is certified by the Yescarta REMS Program

   AND

3. The Member is 18 years of age or older

*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

In addition to the above criteria, the Plan may cover Yescarta 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 Yescarta REMS program[1].

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

Limitations

- Authorization for Yescarta 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
Q2041	Axicabtagene Ciloleucel, up to 200 million autologous Anti-CD19 CAR T Cells, Including leukapheresis and dose preparation procedures, per infusion

Table 2: CPT Codes

CPT Codes	Description
	none

References:

1. Kite Pharma. (2023). *Risk Evaluation and Mitigation Strategy (REMS)*. Yescarta 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 May 31, 2022, at https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374&bc=CAAAAAAAAAAA.
3. Decision memo for chimeric antigen receptor (CAR) T-cell therapy for cancers (CAG-00451N). Centers for https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=291.
4. United States Food and Drug Administration. Package Insert-YESCARTA. Available at fda.gov. Last accessed January 26, 2022.
5. 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.