CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Yescarta (axicabtagene ciloleucel)
BILLING CODE	Q2041
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Inpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Yescarta (axicabtagene ciloleucel) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

LARGE B-CELL LYMPHOMA

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member has a diagnosis of relapsed or refractory large B-cell lymphoma including **one** of the following:
   a) Diffuse large B-cell lymphoma (DLBCL) not otherwise specified;
   b) Primary mediastinal large B-cell lymphoma;
   c) High grade B-cell lymphoma;
   d) DLBCL arising from follicular lymphoma; AND
3. Member's disease is refractory or relapsed, defined as **one** or more of the following:
   a) No response, partial response, disease progression, or relapse after two or more lines of chemotherapy, including both anti-CD20 monoclonal antibody (e.g., rituximab) unless tumor is CD20-negative and anthracycline;
   b) Relapsed after autologous hematopoietic stem cell transplantation (HSCT); AND
4. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
5. Member does **not** have ANY of the following:
   a) Prior allogeneic HSCT;
   b) History or presence of primary central nervous system (CNS) lymphoma;
   c) Prior CAR-T therapy (e.g., Kymriah); AND
6. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (negative results must be submitted); AND
7. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program.
8. **Dosage allowed:** 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Yescarta will not be reauthorized for continued therapy.

FOLLICULAR LYMPHOMA

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member has a diagnosis of relapsed or refractory follicular lymphoma; AND
3. Member has measurable disease after 2 or more lines of systemic therapy, including the combination of an anti-CD20 monoclonal antibody and an alkylating agent; AND
4. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
5. Member does **not** have ANY of the following:
   a) Prior allogeneic HSCT;
   b) History or presence of primary central nervous system (CNS) lymphoma;
   c) Prior CAR-T therapy; AND
6. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (negative results must be submitted); AND
7. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program.
8. **Dosage allowed:** 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Yescarta will not be reauthorized for continued therapy.

CareSource considers Yescarta (axicabtagene ciloleucel) not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
10/24/2017	New policy for Yescarta created.
08/27/2018	Criteria expanded for member's disease history requirement.
08/04/2020	Defined age 18 or older for adults. Specified trial requirement for 2 or more lines of chemo or relapsed after autologous stem cell transplant. Removed pre-treatment regimens because they are already addressed in REMS. Required screening results for active infections. Removed hypersensitivity to aminoglycoside requirement, CNS disorders, and other forms of malignancy from exclusion list. Added prior CAR-T treatment, life expectancy to exclusion list. Updated the name of REMS program.
05/19/2021	Added criteria for new indication of follicular lymphoma. Large B-Cell Lymphoma: Removed life expectancy restriction. Added ECOG score. Added "partial response" to 3a per NCCN slide BCEL-7.

References:

1. Yescarta [package insert]. Santa Monica, CA; Kite Pharma, Inc., April 2021.
2. ClinicalTrials.gov. Identifier NCT02348216. Safety and Efficacy of KTE-C19 in Adults With Refractory Aggressive Non-Hodgkin Lymphoma (ZUMA-1). Available at https://clinicaltrials.gov/ct2/show/NCT02348216.
3. National Comprehensive Cancer Network. B-Cell Lymphomas (Version 4.2021). https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed May 19, 2021.
4. Neelapu SS, et al. Axicabtagene ciloleucel CAR T-cell therapy in refractory large B-cell lymphoma. N Engl J Med. 2017;377(26):2531-2544.
5. A Phase 2 Multicenter Study of Axicabtagene Ciloleucel in Subjects With Relapsed/Refractory Indolent Non-Hodgkin Lymphoma (ZUMA-5). ClinicalTrials.gov identifier: NCT03105336. Updated May 17, 2021. Accessed May 19, 2021. https://clinicaltrials.gov/ct2/show/NCT03105336.

Effective date: 10/1/2021

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Revised date: 05/19/2021