CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
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, 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 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);
   d) Life expectancy less than 12 weeks; AND
5. 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
6. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program.
7. **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 the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Primary central nervous system lymphoma

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.

References:

1. Yescarta [package insert]. Santa Monica, CA; Kite Pharma, Inc., May 2020.
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 3.2020). https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed August 4, 2020.
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.

Effective date: 10/20/2020
Revised date: 08/04/2020