MEDICAL POLICY STATEMENT
OHIO MEDICAID

Policy Name	Policy Number	Date Effective
CAR-T medications – Yescarta (axicabtagene ciloleucel)	MM-1113	08/01/2021-06/30/2022

Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

Table of Contents

A. Subject

CAR-T medications – Yescarta (axicabtagene ciloleucel)

B. Background

Chimeric antigen receptor T cell therapy (CAR-T) is an autologous T-cell immunotherapy. The member's own T lymphocytes are genetically modified with a gene that encodes a CAR-T to the T cells which can then target the lymphoma cells. Once the member's T cells are modifier, the T cells are infused back into the member.

CAR-T is associated with severe complications and may be life-threatening. These complications include cytokine release syndrome and neurological toxicities. Therefore, CAR-T therapy administration should be based on clinical benefits, potential long-term disease control, and toxicity.

This policy is to define medically necessary criteria for Yescarta.

C. Definitions

- **Risk Evaluation and Mitigation Strategy (REMS)** - A drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication.

D. Policy

I. Yescarta
   A. Yescarta may be approved for 3 months.
   B. Yescarta will not be reauthorized for continued therapy.
   C. Yescarta is limited to one infusion per lifetime.

II. Yescarta is a non-preferred product and will only be considered for coverage under the medical benefit when the following medically necessary criteria are met:
   A. Member is 18 years of age or older;
   B. Member has a diagnosis of relapsed or refractory large B-cell lymphoma including one of the following:
      1. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified;
      2. Primary mediastinal large B-cell lymphoma;
      3. High grade B-cell lymphoma; or
      4. DLBCL arising from follicular lymphoma;
   C. Member's disease is refractory or relapsed, defined as one or more of the following:
      1. 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; or
      2. Relapsed after autologous hematopoietic stem cell transplantation (HSCT);
   D. Member does not have any of the following:

1. Prior allogeneic HSCT;
2. History or presence of primary central nervous system (CNS) lymphoma;
3. Prior CAR-T therapy (e.g., Kymriah); or
4. Life expectancy less than 12 weeks;

E. 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

F. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program.

III. CareSource considers Yescarta not medically necessary for the treatment of primary central nervous system lymphoma.

E. Conditions of Coverage

NA

F. Related Policies/Rules

Pharmacy Policy Statement – CAR-T medications
CAR-T medications – Kymriah
CAR-T medications – Tecartus
Pharmacy Policy Statement – Yescarta (axicabtagene ciloleucel)

G. Review/Revision History

	DATE	ACTION
Date Issued	04/14/2021	
Date Revised		
Date Effective	08/01/2021	
Date Archived	06/30/2022	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. 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). Retrieved September 22, 2020 from www.clinicaltrials.gov
3. National Comprehensive Cancer Network. B-Cell Lymphomas (Version 3.2020). Retrieved September 22, 2020 from www.nccn.org
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.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – 08/2020