MEDICAL POLICY STATEMENT
Indiana Marketplace

Policy Name & Number	Date Effective
CAR-T Medications - Yescarta - IN MP - MM-1121	06/01/2022-11/30/2022
Policy Type	
MEDICAL	

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.

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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 patient's own T lymphocytes are genetically modified with a gene to produce chimeric antigen receptors (CARs) on the cell surface, making the lymphocytes a CAR-T cell, allowing recognition of an antigen on targeted tumor cells. Once the T-cells are modified and multiplied, they are infused back into the patient to attack cells with the targeted antigen on the surface, eradicating cancer cells and, possibly, resulting in long-term remission for patients.

CAR-T therapy is associated with severe complications and may be life-threatening. These complications include, but are not limited to, cytokine release syndrome, macrophage activation syndrome, anaphylaxis and neurological toxicities, other toxicities, and other medical conditions. Therefore, CAR-T therapy administration should be based on clinical benefits, potential long-term disease control, and toxicity.

C. Definitions

- **Antigen** – A toxin or other foreign substance that induces an immune response in the body, especially the production of antibodies.
- **Chimeric Antigen Receptors** – Proteins that allow T-cells to recognize an antigen on a targeted tumor cell.
- **Immunotherapy** – A type of treatment that utilizes the body's own immune system to fight cancer, improves the body's ability to detect and kill cancer cells, and is based on the concept that immune cells or antibodies can recognize and kill cancer cells.
- **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.
- **T Lymphocyte (T-cell)** – A subtype of white blood cells comprising a major portion of the immune system and functioning to make antibodies that fight infection by directly killing infected cells in the body.

D. Policy

I. Yescarta
   1. Yescarta may be approved for three (3) months.
   2. Yescarta will not be reauthorized for continued therapy.
   3. 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:
   1. Member is 18 years of age or older.

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
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)
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
   d. Life expectancy less than 12 weeks
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.
6. 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 or other disease states not listed in this document.

E. Conditions of Coverage
NA

F. Related Policies/Rules
Evidence of Coverage and Health Insurance Contract
Pharmacy Policy Statement – Yescarta (axicabtagene ciloleucel)

G. Review/Revision History

	DATE	ACTION
Date Issued	04/14/2021	
Date Revised	02/11/2022	Annual review.
Date Effective	06/01/2022	
Date Archived	11/30/2022	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.

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

H. References

1. ClinicalTrials.gov. Identifier NCT02348216. Safety and Efficacy of KTE-C19 in Adults With Refractory Aggressive Non-Hodgkin Lymphoma (ZUMA-1). Retrieved February 11, 2022 from www.clinicaltrials.gov.

2. National Comprehensive Cancer Network. B-Cell Lymphomas (Version 3.2020). Retrieved February 11, 2022 from www.nccn.org.
3. 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.
4. Yescarta [package insert]. Santa Monica, CA; Kite Pharma, Inc., May 2020.

Independent medical review – 08/2020