CareSource

MEDICAL POLICY STATEMENT
KENTUCKY MARKETPLACE

Policy Name	Policy Number	Date Effective
CAR-T medications – Tecartus (brexucabtagene autoleucel)	MM-1093	07/01/2021-05/31/2022
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 – Tecartus (brexucabtagene autoleucel)

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 Tecartus.

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

II. Tecartus 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 old or older;
   B. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program;
   C. Member has a diagnosis of relapsed or refractory Mantle Cell Lymphoma (MCL), defined as disease progression after last regimen or failure to achieve a partial response or complete response to the last regimen;
   D. Member has had prior treatment with all of the following:
      1. Anthracycline or bendamustine-containing chemotherapy;
      2. Anti-CD20 monoclonal antibody (Rituximab); and
      3. Bruton tyrosine kinase inhibitor (BTKi) (i.e. ibrutinib, acalabrutinib, or zanubrutinib);
   E. Member has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 1; and
   F. Member does not have any of the following:

1. Active or uncontrolled infection;
2. Central nervous system (CNS) lymphoma;
3. History of allogeneic stem cell transplantation; or
4. Prior chimeric antigen receptor (CAR) therapy or other genetically modified T-cell therapy; and

G. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

III. CareSource considers Tecartus not medically necessary for the treatment of disease states not in this document.

E. Conditions of Coverage

NA

F. Related Policies/Rules

Evidence of Coverage and Health Insurance Contract Kentucky
Pharmacy Policy Statement – CAR-T medications
CAR-T medications – Kymriah
CAR-T medications – Yescarta
Pharmacy Policy Statement – Tecartus (brexucabtagene autoleucel)

G. Review/Revision History

	DATE	ACTION
Date Issued	04/14/2021	
Date Revised		
Date Effective	07/01/2021	
Date Archived	05/31/2022	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. Tecartus [package insert]. Santa Monica, CA: Kite Pharma, Inc; 2020.
2. Wang M, Munoz J, Goy A, et al. KTE-X19 CAR-T-Cell Therapy in Relapsed or Refractory Mantle-Cell Lymphoma. *N Engl J Med*. 2020;382(14):1331-1342. doi:10.1056/NEJMoa1914347
3. National Comprehensive Cancer Network. B-Cell Lymphomas (Version 4.2020). Retrieved September 22, 2020 from www.nccn.org
4. Mckay P, Leach M, Jackson B, Robinson S, Rule S. Guideline for the management of mantle cell lymphoma. *British Journal of Haematology*. 2018;182(1):46-62. doi:10.1111/bjh.15283
5. Dreyling M, Campo E, Hermine O, et al. Newly diagnosed and relapsed mantle cell lymphoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Annals of Oncology*. 2017;28:iv62-iv71. doi:10.1093/annonc/mdx223
6. IPD analytics. Accessed August 7, 2020

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