



MEDICAL POLICY STATEMENT OHIO MEDICAID

Policy Name	Policy Number	Date Effective
CAR-T medications – Tecartus (brexucabtagene autoleucl)	MM-1088	08/01/2021-06/30/2022
Policy Type		
MEDICAL	Administrative	Pharmacy
		Reimbursement

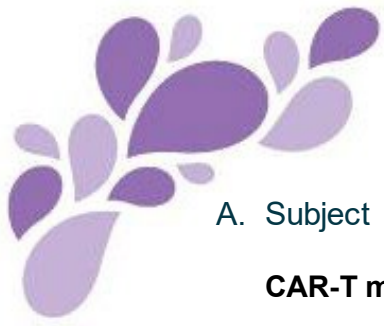
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According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to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

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A. Subject

CAR-T medications – 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 modified, 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 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;
- 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; and
 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

Pharmacy Policy Statement – CAR-T medications

CAR-T medications – Kymriah

CAR-T medications – Yescarta

Pharmacy Policy Statement – Tecartus (brexucabtagene autoleucl)

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. 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
7. **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