CareSource

PHARMACY POLICY STATEMENT **Georgia Medicaid**	
DRUG NAME	Tecartus (Brexucabtagene Autoleucel)
BILLING CODE	Q2043
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Inpatient/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Quantity Limit – 1 infusion per lifetime
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Tecartus (Brexucabtagene Autoleucel) 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.

MANTLE CELL LYMPHOMA (MCL)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program; AND
3. Member has a diagnosis of relapsed or refractory MCL, defined as disease progression after last regimen or failure to achieve a partial response or complete response to the last regimen; AND
4. Member has had prior treatment with ALL of the following:
   a) Anthracycline or bendamustine-containing chemotherapy,
   b) Anti-CD20 monoclonal antibody (Rituximab),
   c) Bruton tyrosine kinase inhibitor (BTKi) (i.e. ibrutinib, acalabrutinib, or zanubrutinib); AND
5. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
6. Member does NOT have ANY of the following:
   a) Active or uncontrolled infection,
   b) Central nervous system (CNS) lymphoma,
   c) History of allogeneic stem cell transplantation,
   d) Prior chimeric antigen receptor (CAR) therapy or other genetically modified T-cell therapy; AND
7. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
8. **Dosage allowed:** 2 x 10^6 chimeric antigen receptor (CAR)-positive viable T cells/kg IV; MAX 2 x 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. Tecartus will not be reauthorized for continued therapy.

CareSource considers Tecartus (Brexucabtagene Autoleucel) not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
08/18/2020	New policy for Tecartus created.
04/22/2021	Updated billing code.

References:

1. Tecartus [package insert]. Santa Monica, CA: Kite Pharma, Inc; 2021.
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 3.2021). https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed April 22, 2021.
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

Effective date: 10/01/2021
Revised date: 04/22/2021