CareSource

PHARMACY POLICY STATEMENT **Georgia Medicaid**	
DRUG NAME	Tecartus (Brexucabtagene Autoleucel)
BILLING CODE	J9999
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 to 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 the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
08/18/2020	New policy for Tecartus created.

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). https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed August 18, 2020.
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: 12/01/2020
Revised date: 08/18/2020