

PHARMACY POLICY STATEMENT

Ohio Medicaid

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| DRUG NAME | Tecartus (Brexucabtagene Autoleucel) |
| BILLING CODE | Q2043 |
| BENEFIT TYPE | Medical |
| SITE OF SERVICE ALLOWED | Inpatient/Outpatient |
| STATUS | Prior Authorization Required |

Tecartus is a CD19-directed genetically modified autologous T cell immunotherapy. To prepare the product, a patient's own T cells are harvested and genetically modified ex vivo to express a chimeric antigen receptor (CAR) comprising a murine anti-CD19 single-chain variable fragment (scFv) linked to CD28 and CD3-zeta co-stimulatory domains. The anti-CD19 CAR T cells are expanded and infused back into the patient, where they can recognize and eliminate CD19- expressing target cells.

Tecartus (Brexucabtagene Autoleucel) will be considered for coverage when the following criteria are met:

Mantle Cell Lymphoma (MCL)

For **initial** authorization:

1. Member is at least 18 years of age; 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 at least one measurable lesion; AND
5. 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
6. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
7. 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
8. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
9. **Dosage allowed/Quantity limit:** 2 x 10⁶ chimeric antigen receptor (CAR)-positive viable T cells/kg IV; MAX 2 x 10⁸ CAR-positive viable T cells.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Tecartus will not be reauthorized for continued therapy.

Acute Lymphoblastic Leukemia (ALL)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program; AND
3. Member has a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) defined as one of the following:
 - a) Primary refractory disease
 - b) First relapse if remission lasted ≤ 12 months
 - c) Relapsed or refractory after 2 or more lines of therapy
 - d) Relapsed or refractory at least 100 days after allogeneic stem cell transplantation (HSCT); AND
4. Documentation of CD19 tumor expression; AND
5. Bone marrow with $\geq 5\%$ lymphoblasts by morphologic assessment; AND
6. If member has Philadelphia chromosome positive (Ph+) disease, they must have relapsed/refractory disease despite treatment with at least 2 different tyrosine kinase inhibitors (TKIs); AND
7. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
8. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV); AND
9. Member does NOT have any of the following:
 - a) Active or serious infection
 - b) Active graft-versus-host disease (GVHD)
 - c) Prior CAR-T therapy
10. **Dosage allowed/Quantity limit:** 1×10^6 CAR-positive viable T cells per kg of body weight [maximum of 1×10^8 CAR-positive viable T cells (for patients 100 kg and above)].

If all the above requirements are met, 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 conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|------------|--|
| 08/18/2020 | New policy for Tecartus created. |
| 04/22/2021 | Updated billing code. |
| 12/29/2021 | Added criteria for new indication of B cell ALL. For MCL, added "at least 1 measurable lesion." |

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
7. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia. (Version 3.2021). https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed December 29, 2021.
8. Shah BD, Ghobadi A, Oluwole OO, et al. KTE-X19 for relapsed or refractory adult B-cell acute lymphoblastic leukaemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study. *Lancet*. 2021;398(10299):491-502. doi:10.1016/S0140-6736(21)01222-8

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