CareSource Rxinnovations

# PHARMACY POLICY STATEMENT
## Marketplace

| 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 $10^6$ chimeric antigen receptor (CAR)-positive viable T cells/kg IV; MAX 2 x $10^8$ 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 ≥ 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 x $10^6$ CAR-positive viable T cells per kg of body weight [maximum of 1 x $10^8$ 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.<br>For MCL, added “at least 1 measurable lesion.” |

References:


1. Tecartus [package insert]. Santa Monica, CA: Kite Pharma, Inc; 2021.
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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
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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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