HAP CareSource™

PHARMACY POLICY STATEMENT

HAP CareSource™ Marketplace

DRUG NAME	Tecartus (brexucabtagene autoleucel)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Tecartus, approved by the FDA in 2020, is a CD19-directed genetically modified autologous T cell immunotherapy. It is indicated for adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). It is also indicated (by accelerated approval) for adults with relapsed or refractory mantle cell lymphoma (MCL) based on overall response rate (ORR) and durability of response (DOR).
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 documented 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 (e.g., rituximab)
   c) Covalent Bruton tyrosine kinase inhibitor (BTKi) (i.e., ibrutinib, acalabrutinib, or zanubrutinib); AND
5. Member has at least one measurable lesion; 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) Central nervous system (CNS) lymphoma
   b) History of allogeneic stem cell transplantation
   c) Prior chimeric antigen receptor (CAR) therapy or other genetically modified T-cell therapy; AND
8. Member has been or will be 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 per kg body weight (maximum of 2 x 10^8 CAR-positive viable T cells)

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

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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 documented diagnosis of B-cell ALL; AND
4. Documentation of one of the following:
   a) Relapsed or refractory Philadelphia chromosome negative (Ph-) disease, or
   b) Relapsed or refractory Philadelphia chromosome positive (Ph+) disease following therapy that has included tyrosine kinase inhibitors (TKI); AND
5. Documentation of CD19 tumor expression; AND
6. Bone marrow with ≥ 5% lymphoblasts by morphologic assessment; AND
7. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
8. Member has been or will be 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 graft-versus-host disease (GVHD)
   b) Prior CAR-T therapy
10. **Dosage allowed/Quantity limit:** 1 x 10^6 CAR-positive viable T cells per kg body weight (maximum of 1 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.

HAP 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.”
12/11/2024	Updated refs. Changed has been screened to has been or will be screened. Removed infection exclusion since we already ask for screening. ALL: Separated relapsed/refractory disease between Ph- and Ph+ (NCCN). MCL: Specified “covalent” BTK (as opposed to non-covalent) (NCCN).

References:

1. Tecartus [package insert]. Santa Monica, CA: Kite Pharma, Inc.; 2024.
2. National Comprehensive Cancer Network. B-Cell Lymphomas (Version 3.2024). https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed December 11, 2024.
3. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia. (Version 2.2024). https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed December 11, 2024.
4. 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
5. 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

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