P&T Date: 06/05/2025

Tecartus™ (brexucabtagene autoleucel)

HCPCS: Q2053

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age
   b. Prescribed by on in consultation with an oncologist
   c. Treatment of adult patients with relapsed or refractory mantle cell lymphoma
      i. Subjects must have received adequate prior therapy including at a minimum:
         1. An anthracycline or bendamustine-containing chemotherapy
         2. An anti-CD20 monoclonal antibody therapy
         3. A Bruton's tyrosine kinase (BTK) inhibitor
      ii. Must have 1 measurable lesion
      iii. Patient must meet all of the following:
         1. ECOG performance status 0 - 2
         2. Platelet count greater than 75,000/µL
         3. Serum alanine aminotransferase/aspartate aminotransferase less than 5 times the upper limit of normal
         4. Creatinine clearance greater than 30 mL/min
         5. Cardiac ejection fraction greater than 40%
         6. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable
         7. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy
         8. No prior allogeneic HSCT
         9. No known active central nervous system malignancy
         10. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months
         11. No thromboembolic events within 6 months
         12. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening
         13. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis

d. Diagnosis of relapsed[a]/refractory[b] B-cell precursor acute lymphoblastic leukemia (ALL)
    i. Patients with Philadelphia chromosome positive (Ph+) ALL are eligible if they are intolerant to or have failed 2 lines of tyrosine kinase inhibitor therapy (TKI), or if TKI therapy is contraindicated
    ii. Patient must meet all of the following:
        1. ECOG performance status 0 - 2
        2. No diagnosis of Burkitt's lymphoma
        3. No grade 2 to 4 graft-versus-host disease
        4. Serum alanine aminotransferase/aspartate aminotransferase less than 5 times the upper limit of normal
        5. Creatinine clearance greater than 30 mL/min
        6. Cardiac ejection fraction greater than 40%
        7. No HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable
        8. No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy
        9. Has not received allogeneic cellular therapy, such as donor lymphocyte infusion within 6 weeks prior to Tecartus infusion
        10. No known active central nervous system malignancy
        11. No myocardial infarction, cardiac angioplasty or stenting, unstable angina, or New York Heart Association Class II or greater congestive heart failure events within 6 months
        12. No thromboembolic events within 6 months
        13. No pulmonary disease requiring oxygen dependence or pulmonary disease such as idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening
        14. No clinically significant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis
e. Have not received prior treatment with any CAR-T therapy despite indication or any other genetically-modified T-cell therapy or are being considered for treatment with any other genetically-modified T-cell therapy
f. Only to be administered at certified bone marrow/stem cell transplant centers
g. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the WyoBlue Advantage utilization management medical drug list
h. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by WyoBlue Advantage
i. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case by case basis until fully evaluated by the WyoBlue Advantage Pharmacy and Therapeutics Committee

B. Quantity Limitations, Authorization Period and Renewal Criteria
    a. Quantity Limits: Align with FDA recommended dosing
    b. Authorization Period: 3 months with the allowance of only one dose per lifetime
    c. Renewal Criteria: Not applicable as no further authorization will be provided

[a] Refractory (resistant) disease is defined as those patients who fail to obtain complete response with induction therapy, ie, failure to eradicate all detectable leukemia cells (<5% blasts) from the bone marrow and blood with subsequent restoration of normal hematopoiesis (>25% marrow cellularity and normal peripheral blood counts).
[b] Relapsed disease describes the reappearance of leukemia cells in the bone marrow or peripheral blood after the attainment of a complete remission with chemotherapy and/or allogeneic stem cell transplant

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- CAR-T therapy is a type of treatment the utilizes the body's own immune system to fight cancer. T-cells are collected from the patient via apheresis and are genetically engineered in the laboratory to produce chimeric antigen receptors on the cell surface, allowing the T-cells to recognize an antigen on target cancer cells. Once the tumor cells are identified, they are attacked and killed by the CAR-T therapy.

- CAR-T therapy has not been studied when given following prior treatment with any CAR-T therapy or following any other genetically-modified T-cell therapy.

- Due to the risk of cytokine release syndrome and neurological toxicities, CAR-T therapies are only allowed to be given at treatment centers certified by their REMS programs. CAR-T REMS programs require certified hospitals and their clinics to have on-site, immediate access to tocilizumab and an understanding of how to manage the risks of the associated CAR-T side effects.

- Tecartus is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) and Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

- Safety and efficacy were established in the ZUMA-2 trial, a single-arm, open-label, multicenter phase II study of 74 adult patients with relapsed or refractory mantle cell lymphoma. Patients had received up to 5 prior lines of therapy, including an anti-CD20 antibody, either an anthracycline- or bendamustine-containing chemotherapy regimen, and a Bruton's tyrosine kinase (BTK) inhibitor. Three patients experienced manufacturing failure, one died of progressive disease, and one withdrew from the study prior to lymphodepleting chemotherapy. One patient received lymphodepleting chemotherapy but did not receive Tecartus due to ongoing active atrial fibrillation. Tecartus was administered as a single intravenous infusion at a target dose of 2×10^6 CAR-positive viable T-cells/kg. The lymphodepleting regimen consisted of cyclophosphamide 500 mg/m^2 intravenously and fludarabine 30 mg/m^2 intravenously given on the fifth, fourth, and third day before Tecartus. Patients with prior allogeneic HSCT, any active central nervous system malignancy, ECOG performance status of 2 or greater, absolute neutrophil count less than 1,000/µL, platelet count < 75,000/µL, creatinine clearance less than 60 mL/min, hepatic transaminases more than 2.5 times the upper limit of normal, cardiac ejection fraction less than 50%, or active serious infection were excluded. The primary endpoint was objective response rate to therapy which was 87%, including 37 patients who had complete response (62%) and 15 who had a partial response (25%). The median time to response was 28 days with median duration of response not yet being reached.

- Safety and efficacy for use in acute lymphoblastic leukemia were established in the ZUMA-3 trial, a multicenter, phase I/II trial of 55 adult patients with relapsed or refractory ALL. Patients must have had documentation of CD19 positive disease and if they were Philadelphia chromosome positive, must have been intolerant to, had a contraindication to, or have failed 2 lines of tyrosine kinase inhibitor therapy. Patients with prior allogeneic SCT within 100 days of therapy, any active central nervous system malignancy, ECOG performance status of 2 or greater, creatinine clearance less than 60 mL/min, hepatic transaminases more than 2.5 times the upper limit of normal, cardiac ejection fraction less than 50%, diagnosis of Burkitt's lymphoma, grade 2 to 4 graft-versus-host disease, or active serious infection were excluded. The primary endpoint is overall complete remission rate. In the study, 70.9% presented with a complete remission rate. The median duration of response was 12.8 months and the median overall survival (OS) was 18.2 months.

- Disease should be measured/staged with PET-CT. Focal uptake in nodal and extranodal sites is considered involvement with lymphoma, including spleen, liver, bone, thyroid, and so on. A measurable node must have a longest diameter (LDi) greater than 1.5 cm. A measurable extranodal lesion should have an LDi greater than 1.0 cm. All other lesions (including nodal, extranodal, and assessable disease) should be followed as nonmeasured disease (eg, cutaneous, GI, bone, spleen, liver, kidneys, pleural or pericardial effusions, ascites).

- While use of Tecartus has not been established in patients with a creatinine clearance of less than 60 mL/minute, other CAR-T therapies have been studied in subjects with a creatinine clearance of 30 mL/minute. The National Institute of Health/National Cancer Institute Common Terminology Criteria of Adverse Events (CTCAE) classify grade 2 chronic kidney disease as a creatinine clearance of 30 – 59 mL/minute. As the classification system uses 30 mL/minute as a cutoff for grade 2 disease and data from other CAR-T therapies support their use in these patients, Tecartus should be able to be tolerated in this population. As there is no data to support administration of CAR-T at levels lower than 30 ml/minute, therapy should not be given in patients not meeting the 30 mL/minute threshold.

- While use of Tecartus has not been established in patients with an alanine aminotransferase of greater than 2.5 times the upper limit of normal (ULN), other CAR-T therapies have been studied in subjects with an alanine aminotransferase of up to 5 times the ULN and the CTCAE recommendations have set 5 times the ULN as the cutoff for grade 2 adverse reactions. As the classification system uses 5 times the ULN and other CAR-T therapies have data supporting use in this patient population, Tecartus should be tolerated in these patients as well. As there is no data to support administration of CAR-T at levels higher than 5 times the ULN, therapy should not be given to patients not meeting that threshold.

- The CTCAE recommendations set the grade 2 cutoff for left ventricular ejection fraction (LVEF) at 40%. While Tecartus has only been studied in patients with a LVEF greater than or equal to 45%, there is data from other CAR-T therapies to support use in those with a LVEF of 40% of greater. Therefore, Tecartus should be tolerated in these patients as well. There is no data supporting use at LVEF levels less than 40%.

- A provider portal that is used to capture clinical outcome information for patients on select high-cost treatments, such as gene and cellular therapies. If a patient meets medical necessity as defined by this policy and is approved for treatment, the requesting physician must attest to providing clinical outcome information within the appropriate provider portal at the requested cadence.

References:

1. Tecartus [prescribing information]. Santa Monica, CA: Kite Pharma, Inc.; April 2024.
2. National Comprehensive Cancer Network. Acute lymphoblastic leukemia (Version 3.2024). 2024 Dec 20. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed on March 25, 2025.

3. National Comprehensive Cancer Network. B-cell lymphomas (Version 2.2025). 2025 Feb 10. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed on March 25, 2025.
4. Lee DW et al. Current concepts in the diagnosis and management of cytokine release syndrome. Blood. 2014 Jul 10; 124 (2): 188 - 195.
5. Wang M, Munoz J, Goy A, et al. KTE-X19 CAR T-cell therapy in relapsed or refractory mantle cell lymphoma. NEJM. 2020 Apr 2; 382 (14): 1331 – 42.
6. Shah BJ, Bishop MR, Oluwole OO, et al. KTE-X19 anti-CD19 CAR T-cell therapy in adult relapsed/refractory acute lymphoblastic leukemia: ZUMA-3 phase 1 results. Blood. 2021 Jul 8; 138 (1): 11-22.
7. GlobalData Healthcare. ASCO 2021: tecartus' ZUMA-3 trial to support a first label in adult r/r all. 2021 June 10. Available at: https://www.clinicaltrialsarena.com/comment/asco-2021-tecartus-zuma-3-all/. Accessed on June 21, 2021.
8. Businesswire. Kite submits supplemental biologics license application to US food and drug administration for tecartus in adult patients with relapsed or refractory acute lymphoblastic leukemia. 2021 April 1. Available at: https://www.businesswire.com/news/home/20210401005666/en/Kite-Submits-Supplemental-Biologics-License-Application-to-U.S.-Food-and-Drug-Administration-for-Tecartus%C2%AE-in-Adult-Patients-With-Relapsed-or-Refractory-Acute-Lymphoblastic-Leukemia. Accessed on June 21, 2021.
9. U.S. Department of Health and Human Services. Common terminology criteria for adverse events (Version 5.0). 2017 Nov 27. Available at: https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf. Accessed on July 6, 2022.

Policy History		
#	Date	Change Description
1.0	Initial Effective Date: 01/01/2026	New policy

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*