Tecartus® (brexucabtagene autoleucel)
(Intravenous)

Document Number: IC-0558

Last Review Date: 10/30/2023
Date of Origin: 08/04/2020
Dates Reviewed: 08/2020, 11/2020, 01/2021, 04/2021, 11/2021, 11/2022, 11/2023

I. Length of Authorization

Coverage will be provided for one treatment course (1 dose of Tecartus) and may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 1 infusion bag of up to 200 million autologous anti-CD19 CAR-positive viable T cells

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit (1 infusion of up to 200 million autologous anti-CD19 CAR-positive viable T cells)

III. Initial Approval Criteria [1-5]

Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e. genetic and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

- Patient is at least 18 years of age, unless otherwise specified; **AND**
- Healthcare facility has enrolled in the YESCARTA & TECARTUS REMS Program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
- Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
- Prophylaxis for infection will be followed according to local guidelines; **AND**
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during brexucabtagene autoleucel treatment and until immune recovery following treatment; **AND**

- Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Used as a single agent *(not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)*; **AND**
- Patient has an ECOG performance status of 0-1; **AND**
- Patient has not received prior CAR-T therapy; **AND**

Mantle Cell Lymphoma † ‡ Φ [1,2,4]

- Patient has relapsed or refractory disease; **AND**
- Patient has at least one measurable lesion; **AND**
- Patient must have received previous systemic therapy which included at least one agent from each of the following categories:
  - Bruton tyrosine kinase (BTK) inhibitor (e.g., ibrutinib, acalabrutinib, zanubrutinib, etc.)
  - Anti-CD20 monoclonal antibody (e.g., rituximab, obinutuzumab, etc.)
  - Anthracycline- OR bendamustine-containing chemotherapy

B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)* † ‡ [1,5]

- Patient has relapsed or refractory disease; **AND**
- Patient has not received other anti-CD19 therapy, (e.g., blinatumomab, tafasitamab, loncastuximab tesirine, etc.) OR patient previously received other anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
  - Patient has Philadelphia chromosome (Ph)-positive disease; **AND**
    - Previous therapy has included tyrosine kinase inhibitors (TKIs) (e.g., bosutinib, dasatinib, imatinib, nilotinib, or ponatinib); **OR**
  - Patient has Philadelphia chromosome (Ph)-negative disease

**May also be applicable to adolescent and young adult (AYA) patients 15 to 39 years of age, who are treated in the pediatric oncology setting.*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria

Coverage cannot be renewed.

V. Dosage/Administration [1]

Indication	Dose
Mantle Cell Lymphoma	**Lymphodepleting chemotherapy**: • Administer cyclophosphamide 500 mg/m^2 and fludarabine 30 mg/m^2 intravenously on the fifth, fourth, and third day before infusion of Tecartus.

	Tecartus infusion: • Each single infusion bag of Tecartus contains a suspension of chimeric antigen receptor (CAR)-positive T cells in approximately 68 mL. The target dose is 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells (for patients 100 kg and above).
B-Cell Precursor ALL	**Lymphodepleting chemotherapy**: • Administer fludarabine 25 mg/m^2 intravenously on the fourth, third, and second day and administer cyclophosphamide 900 mg/m^2 on the second day before infusion of Tecartus. **Tecartus infusion**: • Each single infusion bag of Tecartus contains a suspension of chimeric antigen receptor (CAR)-positive T cells in approximately 68 mL. The target dose is 1×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 1×10^8 CAR-positive viable T cells (for patients 100 kg and above).
For autologous use only. For intravenous use only. • Tecartus is prepared from the patient's peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure. • One treatment course consists of lymphodepleting chemotherapy followed by a single infusion of Tecartus. • Confirm Tecartus availability prior to starting the lymphodepleting regimen. • Confirm the patient's identity matches the patient identifiers on the Tecartus cassette.	
Premedication: • Premedicate with acetaminophen and diphenhydramine (or another H1-antihistamine) 30-60 minutes prior to infusion. Avoid prophylactic systemic corticosteroids which may interfere with Tecartus activity. **Monitoring after infusion**: • Monitor patients at the certified healthcare facility daily for at least seven days for patients with MCL and at least 14 days for patients with ALL following infusion for signs and symptoms of Cytokine Release Syndrome (CRS) and neurologic events. • Instruct patients to remain within proximity of the certified healthcare facility for at least 4 weeks following infusion. • Instruct patients to refrain from driving or hazardous activities for at least 8 weeks following infusion.	
• Store infusion bag in the vapor phase of liquid nitrogen (less than or equal to minus 150°C). Thaw prior to infusion. • In case of manufacturing failure, a second manufacturing may be attempted. • Additional chemotherapy (not the lymphodepletion) may be necessary while the patient awaits the product. • Ensure that 2 doses of tocilizumab and emergency equipment are available prior to infusion and during the recovery period. • Tecartus contains human blood cells that are genetically modified with replication incompetent retroviral vector. Follow universal precautions and local biosafety guidelines for handling and disposal.	

VI. Billing Code/Availability Information

HCPCS Code:

- Q2053 – Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose; 1 billable unit = 200 million autologous anti-cd19 car positive viable t cells

NDC(s):

- Tecartus suspension for intravenous infusion (MCL); 1 infusion bag (~68 mL): 71287-0219-xx
- Tecartus suspension for intravenous infusion (ALL); 1 infusion bag (~68 mL): 71287-0220-xx

VII. References

1. Tecartus [package insert]. Santa Monica, CA; Kite Pharma, Inc.; October 2021. Accessed October 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) brexucabtagene autoleucel. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2023.
3. Majzner RG, Mackall CL. Tumor Antigen Escape from CAR T-cell Therapy. *Cancer Discov* 2018;8:1219-1226.
4. 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 Apr 2;382(14):1331-1342. doi: 10.1056/NEJMoa1914347.
5. 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 Aug 7;398(10299):491-502. doi: 10.1016/S0140-6736(21)01222-8. Epub 2021 Jun 4.
6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Lymphoblastic Leukemia Version 3.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed October 2023.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C83.10	Mantle cell lymphoma, unspecified site
C83.11	Mantle cell lymphoma, lymph nodes of head, face and neck
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites

C83.50	Lymphoblastic (diffuse) lymphoma, unspecified site
C83.51	Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck
C83.52	Lymphoblastic (diffuse) lymphoma, intrathoracic lymph nodes
C83.53	Lymphoblastic (diffuse) lymphoma, intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma, lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma, lymph nodes of inguinal region and lower limb
C83.56	Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes
C83.57	Lymphoblastic (diffuse) lymphoma, spleen
C83.58	Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites
C83.59	Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC