

## Tecartus™ (brexucabtagene autoleucel) (Intravenous)

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### 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

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

- 1 billable unit (1 infusion of up to 200 million autologous anti-cd19 CAR<sup>+</sup>-positive viable T cells)

### III. Initial Approval Criteria <sup>1,4</sup>

- Submission of medical records 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 via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

- Patient aged 18 years or greater; **AND**
- Healthcare facility has enrolled in the YESCARTA & TECARTUS REMS 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 has been followed according to local guidelines; **AND**
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during brexucabtagene autoleucel treatment, and will not receive live vaccines 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 single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**
- Patient did not receive prior allogeneic hematopoietic stem cell transplantation (HSCT); **AND**
- Patient does not have central nervous system lymphoma, detectable cerebrospinal fluid malignant cells or brain metastases; **AND**

#### Mantle Cell Lymphoma † Φ 1,2,4

- Patient's 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)
  - Anti-CD20 monoclonal antibody (e.g., rituximab)
  - Anthracycline- OR bendamustine-containing chemotherapy

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

#### IV. Renewal Criteria

Coverage cannot be renewed.

#### V. Dosage/Administration

Indication	Dose
Mantle Cell Lymphoma	<p><b><u>Lymphodepleting chemotherapy:</u></b></p> <ul style="list-style-type: none"> <li>• Administer cyclophosphamide 500 mg/m<sup>2</sup> and fludarabine 30 mg/m<sup>2</sup> intravenously on the fifth, fourth, and third day before infusion of Tecartus.</li> </ul> <p><b><u>Tecartus Infusion:</u></b></p> <ul style="list-style-type: none"> <li>• Premedicate with acetaminophen and diphenhydramine (or other H1-antihistamine) 30-60 minutes prior to infusion. Avoid prophylactic systemic corticosteroids which may interfere with Tecartus activity.</li> <li>• Infuse the entire contents of the Tecartus bag within 30 minutes by either gravity or a peristaltic pump. Tecartus is stable at room temperature for up to 3 hours once thawed.</li> <li>• 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 <math>2 \times 10^6</math> CAR-positive viable T cells per kg body weight, with a maximum of <math>2 \times 10^8</math> CAR-positive viable T cells (for patients 100 kg and above).</li> </ul> <p><b><u>Monitoring:</u></b></p> <ul style="list-style-type: none"> <li>• Monitor patients daily for at least 7 days at the certified healthcare facility following infusion for signs and symptoms of CRS and neurologic toxicities.</li> </ul>

	<ul style="list-style-type: none"> <li>Instruct patients to remain within proximity of the certified healthcare facility for at least 4 weeks following infusion.</li> </ul>
<p><b>For autologous use only. For intravenous use only.</b></p> <ul style="list-style-type: none"> <li>Tecartus is prepared from the patient’s peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure</li> <li>One treatment course consists of lymphodepleting chemotherapy followed by a single infusion of Tecartus.</li> <li>Confirm Tecartus availability prior to starting the lymphodepleting regimen.</li> </ul>	
<ul style="list-style-type: none"> <li>Store infusion bag in the vapor phase of liquid nitrogen (less than or equal to minus 150°C). Thaw prior to infusion.</li> <li>In case of manufacturing failure, a second manufacturing may be attempted.</li> <li>Additional chemotherapy (not the lymphodepletion) may be necessary while the patient awaits the product.</li> <li>Ensure that 2 doses of tocilizumab and emergency equipment are available prior to infusion and during the recovery period.</li> <li>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.</li> </ul>	

## VI. Billing Code/Availability Information

### HCPCS code:

- J9999 – Not otherwise classified, antineoplastic drugs (*Discontinued on 04/01/21*)
- 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 (*Effective 04/01/21*)
- C9073 – 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 (*HOPPS-Hospital Outpatient Prospective Payment System Use Only*) (*Discontinued on 04/01/21*)

### NDC:

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

## VII. References

- Tecartus [package insert]. Santa Monica, CA; Kite Pharma, Inc., July 2020. Accessed October 2020.
- Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) brexucabtagene autoleucel. National Comprehensive Cancer Network, 2020. 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 2020.
- Majzner RG, Mackall CL. Tumor Antigen Escape from CAR T-cell Therapy. *Cancer Discov* 2018;8:1219-1226.
- 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.

## 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

## 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: <http://www.cms.gov/medicare-coverage-database/search/advanced-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 Government Benefit Administrators, 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