

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 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; **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 has not received 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**
- 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, 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 prior anti-CD19 therapy, (e.g., blinatumomab, etc.) OR patient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- Patient does not have CNS-3 disease or CNS-2 disease with neurological changes; **AND**
 - Patient has Philadelphia chromosome (Ph)-positive disease; **AND**
 - Disease is tyrosine kinase inhibitor (TKI) intolerant OR refractory to at least two (2) different TKIs; **OR**
 - Patient has Philadelphia chromosome (Ph)-negative disease

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

IV. Renewal Criteria

Coverage cannot be renewed.

V. Dosage/Administration ¹

Indication	Dose
Mantle Cell Lymphoma	<u>Lymphodepleting chemotherapy:</u> - Administer cyclophosphamide 500 mg/m² and fludarabine 30 mg/m² intravenously on the fifth, fourth, and third day before infusion of Tecartus. <u>Tecartus infusion:</u> - 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	<u>Lymphodepleting chemotherapy:</u> - Administer fludarabine 25 mg/m² intravenously on the fourth, third, and second day and administer cyclophosphamide 900 mg/m² on the second day before infusion of Tecartus. <u>Tecartus infusion:</u> - 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.	
<u>Premedication:</u> 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.	
<u>Monitoring after infusion:</u> - 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 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) brexucabtagene autoleucel. National Comprehensive Cancer Network, 2022. 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 2022.
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.

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
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

Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provide free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

If you believe that we have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, you can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1.866.631.5404 (TTY: 711)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلی رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

Traditional Chinese: 注意: 如果您使用繁體中文, 您可以免費獲得語言援助服務。請致電 1.866.631.5404 (TTY: 711)。

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzschts, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

Lao: ໄປດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY: 711).