Drug Policy:

Tecartus™ (brexucabtagene autoleucel)

POLICY NUMBER UM ONC_1413	**SUBJECT** Tecartus™ (brexucabtagene autoleucel)		**DEPT/PROGRAM** UM Dept	**PAGE 1 of 3**
DATES COMMITTEE REVIEWED 09/09/20, 02/10/21, 05/12/21, 11/10/21, 02/09/22, 05/11/22, 09/14/22, 07/12/23, 02/14/24	**APPROVAL DATE** February 14, 2024	**EFFECTIVE DATE** February 23, 2024	**COMMITTEE APPROVAL DATES** 09/09/20, 02/10/21, 05/12/21, 11/10/21, 02/09/22, 05/11/22, 09/14/22, 07/12/23, 02/14/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Tecartus (brexucabtagene autoleucel) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. B-Cell Acute Lymphoblastic Leukemia (B-Cell ALL), Confirmed CD-19 Positive

1. Tecartus (brexucabtagene autoleucel) may be used in adult members with relapsed or refractory B-Cell ALL.

C. Mantle Cell Lymphoma, Confirmed CD-19 Positive

1. Tecartus (brexucabtagene autoleucel) may be used in adult members with relapsed or refractory Mantle Cell Lymphoma.

III. EXCLUSION CRITERIA

A. Tecartus (brexucabtagene autoleucel) is being used after disease progression on or after the same regimen or another CAR-T cell therapy directed towards CD19 antigen [e.g., Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel)].

B. Concurrent use of other systemic immunosuppressive therapy or live virus vaccines.

C. Lack of confirmed documentation of CD-19 positivity in tumor cells.

D. Treatment with Tecartus (brexucabtagene autoleucel) exceeds the maximum limit of 2×10^8 CAR-positive viable T cells (for Mantle Cell Lymphoma); 1×10^8 CAR-positive viable T cells (for B-Cell ALL).

E. Treatment exceeds the maximum duration limit as one time administration.

F. Investigational use of Tecartus (brexucabtagene autoleucel) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Wang M, et al. Zuma-2 Trial. KTE-X19 CAR T-Cell Therapy in Relapsed or Refractory Mantle-Cell Lymphoma. N Engl J Med. 2020 Apr 2;382(14):1331-1342.

B. Wang et al. Updated Survival of Zuma-2 trial. J Clin Oncol- June 2022. DOI: https://doi.org/10.1200/JCO.21.02370

C. Shah BD, 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.

D. Tecartus prescribing information. Kite Pharma, Inc Santa Monica, CA 2024.

E. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

F. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.