New Century Health

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	**APPROVAL DATE** July 12, 2023	**EFFECTIVE DATE** July 28, 2023	**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	
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.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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 NCH 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 when the following criteria are met:
    a. Member is an adult, 18 years of age and older, with B-Cell Acute Lymphoblastic Leukemia with confirmed documentation of CD19 tumor expression (demonstrated in bone marrow or peripheral blood by flow cytometry) AND
    b. Member has experienced disease relapse at least 100 days from allogeneic stem cell transplantation (SCT) at the time of infusion OR
    c. Member has relapsed/refractory B-Cell ALL that has progressed after 2 lines of standard chemotherapy with or without TKI; use with a TKI [i.e., Gleevec (imatinib)] is for members with Philadelphia chromosome-positive B-Cell ALL

C. Mantle Cell Lymphoma, Confirmed CD-19 Positive

1. Tecartus (brexucabtagene autoleucel) may be used as monotherapy in members 18 years or older with a diagnosis Mantle Cell Lymphoma that has either relapsed or is refractory to prior therapy (up to 5 prior regimens); prior therapy should have included a chemo-immunotherapy regimen (e.g., R-CHOP, BR, R-Hyper CVAD) and a BTK (Bruton Tyrosine Kinase) inhibitor (e.g., ibrutinib, acalabrutinib, or zanubrutinib) AND
2. Member should have a confirmed diagnosis of Mantle Cell Lymphoma, either with cyclin D1 overexpression or a positive t(11;14) translocation in the lymphoma cells AND
3. Member's Mantle Cell Lymphoma should be confirmed to be CD-19 positive.

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. The member does not have adequate bone marrow reserve defined by ALL the following:
    1. Absolute neutrophil count (ANC) greater than or equal to 1000 cells/uL
    2. Platelet Count greater than or equal to 75,000/uL.

E. The member does not have adequate hepatic, renal, and cardiac function defined as:
    1. Serum ALT/AST (hepatic transaminases) less than or equal to 2.5 times the upper limit of normal or total bilirubin less than or equal to 1.5mg/dL
    2. Creatinine clearance greater than or equal to 60 mL/min
    3. Cardiac ejection fraction greater than or equal to 50% and there is no evidence of pericardial effusion as determined by an echocardiogram (ECHO).

F. 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).

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

H. 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 2022.

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.

G. NCQA UM 2023 Standards and Elements.