

Drug Policy:

Tecartus™ (brexucabtagene autoleucel)

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| POLICY NUMBER UM ONC_1413 | SUBJECT Tecartus™ (brexucabtagene autoleucel) | | DEPT/PROGRAM UM Dept | PAGE 1 of 4 |
| DATES COMMITTEE REVIEWED 09/09/20, 02/10/21, 05/12/21, 11/10/21, 02/09/22, 05/11/22, 09/14/22 | APPROVAL DATE September 14, 2022 | EFFECTIVE DATE September 30, 2022 | COMMITTEE APPROVAL DATES 09/09/20, 02/10/21, 05/12/21, 11/10/21, 02/09/22, 05/11/22, 09/14/22 | |
| PRIMARY BUSINESS OWNER: UM | | COMMITTEE/BOARD APPROVAL Utilization Management Committee | | |
| URAC STANDARDS HUM v8: UM 1-2; UM 2-1 | 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. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the [Preferred Drug Guidelines shall follow NCH L1 Pathways](#)

(<http://pathways.newcenturyhealth.com/>) when applicable, otherwise shall follow NCH drug policies AND

4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs AND
6. When there is a documented drug shortage, disease progression, contraindication, or confirmed intolerance to a Preferred drug/regimen, per NCH Policy and Pathway, the available alternative product may be used if deemed medically appropriate and the indication is listed in a standard reference compendia or accepted peer review literature. For a list of current drug shortages, please refer to FDA drug shortage website in the reference section.

B. Mantle Cell Lymphoma, Confirmed CD-19 Positive

1. Tecartus (brexucabtagene autoleucl) may be used as monotherapy in members 18 years or older and have Mantle Cell Lymphoma that was either relapsed or refractory 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 cyclinD1 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.

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

1. Tecartus (brexucabtagene autoleucl) 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.

III. EXCLUSION CRITERIA

- A. Tecartus (brexucabtagene autoleucl) 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 (tisagenlecleucl), Yescarta (axicabtagene ciloleucl)].
- B. CD-19 positivity not confirmed and documented.
- C. The member does not have adequate bone marrow reserve defined by ALL the following:
 1. Absolute neutrophil count (ANC) \geq 1000 cells/uL
 2. Platelet Count \geq 75,000/uL.
- D. The member does not have adequate hepatic, renal, and cardiac function defined as:
 1. Serum ALT/AST (hepatic transaminases) \leq 2.5 times the upper limit of normal or total bilirubin \leq 1.5mg/dL
 2. Creatinine clearance \geq 60 mL/min
 3. Cardiac ejection fraction \geq 50% and there is no evidence of pericardial effusion as determined by an echocardiogram (ECHO).

- E. History of CNS lymphoma (including lymphomatous meningitis), history of brain metastases, or any CNS disorder.
- F. Active serious infection.
- G. Dosing exceeds single dose limit of Tecartus (brexucabtagene autoleucel) 2×10^8 CAR-positive viable T cells (for Mantle Cell Lymphoma); 1×10^8 CAR-positive viable T cells (for B-Cell ALL).
- H. Does not exceed duration limit as one time administration.
- I. 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 definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
 4. Whether the experimental design, in light of 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. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.
- H. NCQA UM 2022 Standards and Elements.