# Drug Policy:
## Tecartus™ (brexucabtagene autoleucel)

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<tr>
<th>POLICY NUMBER</th>
<th>UM ONC_1413</th>
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<tr>
<td>SUBJECT</td>
<td>Tecartus™ (brexucabtagene autoleucel)</td>
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<td>DEPT/PROGRAM</td>
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<tr>
<th>DATES COMMITTEE REVIEWED</th>
<th>09/09/20, 02/10/21, 05/12/21, 11/10/21, 02/09/22</th>
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<tr>
<td>APPROVAL DATE</td>
<td>February 9, 2022</td>
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<td>EFFECTIVE DATE</td>
<td>February 25, 2022</td>
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<th>PRIMARY BUSINESS OWNER</th>
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<tr>
<td>COMMITTEE/BOARD APPROVAL</td>
<td>Utilization Management Committee</td>
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## 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 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.

B. Mantle Cell Lymphoma, CD-19 positive

1. Tecartus (brexucabtagene autoleucel) may be used as monotherapy in members 18 years or older and have Mantle Cell Lymphoma that was either relapsed or refractory to 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. Acute Lymphoblastic Leukemia (ALL)

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 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 Philadelphia chromosome-negative B-ALL that has progressed after failure with at least 2 lines of systemic therapy, including Blincyto (blinatumomab) OR
   d. Member has relapsed/refractory Philadelphia chromosome-positive B-ALL that has progressed after failure with at least 2 different TKI-containing regimens with Gleevec (imatinib), Bosulif (bosutinib), Sprycel (dasatinib), Tasigna (nilotinib), or Iclusig (ponatinib).

III. EXCLUSION CRITERIA

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

B. CD-19 positivity not confirmed.

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

D. The member does not have adequate hepatic, renal, and cardiac function defined as:
   1. Serum ALT/AST (hepatic transaminases) ≤ 2.5 times the upper limit of normal or total bilirubin ≤ 1.5mg/dL
   2. Creatinine clearance ≥ 60 mL/min
   3. Cardiac ejection fraction ≥ 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) $2 \times 10^8$ CAR-positive viable T cells (for Mantle Cell Lymphoma); $1 \times 10^8$ CAR-positive viable T cells (for 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

C. Tecartus prescribing information. Kite Pharma, Inc Santa Monica, CA 2021.
