

## POLICY SECTIONS

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## DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

## POLICY DESCRIPTION

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.

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.

## RELATED POLICIES

Policy No.	Policy Title
N/A	

## INDICATIONS and/or LIMITATIONS OF COVERAGE

### 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, 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).

#### **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)  $\geq$  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)  $2 \times 10^8$  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

## MEDICATION MANAGEMENT

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

## ATTACHMENTS

None.

## APPLICABLE CPT / HCPCS PROCEDURE CODES

### CPT Codes

CPT	Description
<b>0537T</b>	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
<b>0538T</b>	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)
<b>0539T</b>	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for Administration
<b>0540T</b>	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous

### HCPCS Codes

HCPCS	Description
<b>Q2053</b>	Brexucabtagene autoleucel, up to 200 million autologous anti-cd 19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

**AVAILABLE DOSAGE FORMS:** Supplied in an infusion bag containing approximately 68mL of frozen suspension of genetically modified autologous T cells in 5% DMSO and human serum albumin

**CODING DISCLAIMER.** Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

## REFERENCES

- Wang M, et al. Zuma-2 Trial. KTE-X19 CAR T-Cell Therapy in Relapsed or Refractory MantleCell Lymphoma. N Engl J Med. 2020 Apr 2;382(14):1331-1342.
- 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.
- Tecartus prescribing information. Kite Pharma, Inc Santa Monica, CA 2021.
- 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.
- Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.
- Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

## APPENDIX

**Reserved for State specific information.** Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.