Molina Clinical Policy
Tecartus™ (brexucabtagene autoleucel): Policy No. 378

Last Approval: 8/9/2023
Next Review Due: August 2024

POLICY SECTIONS

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

This policy is intended 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.

INDICATIONS and/or LIMITATIONS OF COVERAGE

A. Continuation requests for a not-approvable medication shall be exempt from this 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. Mantle Cell Lymphoma, CD-19 positive

1. Tecartus (brexucabtagene autoleucel) may be used as monotherapy in members 18 years or older with a diagnosis of 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 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 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.

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. 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:
   a. Absolute neutrophil count (ANC) ≥ 1000 cells/uL
   b. Platelet Count ≥ 75,000/uL.

E. The member does not have adequate hepatic, renal, and cardiac function defined as:
   a. Serum ALT/AST (hepatic transaminases) ≤ 2.5 times the upper limit of normal or total bilirubin ≤ 1.5mg/dL
   b. Creatinine clearance ≥ 60 mL/min
   c. Cardiac ejection fraction ≥ 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 × 108 CAR-positive viable T cells (for 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 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, 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.

MEDICATION MANAGEMENT

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

APPLICABLE CPT / HCPCS PROCEDURE CODES

CPT Codes

CPT	Description
0537T	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
0538T	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)
0539T	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for Administration
0540T	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous

HCPCS Codes

HCPCS	Description
Q2053	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.

APPROVAL HISTORY

08/09/2023 Criteria revised to remove preferred medication guidance. Criteria for continuation of existing therapy added. Exclusion criteria revised to add lack of documented CD-19 positivity and remove criteria of CNS lymphoma and active infection. Policy reviewed by board certified Oncologist.
08/10/2022 Adopted NCH policy and retired MCP.

REFERENCES

A. 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.
B. 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.
C. Tecartus prescribing information. Kite Pharma, Inc Santa Monica, CA 2021.
D. 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.
E. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.
F. 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.*