MetroPlus Health

Policy and Procedure

Title: Tecartus (brexucabtagene autoleucel)	**Division: Medical Management** **Department: Utilization Management**
Approval Date: 4/26/2022	**LOB: Medicaid, HIV SNP, HARP, CHP, MetroPlus Gold, GoldCare, Marketplace, Essential**
Effective Date: 4/26/2022	**Policy Number: UM-MP335**
Review Date: 3/17/2026	**Cross Reference Number:**
Retired Date:	**Page 1 of 7**

I. POLICY DESCRIPTION:

Medical Oncology – Anti-CD19 CAR-T immunotherapy, Tecartus (brexucabtagene autoleucel)

II. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

III. DEFINITIONS:

Tecartus is a CD19-directed genetically modified autologous T-cell immunotherapy that binds to CD19-expressing cancer cells and normal B cells. Studies demonstrated that following anti-CD19 CAR-T cell engagement with CD19-expressing target cells, the CD28 and CD3-zeta co-stimulatory domains activate downstream signaling cascades that lead to T-cell activation, proliferation, acquisition of effector functions, and secretion of inflammatory cytokines and chemokines. This sequence of events leads to killing of CD19-expressing cells.

Tecartus is indicated for the treatment of:

Adult patients with relapsed or refractory mantle cell lymphoma (MCL)

Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

All other uses for Tecartus are considered experimental and investigational.

IV. POLICY:

For the Medicare and UltraCare lines of business, MetroPlusHealth determines medical necessity based on applicable Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD).
https://www.cms.gov/medicare-coverage-database/search.aspx

For Medicaid, SNP, HARP Plan members Only: Confirmed diagnosis of FDA-approved or compendia supported indication and Medicaid covered indication.

For all other LOBs:

Tecartus will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

INITIAL REQUEST:

1. **Adult Relapse or Refractory Mantle cell lymphoma (MCL)**
   - **A.** Member is 18 years of age or older;

   AND
   - **B.** Member has a diagnosis confirmed by submitted documentation including chart notes of refractory or relapsed Mantle Cell Lymphoma (MCL);

   AND
   - **C.** Member has had at least TWO previous treatment that included ALL of the following:
     - **a.** Anthracycline (e.g., doxorubicin) or bendamustine-containing chemotherapy;

     AND
     - **b.** Anti-CD20 monoclonal antibody therapy (e.g., Rituxan (rituximab));

     AND
     - **c.** Bruton tyrosine kinase (BTK) inhibitor (e.g., Imbruvica (ibrutinib), Calquence (acalabrutinib), Brukinda (zanubrutinib));

   AND
   - **D.** Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1;

   AND
   - **E.** Member is screened for HBV, HCV, and HIV in accordance with clinical guidelines prior to collection of cells for manufacturing;

   AND
   - **F.** Member has not received any live vaccines within the past 6 weeks;

   AND
   - **G.** Member does not have an active systemic infection or inflammatory disorder**;**

   AND
   - **H.** Member has not previously been treated with Tecartus or any other CAR-T therapy;

   AND
   - **I.** Authorization is for no more than one dose.

2. **Adult Relapse or Refractory B-cell precursor Acute Lymphoblastic Leukemia (B-ALL)**
   - **A.** Member is 18 years of age or older;

AND

B. Member has a diagnosis confirmed by submitted documentation including chart notes of B-cell precursor Acute Lymphoblastic Leukemia (B-ALL) that is in relapse or refractory;

AND

C. ONE of the following:

- **a.** Member has Philadelphia chromosome-negative disease that is relapsed or refractory as defined as ONE of the following:
  - **i.** Primary refractory disease;

  OR

  - **ii.** First relapse with remission of 12 months or less;

  OR

  - **iii.** Relapsed or refractory disease after at least two previous lines of systemic therapy;

  OR

  - **iv.** Relapsed or refractory disease after allogeneic stem cell transplant;

OR

- **b.** Member has Philadelphia chromosome-positive disease that meets any ONE of the following:
  - **i.** Member has relapsed or refractory disease despite treatment with at least two different tyrosine kinase inhibitors (TKIs) (e.g., Bosulif (bosutinib), Sprycel (dasatinib), Gleevec (imatinib), Tasigna (nilotinib), Iclusig (ponatinib));

  OR

  - **ii.** Member is intolerant to TKI therapy;

AND

D. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1;

AND

E. Member is screened for HBV, HCV, and HIV in accordance with clinical guidelines prior to collection of cells for manufacturing;

AND

F. Member has not received any live vaccines within the past 6 weeks;

AND

G. Member does not have an active systemic infection or inflammatory disorder**;**

AND

H. Member has not previously been treated with Tecartus or any other CAR-T therapy;

AND

I. Authorization is for no more than one dose.

RENEWAL REQUEST:
Repeat administration of Tecartus is investigational and will not be covered.

V. LIMITATIONS/EXCLUSIONS

- Repeat administration of Tecartus is considered to be experimental or investigational because there have been no established studies to demonstrate effectiveness
- Any history of CNS disorders including CNS-2 disease with neurologic changes and CNS-3 disease irrespective of neurological changes

VI. APPLICABLE PROCEDURE CODES:

CPT	Description
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

VII. APPLICABLE DIAGNOSIS CODES:

CODE	Description
C83.11	Mantle cell lymphoma, lymph nodes of head, face, and neck
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse

VIII. REFERENCES:

1. Tecartus [package insert]. Santa Monica, CA: Kite Pharma; June 2024.
2. Study to evaluate the efficacy of Brexucabtagene Autoleucel (KTE-X19) in participants with relapsed/refractory mantle cell lymphoma - full text view. Study to Evaluate the Efficacy of Brexucabtagene Autoleucel (KTE-X19) in Participants With Relapsed/Refractory Mantle Cell Lymphoma - Full Text View - ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/study/NCT02601313?term=BREXUCABTAGENE&draw=2&rank=3. Published August 2021. Accessed April 7, 2022.
3. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org.
4. The NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas (Version 1.2024).© 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org.
5. Wang M, Munoz J, Goy A, et al. KTE-X19 CAR T-Cell Therapy in Relapsed or Refractory Mantle-Cell Lymphoma. NEJM 2020; 382:1331-1342.
6. Shah BD, Ghobadi A, Oluwole OO, et al. KTE-X19 for relapsed or refractory adult B-cell acute lymphoblastic leukaemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study. Lancet. 2021;398(10299):491-502.
7. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 4.2023; February 5, 2024).© 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org.

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REVISION LOG:

REVISIONS	DATE
Creation date	4/14/2022
Annual review	4/25/2023
Annual review	4/23/2024
Update LOBs to remove Medicare and Ultracare	8/9/2024
Annual review	05/27/2025
Annual review and updates	3/17/2026

Approved: David Ackman Digitally signed by David Ackman Date: 2026.04.02 12:11:58 -04'00' **Date:**	**Approved:** Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2026.04.07 16:58:12 -04'00' **Date:**
David Ackman, MD **VP of Medical Directors**	**Sanjiv Shah, MD** **Chief Medical Officer**

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. 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 andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.