

Brexucabtagene autoleucel (Tecartus)

HCPCS: Q2053 Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR positive viable T cells

LOB:	MCAL
Duration of Approval:	One single dose per lifetime
Quantity Limit:	Per FDA-Approved/Compendia-Supported Dosing
MCG Available:	Yes
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

Tecartus (brexucabtagene autoleucel) injection

****All requests must be approved by a Medical Director******PA CRITERIA FOR APPROVAL:**

1. The member has a diagnosis for a Food and Drug Administration (FDA)-approved indication (refer to package insert under References) **OR** a National Comprehensive Cancer Network (NCCN)-supported indication **AND**
2. The medication is prescribed by an oncologist or hematologist **AND**
3. The member does not have any active infection (including tuberculous, HIV, hepatitis B virus [HBV] and hepatitis C virus [HCV]) or inflammatory disorders **AND**
4. **For diagnosis of mantle cell lymphoma (MCL), ALL** of the following are met **(a–b)**:
 - a. The request is for second-line or subsequent therapy
 - b. The member has relapsed or refractory disease from a Bruton's tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, zanubrutinib) **AND**
5. **For diagnosis of acute lymphoblastic leukemia (ALL), ALL** of the following are met **(a–b)**:
 - a. The member has **ONE** of the following:
 - 1) Primary refractory disease
 - 2) First relapse following a remission lasting ≤ 12 months
 - 3) Relapsed or refractory disease after second-line or higher therapy
 - 4) Relapsed or refractory disease at least 100 days after allogeneic stem cell transplantation (HSCT)
 - b. If member is Philadelphia chromosome positive (Ph+), they must have tried and failed previous therapy that included a tyrosine kinase inhibitor (TKI) (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib) **OR** have documented intolerance to TKI therapy (**Note:** bosutinib and nilotinib have NCCN-supported off-label use for acute lymphoblastic leukemia [ALL]) **AND**
6. The member has not been previously treated with Tecartus or any other chimeric antigen receptor T cell (CAR-T) therapy (such as Abecma, Aucatzyl, Breyanzi, Carvykti, Kymriah or Yescarta) **AND**
7. The medication will be provided by an authorized treatment center (such as City of Hope, Cedar Sinai, UCLA, UCSD) (**NOTE:** Other authorized treatment centers can be found here: www.tecartus.com/receiving-tecartus)

OTHER INFORMATION:

HCPCS	Description	Brand name
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Tecartus
**Refer to DHCS Physician-Administered Drugs (PADs) Special Billing for Tecartus for billing information and follow allowable number of units to approve. **		

REFERENCES:

1. Tecartus Prescribing Information. www.gilead.com/-/media/files/pdfs/medicines/oncology/tecartus/tecartus-pi.pdf. 04/2026.

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2. National Comprehensive Cancer Network (NCCN) B-Cell Lymphomas.
www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Version 4.2026. 05/2026.
3. National Comprehensive Cancer Network (NCCN) Acute Lymphoblastic Leukemia.
www.nccn.org/professionals/physician_gls/pdf/all.pdf. Version 1.2026. 04/2026.
4. Kite, A Gilead Company. Study of Brexucabtagene Autoleucel (KTE-X19) in Participants with Relapsed/Refractory Mantle Cell Lymphoma (Cohort 1 and Cohort 2) (ZUMA-2). clinicaltrials.gov/study/NCT02601313. NLM Identifier: NCT02601313.
5. Kite, A Gilead Company. A Study Evaluating the Safety and Efficacy of Brexucabtagene Autoleucel (KTE-X19) in Adult Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia (ZUMA-3).
clinicaltrials.gov/study/NCT02614066. NLM Identifier: NCT02614066.
6. DHCS Cell and Gene Therapy Overview. mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/821726E2-2EAB-4A86-AA42-4778E89A38FD/celgenover.pdf?access_token=6UyVkRRfByXTZEWIh8j8QaYyIPyP5ULO. 09/2025.

P&T APPROVAL HISTORY:

November 2020 P&T Drug Review