Brexucabtagene autoleucel (Tecartus™)	Place of Service **Outpatient Facility Administration** **Hospital Administration** HCPCS: **Q2053** per up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Condition listed in policy (*see criteria for details*)

- Acute lymphoblastic leukemia (B-cell precursor)
- Mantle cell lymphoma

AHFS therapeutic class: Antineoplastic agent - CAR-T cell immunotherapy

Mechanism of action: CD19-directed genetically modified autologous T cell immunotherapy

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for brexucabtagene autoleucel (Tecartus®) must be sent for clinical review and receive authorization for both brexucabtagene autoleucel and for hospital admission prior to drug administration or claim payment.

Acute lymphoblastic leukemia (B-cell precursor)

1. Diagnosis of B-cell precursor acute lymphoblastic leukemia, **AND**
2. Patient is ≥ 18 years old, **AND**
3. Being used as a single agent, **AND**
4. Either of the following:
    a. Patient has not achieved remission or has experienced loss of response after receiving at

least one prior treatment with chemotherapy or hematopoietic stem cell transplantation, or

b. For Philadelphia chromosome-positive (Ph+), treatment failure or intolerance to a tyrosine kinase inhibitor (TKI) drug

Covered Dose
1 x 10^6 CAR-positive viable T cells as a single IV infusion

Coverage Period
Once per lifetime

ICD-10:
C83.50-C83.59, C91.00, C91.02

Mantle cell lymphoma

1. Patient has received prior treatment with chemoimmunotherapy and a BTK inhibitor, **AND**
2. Patient is ≥ 18 years old, **AND**
3. Patient has not received prior treatment with CAR-T therapy, including Tecartus, **AND**
4. Being used as single-agent therapy

Covered Dose
2 x 10^6 CAR-positive viable T cells as a single IV infusion

Coverage Period
Once per lifetime

ICD-10:
C83.10-C83.19

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for brexucabtagene autoleucel (Tecartus®) must be sent for clinical review and receive authorization for both brexucabtagene autoleucel and for hospital admission prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

MCL: 2 × 10^6 CAR-positive viable T cells per kg of body weight [maximum of 2 × 10^8 CAR-positive viable T cells (for patients 100 kg and above)] in approximately 68 mL suspension in an infusion bag (single dose)

ALL: 1 x 10^6 CAR-positive viable T cells per kg of body weight [maximum of 1 x 10^8 CAR-positive viable T cells (for patients 100 kg and above)] in approximately 68 mL suspension in an infusion bag (single dose)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network Drugs & Biologics Compendium. Tecartus® (2023). Available by subscription at: https://www.nccn.org/
- Available by subscription at: http://www.nccn.org National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia (Version 1.2022). Available by subscription at: https://www.nccn.org/
- National Comprehensive Cancer Network. B-cell lymphomas (Version 5.2022). Available at http://www.nccn.org.
- Tecartus® (brexucabtagene autoleucel) [Prescribing information]. Santa Monica, CA: Kite Pharma, Inc.; 10/2021.

(7) Policy Update

Date of last revision: 4Q2023
Date of next review: 1Q2024
Changes from previous policy version:

- No clinical change to policy following revision.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee