

brexucabtagene autoleucel (Tecartus®)

Medical Benefit Drug Policy

Place of Service

Hospital Administration

Outpatient Facility Infusion Administration

Drug Details

USP Category: ANTINEOPLASTICS

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

HCPCS:

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

How Supplied:

MCL: 2×10^5 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: 1×10^6 CAR-positive viable T cells per kg of body weight [maximum of 1×10^8 CAR-positive viable T cells (for patients 100 kg and above)] in approximately 68 mL suspension in an infusion bag (single dose)

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

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

Special Instructions and pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

The following condition(s) require Prior Authorization/Preservice:

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

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Covered Doses:

1 x 10⁶ CAR-positive viable T cells as a single IV infusion

Coverage Period:

Once per lifetime

Mantle cell lymphoma

1. Patient has received prior treatment with chemoimmunotherapy and a BTK inhibitor, AND
2. Patient is \geq 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 Doses:

2 x 10⁶ CAR-positive viable T cells as a single IV infusion

Coverage Period:

Once per lifetime

References

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

Review History

Date of Last Annual Review: 1Q2024

Date of last revision: 04/03/2024

Changes from previous policy version:

- No clinical change to policy following routine annual review

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*