



## UTILIZATION MANAGEMENT MEDICAL POLICY

**POLICY:** Oncology (Injectable – CAR-T) – Tecartus Utilization Management Medical Policy

- Tecartus® (brexucabtagene autoleucel intravenous infusion – Kite Pharma)

**REVIEW DATE:** 08/21/2024

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### OVERVIEW

Tecartus, a CD19-directed genetically modified autologous T cell immunotherapy, is indicated for the treatment of adults with relapsed or refractory:<sup>1</sup>

- **B-cell precursor acute lymphoblastic leukemia.**
- **Mantle cell lymphoma.**

Tecartus is supplied in infusion bag(s) containing frozen suspension of genetically modified autologous T cells in human serum albumin.<sup>1</sup> Each bag is supplied in a metal cassette stored in the vapor phase of liquid nitrogen. Store Tecartus frozen in the vapor phase of liquid nitrogen and thaw prior to administration.

### Guidelines

Tecartus is addressed in National Comprehensive Cancer Network guidelines:

- **Acute lymphoblastic leukemia:** Guidelines (version 2.2024 – July 19, 2024) recommend Tecartus for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia.<sup>3,4</sup>
- **B-cell lymphomas:** Guidelines (version 2.2024 – April 30, 2024) recommend Tecartus for the second-line and subsequent treatment of relapsed or refractory mantle cell lymphoma, following treatment with Bruton tyrosine kinase inhibitor therapy.<sup>2,3</sup>

### Safety

Tecartus has a Boxed Warning regarding cytokine release syndrome, neurological toxicities, and T-cell malignancies.<sup>1</sup> Due to these risks, Tecartus is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Tecartus REMS.

### POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Tecartus. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Because of the specialized skills required for evaluation and diagnosis of patients treated with Tecartus as well as the monitoring required for adverse events and long-term efficacy, approval requires Tecartus to be prescribed by or in consultation with a physician who specializes in the condition being treated. The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tecartus is recommended in those who meet one of the following criteria:

## FDA-Approved Indications

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- 1. Acute Lymphoblastic Leukemia.** Approve a single dose if the patient meets ALL of the following (A, B, C, D, E, and F):
- A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has B-cell precursor disease; AND
  - C) Patient has relapsed or refractory disease; AND
  - D) Patient received or plans to receive lymphodepleting chemotherapy prior to Tecartus infusion; AND
  - E) Patient has not been previously treated with CAR-T therapy; AND
- Note: Examples of CAR-T therapy include Tecartus, Breyanzi (lisocabtagene maraleucel intravenous infusion), Kymriah (tisagenlecleucel intravenous infusion), Yescarta (axicabtagene intravenous infusion) and Abecma (idecabtagene vicleucel intravenous infusion).
- F) Tecartus is prescribed by or in consultation with an oncologist.

**Dosing.** Approve up to  $1 \times 10^8$  chimeric antigen receptor (CAR)-positive viable T-cells administered intravenously.

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- 2. Mantle Cell Lymphoma.** Approve a single dose if the patient meets ALL of the following (A, B, C, D, and E):
- A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has relapsed or refractory disease; AND
  - C) Patient received or plans to receive lymphodepleting chemotherapy prior to Tecartus infusion; AND
  - D) Patient has not been previously treated with CAR-T therapy; AND
- Note: Examples of CAR-T therapy include Tecartus, Breyanzi (lisocabtagene maraleucel intravenous infusion), Kymriah (tisagenlecleucel intravenous infusion), Yescarta (axicabtagene intravenous infusion) and Abecma (idecabtagene vicleucel intravenous infusion).
- E) Tecartus is prescribed by or in consultation with an oncologist.

**Dosing.** Approve up to  $2 \times 10^8$  chimeric antigen receptor (CAR)-positive viable T-cells administered intravenously.

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## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tecartus is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Tecartus® intravenous infusion [prescribing information]. Santa Monica, CA: Kite Pharma; June 2024.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2024 – April 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 13, 2024.
3. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 13, 2024. Search term: brexucabtagene.
4. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2024 – July 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 13, 2024.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/16/2023
Annual Revision	<b>Mantle Cell Lymphoma:</b> Requirement that the patient has received chemotherapy and a Bruton tyrosine kinase inhibitor was removed. Added requirement that the patient has relapsed or refractory disease.	08/21/2024