Utilization Review Policy 231A

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

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

EFFECTIVE DATE: 12/1/2020
LAST REVISION DATE: 08/20/2025

COVERAGE CRITERIA FOR: UCare Medical Assistance and Exchange Plans Only (PMAP, Connect, MSC+, MnCare, all Individual and Family Plans)

OVERVIEW

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

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

The mantle cell lymphoma indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Tecartus is supplied in infusion bag(s) containing frozen suspension of genetically modified autologous T cells in human serum albumin.[1] 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 2.2025 – June 27, 2025) recommend Tecartus for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia.[3,4]
- **B-cell lymphomas:** Guidelines (version 2.2025 – February 10, 2025) recommend Tecartus for the second-line and subsequent treatment of relapsed or refractory mantle cell lymphoma, following treatment with Bruton tyrosine kinase inhibitor therapy.[2,3]

Safety

Tecartus has a Boxed Warning regarding cytokine release syndrome, neurological toxicities, and T-cell malignancies.[1]

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 ≥ 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 x 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 ≥ 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 x 10^8 chimeric antigen receptor (CAR)-positive viable T-cells administered intravenously.

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 2025.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2025 – February 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 17, 2025.
3. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 17, 2025. Search term: brexucabtagene.
4. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2025 – June 27, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 17, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/16/2023
Annual Revision	**Mantle Cell Lymphoma:** 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
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Revision	No criteria changes.	08/20/2025
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/15/2025