**Utilization Review Policy 231B**

**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:** 09/05/2025

**COVERAGE CRITERIA FOR:** UCare Medicare Plans Only (UCare Medicare, EssentiaCare, Group Plans, MSHO, Connect + Medicare, UCare Your Choice)

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## SUMMARY OF EVIDENCE

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]

## ANALYSIS OF EVIDENCE

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

**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 indication(s). The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the Sources of Information section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Sources of Information section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

*Indications with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.*

*Indications with a @ below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.*

*Indications with a # below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.*

## RECOMMENDED AUTHORIZATION CRITERIA

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

**FDA-Approved Indications**

**1. Acute Lymphoblastic Leukemia.** ^

**Criteria.** Approve a single dose if the patient meets all of the following criteria (A, B, C, D, and E):
**A)** Patient is ≥ 18 years of age; [IC-COMP] AND
**B)** Patient has B-cell precursor disease; [IC-COMP] AND
**C)** Patient has relapsed or refractory disease; [IC-COMP] AND
**D)** Patient received or plans to receive lymphodepleting chemotherapy prior to Tecartus infusion; [IC-COMP] AND
**E)** Patient has not been previously treated with CAR-T therapy. [IC-COMP]
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).

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

**2. Mantle Cell Lymphoma.** ^

**Criteria.** Approve a single dose if the patient meets the following criteria (A, B, C and D):
**A)** Patient is ≥ 18 years of age; [IC-COMP] AND
**B)** Patient has relapsed or refractory disease; [IC-COMP] AND
**C)** Patient received or plans to receive lymphodepleting chemotherapy prior to Tecartus infusion; [IC-COMP] AND
**D)** Patient has not been previously treated with CAR-T therapy. [IC-COMP]
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).

**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.

## SOURCES OF INFORMATION

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.
5. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). Original effective date 8/7/2019. Implementation date 2/16/2021. Revision date: 07/2025. Accessed September 5, 2025.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| New Policy | -- | 9/9/2020 |
| Policy revision | **Mantle cell lymphoma:** Removed criterion that Patient has previously received anthracycline or bendamustine-based chemotherapy and an anti-CD20 monoclonal antibody. Added criterion for "Patient has previously received the following chemoimmunotherapy. Included Note with examples of chemoimmunotherapy. Added criterion for patient has not been previously treated with CAR-T therapy. Added Note listing the CAR-T therapies. | 04/14/2021 |
| Policy revision | **Acute Lymphoblastic Leukemia:** Added new condition of approval. | 01/05/2022 |
| Policy revision | **Acute Lymphoblastic Leukemia:** Added "or plan to receive" to the requirement that the patient receive lymphodepleting chemotherapy prior to Tecartus infusion.<br>**Mantle Cell Lymphoma:** Added "or plan to receive" to the requirement that the patient receive lymphodepleting chemotherapy prior to Tecartus infusion. | 01/14/2022 |
| Policy revision | Added: "The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy." to the Policy Statement. | 07/26/2023 |
| Policy 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. | 09/05/2024 |
| UCare P&T Review | Policy reviewed and approved by UCare P&T committee. Annual review process | 09/16/2024 |
| Policy review | No criteria changes.<br><br>Review based on NCD surveillance review. | 01/06/2025 |
| Policy revision | No criteria changes. Formatting and notation updates. | 03/11/2025 |
| Policy review | No criteria changes.<br><br>Review based on NCD surveillance review. | 06/03/2025 |
| Policy review | No criteria changes.<br><br>Review based on NCD surveillance review and commercial policy annual review. | 09/05/2025 |
| UCare P&T Review | Policy reviewed and approved by UCare P&T committee. Annual review process | 09/15/2025 |