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: 09/16/2024

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

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**.

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 2.2024 – July 19, 2024) recommend Tecartus for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia.[3,4]
- **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.[2,3]

Safety

Tecartus has a Boxed Warning regarding cytokine release syndrome, neurological toxicities, and T-cell malignancies.[1] 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 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 References 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 Reference 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 also covered (and, if applicable, further detailed/referenced) in the corresponding Commercial Utilization Management Policy. Note: Additional criteria requirements for coverage of the same indication as outlined in the Commercial Utilization Management Policy and this Medicare Advantage Utilization Management Policy may NOT be the same.

Indications noted with eviCore are managed by eviCore healthcare for those clients who use eviCore for oncology and/or oncology-related reviews. For these indications, a prior authorization should be initiated through eviCore at www.eviCore.com.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. Acute Lymphoblastic Leukemia. ^ *eviCore*

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; 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.
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.

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2. Mantle Cell Lymphoma. ^ *eviCore*

Criteria. Approve a single dose if the patient meets the following criteria (A, B, C and D):
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.
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.

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.
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. Accessed September 5, 2024.

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. **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