POLICY: Oncology – Tecartus™ (brexucabtagene autoleucel suspension for intravenous injection – Kite Pharma)

EFFECTIVE DATE: 1/1/2021
LAST REVISION DATE: 1/14/2022

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Tecartus, a CD19-directed genetically modified autologous T cell immunotherapy, is indicated for the treatment of adult patients with relapsed or refractory:

- **B-cell precursor acute lymphoblastic leukemia**.
- **Mantle cell lymphoma**. This indication was approved under accelerated approval based on the 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.[1]

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 have not addressed Tecartus for the treatment of acute lymphoblastic leukemia.
- **B-cell lymphomas:** Guidelines (version 4.2021 – May 5, 2021) recommend Tecartus for the third-line treatment of relapsed or refractory mantle cell lymphoma, following treatment with chemoimmunotherapy and Bruton tyrosine kinase inhibitor therapy.[2,3]

Safety

Tecartus has a Boxed Warning regarding cytokine release syndrome and neurological toxicities. 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).

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.

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 previously received the following (i and ii):
i. Chemoimmunotherapy; AND

Note: Examples of chemoimmunotherapy include bendamustine + rituximab, DHAP (dexamethasone, cisplatin, cytarabine) + rituximab, DHAX (dexamethasone, cytarabine, oxaliplatin) + rituximab.

ii. A Bruton tyrosine kinase inhibitor; AND
Note: Bruton tyrosine kinase inhibitors include Brukinsa™ (zanubrutinib capsules), Calquence® (acalabrutinib capsules), and Imbruvica® (ibrutinib capules and tablets).

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. The dose is up to 2 x 10^8 chimeric antigen receptor (CAR)-positive viable T-cells administered intravenously.[1]

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; October 2021.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2021 – May 5, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 4, 2021.
3. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 4, 2021. Search term: brexucabtagene.
4. 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 January 14, 2022.

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.	01/14/2022

	Mantle Cell Lymphoma: Added "or plan to receive" to the requirement that the patient receive lymphodepleting chemotherapy prior to Tecartus infusion.	