Effective Date 12/15/2024
Coverage Policy Number IP0199

Brexucabtagene autoleucel

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for brexucabtagene autoleucel (Tecartus®).

Medical Necessity Criteria

Brexucabtagene autoleucel (Tecartus) is considered medically necessary when ONE of the following is met:

1. **Acute Lymphoblastic Leukemia.** Individual meets **ALL** of the following criteria:
    A. Age 18 years or older
    B. Documentation of **BOTH** of the following:
        i. B-cell precursor disease
        ii. Relapsed or refractory disease
    C. Documentation of **BOTH** of the following:
        i. Received or plans to receive lymphodepleting chemotherapy prior to Tecartus infusion
        ii. Not been previously treated with CAR-T therapy

CAR-T therapy includes Tecartus, Breyanzi® (lisocabtagene maraleucel injection), Kymriah® (tisagenlecleucel injection), Yescarta® (axicabtagene injection) and Abecma® (idecabtagene vicleucel injection).

D. Tecartus is prescribed by, or in consultation with, an oncologist.

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

2. **Mantle Cell Lymphoma.** Individual meets **ALL** of the following criteria:
   A. Age 18 years or older
   B. Has relapsed or refractory disease
   C. Documentation the individual has of **BOTH** of the following:
      i. Received or plans to receive lymphodepleting chemotherapy prior to Tecartus infusion
      ii. Not been previously treated with CAR-T therapy

   Note: CAR-T therapy includes Tecartus, Breyanzi® (lisocabtagene maraleucel injection), Kymriah® (tisagenlecleucel injection), Yescarta® (axicabtagene injection) and Abecma® (idecabtagene vicleucel injection).

   D. Tecartus is prescribed by, or in consultation with, an oncologist.

   Dosing. Up to 2 x 10^8 chimeric antigen receptor (CAR)-positive viable T-cells administered intravenously.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Authorization Duration

Authorization is for a one-time approval.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description

0537T	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
0538T	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)
0539T	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
0540T	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous

HCPCS Codes	Description
C9073	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose (Code deleted 03/31/2021)
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Background

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.

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.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	**Acute Lymphoblastic Leukemia.** **Updated from** "Received lymphodepleting chemotherapy prior to Tecartus infusion **to** "Received or plans to receive lymphodepleting chemotherapy prior to Tecartus infusion" **Updated from** "Medication is prescribed by, or in consultation with, an oncologist or hematologist" **to** "Tecartus is prescribed by, or in consultation with, an oncologist." **Mantle Cell Lymphoma.** **Removed** "Documentation that individual previously received **BOTH** of the following: A. Chemoimmunotherapy, B. A bruton tyrosine kinase inhibitor" **Added** "has relapsed or refractory disease" **Updated from** "Received lymphodepleting chemotherapy prior to Tecartus infusion **to** "Received or plans to receive lymphodepleting chemotherapy prior to Tecartus infusion" **Updated from** "Medication is prescribed by, or in consultation with, an oncologist or hematologist" **to** "Tecartus is prescribed by, or in consultation, with an oncologist."	12/15/2024

The policy effective date is in force until updated or retired.

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