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Coverage Policy Number IP0199

Brexucabtagene autoleucl

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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 autoleucl (Tecartus®).

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

Medical Necessity Criteria

Brexucabtagene autoleucl (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 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. Medication is prescribed by, or in consultation with, an oncologist or hematologist

Dosing. Up to 1×10^8 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. Documentation that individual previously received **BOTH** of the following:
 - i. Chemoimmunotherapy
 - ii. A bruton tyrosine kinase inhibitor
- C. Documentation of **BOTH** of the following:
 - i. Received 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. Medication is prescribed by, or in consultation with, an oncologist or hematologist

Dosing. Up to 2×10^8 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.

Authorization Duration

Authorization is for a one-time approval.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

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
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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 2.2023 – July 28, 2023) recommend Tecartus for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia.^{3,4}
- **B-cell lymphomas:** Guidelines (version 5.2023 – July 7, 2023) 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.

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 5.2023 – July 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 11, 2023.
3. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 11, 2023. Search term: brexucabtagene.

4. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2023 – July 28, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 11, 2023.

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