BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.21.155

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	August 27, 2020
Subject:	Tecartus	**Page:**	1 of 6

Last Review Date: March 8, 2024

Tecartus

Description

Tecartus (brexucabtagene autoleucel)

Background
Tecartus (brexucabtagene autoleucel) is a genetically modified autologous T cell immunotherapy indicated for the treatment of relapsed or refractory mantle cell lymphoma (MCL) and relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). The patient's own T-cells are collected and sent to a manufacturing center where they are genetically modified to include a new gene that contains a specific protein (a chimeric antigen receptor or CAR) that directs the T-cells to target and kill cancer cells that have a specific antigen (CD19) on the surface. Once the cells are modified, they are infused back into the patient to kill the cancer cells (1).

Regulatory Status
FDA-approved indications: Tecartus is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of: (1)

- Adult patients with relapsed or refractory mantle cell lymphoma (MCL)
- Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

Tecartus has a boxed warning for cytokine release syndrome (CRS) and neurological toxicities. Patients with an active infection or inflammatory disorders should not receive Tecartus and monitoring for neurological events should be done after treatment of Tecartus (1).

Tecartus is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Healthcare facilities that dispense and administer Tecartus must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available for each patient for administration within 2 hours after Tecartus infusion, if needed for treatment of CRS (1).

Serious infections, including life-threatening or fatal infections, occurred in patients after Tecartus infusion. Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, and hepatic failure, can occur in patients treated with drugs directed against B cells. Perform screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing (1).

CD19-directed CAR-T cell therapy is supported by the National Comprehensive Cancer Network (NCCN) Guidelines for the treatment of B-cell lymphomas only after two or more chemoimmunotherapy regimens and if not previously given (2).

The safety and effectiveness of Tecartus have not been established in pediatric patients (1).

Related policies
Breyanzi, Kymriah, Yescarta

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tecartus may be considered **medically necessary** if the conditions indicated below are met.

Tecartus may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Relapsed or refractory mantle cell lymphoma (MCL)

a. Patient must have previously received **ALL** of the following therapies:
    i. Anthracycline **OR** bendamustine-containing chemotherapy
    ii. Anti-CD20 monoclonal antibody
    iii. Bruton tyrosine kinase inhibitor
b. Patient experienced disease progression after their last regimen **OR** refractory disease to their most recent therapy
c. Patient has adequate organ and bone marrow function as determined by the prescriber
d. **NO** history of primary central nervous system lymphoma or CNS disorders (such as seizures or cerebrovascular ischemia)
e. **NO** detectable cerebrospinal fluid malignant cells or brain metastases

2. B-cell precursor acute lymphoblastic leukemia (ALL)
    a. Patient has **ONE** of the following:
        i. Primary refractory ALL, first relapse following a remission lasting ≤ 12 months
        ii. Relapsed or refractory ALL after second-line or higher therapy
        iii. Relapsed or refractory ALL at least 100 days after allogeneic stem cell transplantation (HSCT)
    b. Documentation of CD19 tumor expression in bone marrow or peripheral blood
    c. **Philadelphia chromosome-positive (Ph+) ALL only**: patient must have received 2 lines of tyrosine kinase inhibitor (TKI) therapy
    d. Lymphoblasts ≥ 5%
    e. Patient has adequate organ function with no significant deterioration in organ function expected within 4 weeks after apheresis

AND NONE of the following:

a. Burkitt lymphoma
b. Active graft-versus-host disease
c. Concomitant genetic syndrome associated with bone marrow failure with the exception of Down syndrome
d. Received immunosuppressive medications within 4 weeks prior to treatment with Tecartus
e. Active central nervous system acute lymphoblastic leukemia (ALL) (i.e., white blood cell count ≥5 cells/μL in cerebrospinal fluid with presence of lymphoblasts)

f. Received allogeneic cellular therapy, such as donor lymphocyte infusion, within six weeks prior to Tecartus infusion
g. History of any CNS disorders, including CNS-2 disease with neurologic changes and CNS-3 disease irrespective of neurological changes

AND ALL of the following for **ALL** diagnoses:

a. **NO** active infections (including TB, HBV, HCV, and HIV)
b. Patient is not at risk for HBV infection **OR** patient is at risk for HBV infection and HBV infection has been ruled out or treatment for HBV infection has been initiated
c. Prescriber agrees to monitor the patient for signs and symptoms of cytokine release syndrome (CRS) and administer tocilizumab if needed
d. Prescriber agrees to monitor the patient for signs and symptoms of neurological toxicities
e. Prescriber agrees to monitor for Hemophagocytic Lymphohistiocytosis/Macrophage activation Syndrome and treat per institutional standards
f. Administered in a healthcare facility enrolled in the Tecartus REMS Program
g. **NO** prior therapy with any other gene therapy (e.g., Abecma, Breyanzi, Carvykti, Kymriah, Yescarta)
h. **NO** dual therapy with any other gene therapy (e.g., Abecma, Breyanzi, Carvykti, Kymriah, Yescarta)

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Quantity One infusion (only one PA approval for one infusion per lifetime)

Rationale

Summary
Tecartus is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) and relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). Tecartus may cause cytokine release syndrome (CRS) and neurological toxicities. Tecartus should not be administered in patients with an active infection, central nervous system lymphoma or CNS disorders. Safety and efficacy have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Tecartus while maintaining optimal therapeutic outcomes.

Reference
1. Tecartus [package insert]. Santa Monica, CA: Kite Pharma, Inc.; December 2023.
2. NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas (Version 1.2024). National Comprehensive Cancer Network, Inc. January 2024. Accessed on January 19, 2024.
3. NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 3.2023). National Comprehensive Cancer Network, Inc. October 2023. Accessed on January 19, 2024.

Policy History

Date	Action
August 2020	Addition to PA
September 2020	Annual review
December 2020	Annual editorial review
March 2021	Added the requirement: No prior therapy with another CD19-directed CAR-T cell therapy, and No dual therapy with another CD19-directed CAR-T cell therapy per NCCN Guidelines. Revised PA quantity limit from 1 infusion per lifetime to 1 infusion, 3 months duration. Added clarifying statement indicating that only 1 infusion/one PA approval allowed per member's lifetime
April 2021	Revised no prior therapy and no dual therapy statements to include any other gene therapy
June 2021	Annual review and reference update
October 2021	Addition of indication: Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). Added requirement "Prescriber agrees to

	monitor for Hemophagocytic Lymphohistiocytosis/Macrophage activation Syndrome and treat per institutional standards”
December 2021	Annual review and reference update
March 2022	Per FEP: Added requirement for MCL to include "patient has adequate organ and bone marrow function as determined by the prescriber”. Removed MCL requirement of **NO** prior allogenic hematopoietic stem cell transplant (HSCT). Added ALL requirement "patient has adequate organ function with no significant deterioration in organ function expected within 4 weeks after apheresis" and added/revised "NONE of the following: Burkitt lymphoma; Concomitant genetic syndrome associated with bone marrow failure with the exception of Down syndrome; Active central nervous system ALL; Received allogeneic cellular therapy, such as donor lymphocyte infusion, within six weeks prior to Tecartus infusion"
June 2022	Annual review and reference update. Addition of Carvykti to gene therapy requirement
October 2022	Per FEP, removed duration from PA
December 2022	Annual review
March 2023	Annual review and reference update
June 2023	Annual review and reference update
March 2024	Annual editorial review and reference update.Per BCBSA policy alignment: added requirement to t/f 2 TKIs for Ph+ patients

Keywords

This policy approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.