



Tecartus (brexucabtagene autoleucel) PAM – 028

Iowa Medicaid Program	Prior Authorization	Effective Date	04/01/2021
Revision Number	5	Last Reviewed	01/17/2025
Reviewed By	Medicaid Medical Director	Next Review	01/16/2026
Approved By	Medicaid Clinical Advisory Committee	Approved Date	01/15/2021

Overview

Medication: ¹	brexucabtagene autoleucel
Brand Name:	Tecartus®
Pharmacologic Category:	Antineoplastic Agent; Genetically modified autologous T cell immunotherapy (CAR-T Immunotherapy), CD19-directed
FDA-Approved Indication(s):	Indicated for adults with: <ul style="list-style-type: none">• Relapsed or refractory mantle cell lymphoma (MCL)<ul style="list-style-type: none">➢ This indication is approved under accelerated approval based on 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.• Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)
How Supplied:	Supplied in an infusion bag containing approximately 68 mL of frozen suspension of genetically modified autologous T cells in 5% DMSO and human serum albumin.
Dosage and Administration:	For autologous use only. For intravenous use only. <ul style="list-style-type: none">• MCL: The target dose is 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.• ALL: The target dose is 1×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 1×10^8 CAR-positive viable T cells.
Benefit Category:	Medical

BOXED WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITIES

- Cytokine Release Syndrome (CRS), including life-threatening reactions, occurred in patients receiving Tecartus®. Do not administer Tecartus® to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.
- Neurologic toxicities, including life-threatening reactions, occurred in patients receiving Tecartus®, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with Tecartus®. Provide supportive care and/or corticosteroids, as needed.

BOXED WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITIES

- T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies.
- Tecartus® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program.

Descriptive Narrative

Acute lymphoblastic leukemia (ALL) is a heterogeneous group of lymphoid disorders resulting from the clonal proliferation of immature lymphocytes of B- or T-cell lineage in the blood, bone marrow, and other organs. The estimated annual incidence of ALL worldwide is 1 to 5 cases per 100,000 population, and more than two-thirds of ALL are B-cell phenotype. B-ALL/LBL is primarily a disease of children, with three-quarters of cases occurring in children less than 6 years old; there is a second peak of incidence in adults greater than 60 years of age.²

Mantle cell lymphoma (MCL) is a mature B-cell non-Hodgkin lymphoma with a variable clinical course. MCL can involve lymph nodes and extranodal sites, such as the gastrointestinal tract or blood and bone marrow. The median age at diagnosis is 68 years. In members with MCL, B-cells, a type of white blood cell that helps the body fight to infection, transform into malignant cells. These cells form tumors in the mantle zone of the lymph nodes and quickly spread to other areas of the body.

Approximately three-quarters of patients with MCL are male, and White individuals are affected almost twice as frequently as Black individuals. MCL comprises about 3 to 7 percent of non-Hodgkin lymphomas in the United States and Europe, with an incidence of approximately 4 to 8 cases per million persons per year. Incidence increases with age and appears to be increasing overall in the United States.³

Guidelines

The National Comprehensive Cancer Network (NCCN) publishes guidelines for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines® are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. The guidelines are developed and updated by 61 individual panels, comprising over 1,700 clinicians and oncology researchers from the 33 NCCN Member Institutions.

Guidelines are reviewed and updated on a continual basis to ensure that the recommendations take into account the most current evidence. To view the most recent and complete version of the guidelines, go online to [NCCN.org](https://www.nccn.org). NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.^{4,5}

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):⁶

- Acute Lymphoblastic Leukemia (v.2.2024 – July 19, 2024)
- B-Cell Lymphomas (v.3.2024 – August 26, 2024)

NCCN Guidelines® Recommendation(s) for Acute Lymphoblastic Leukemia	
<p>(1) Relapsed or refractory Ph-positive B-ALL^{a, b}</p> <p style="margin-left: 20px;">a. Other Recommended Regimens</p> <p style="margin-left: 40px;">i. Brexucabtagene autoleucel (following therapy that has included tyrosine kinase inhibitors [TKIs]): Category 2A</p> <p>(2) Relapsed or refractory Ph-negative B-ALL^{a, c, d, e}</p> <p style="margin-left: 20px;">a. Preferred Regimens</p> <p style="margin-left: 40px;">i. Brexucabtagene autoleucel (CD19 antigen directed): Category 2A</p> <p>^a All regimens include CNS prophylaxis with systemic therapy (e.g., methotrexate, cytarabine) and/or IT therapy (e.g., IT methotrexate, IT cytarabine; triple IT therapy with methotrexate, cytarabine, corticosteroid).</p> <p>^b The safety of relapsed/refractory regimens in adults ≥65 years or adults with substantial comorbidities has not been established.</p> <p>^c For patients in late relapse (>3 years from initial diagnosis), consider treatment with the same induction regimen.</p> <p>^d For patients who develop hypersensitivity to E. coli-derived asparaginase, ERW-rywn should be substituted as a component of the multi-agent therapeutic regimen to complete the full treatment course.</p> <p>^e PEG is substituted with Cal-PEG, an asparagine-specific enzyme, in patients aged 15 to ≤21 years for more sustained asparaginase activity. Silverman LB, et al. Blood 2016;128:175; Angiolillo AL, et al. J Clin Oncol 2014;32:3874-3882.</p>	

NCCN Guidelines® Recommendation(s) for Mantle Cell Lymphoma (MCL)	
<p>(1) Mantle Cell Lymphoma</p> <p style="margin-left: 20px;">a. Second-Line and Subsequent Therapy</p> <p style="margin-left: 40px;">i. Brexucabtagene autoleucel (CD19 antigen directed): Category 2A, Useful in Certain Circumstances</p>	

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale ⁷

Developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group, and published in 1982, the ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). It is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient, and to determine appropriate treatment and prognosis.

Grade	ECOG Performance Status	[Synonyms: WHO/Zubrod score]
0	Fully active, able to carry on all pre-disease performance without restriction.	
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours.	
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.	
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair.	
5	Dead.	

Criteria

Tocilizumab (Actemra®) may be required to manage cytokine release syndrome or neurologic toxicities. If tocilizumab therapy is required, may be approved for up to 4 doses of 800 mg each. HCPCS code J3262 suspends for claims review.

Prior authorization is required.

Acute Lymphoblastic Leukemia

Tecartus® is considered medically necessary when **ALL** of the following are met:

1. Request meets **ONE** of the following:
 - a. Diagnosis of relapsed or refractory B-precursor acute lymphoblastic leukemia (ALL) as defined by **ONE** of the following:
 - i. Primary refractory disease; or
 - ii. First relapse following a remission lasting 12 months or less; or

- iii. Relapsed or refractory disease after 2 or more lines of systemic therapy; or
- iv. Relapsed or refractory disease after allogeneic transplant (provided that member is at least 100 days from stem cell transplant and has been off of immunosuppressive medications for at least 4 weeks); **OR**
- b. Disease is Philadelphia chromosome positive (Ph+) ALL, and there is documentation of failure or inadequate response to at least 2 tyrosine kinase inhibitors (TKIs) (e.g., imatinib, Sprycel®, Tasigna®, Bosulif®, Iclusig®); **AND**
- 2. Member has morphological disease in the bone marrow (> 5% blasts); **AND**
- 3. If previously treated with blinatumomab (Blinicyto®), member has CD19 tumor expression in bone marrow or peripheral blood; **AND**
- 4. Member is 18 years of age or older; **AND**
- 5. Member has adequate bone marrow reserve, and adequate renal, hepatic, pulmonary, and cardiac function (*definitions following criteria*); **AND**
- 6. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
- 7. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
- 8. Member does not have **ANY** of the following:
 - a. Presence of central nervous system-3 (CNS-3) or CNS-2 disease (*definitions following criteria*), or history or presence of any CNS disorder such as a seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease with CNS involvement; and/or
 - b. History of concomitant genetic syndrome associated with bone marrow failure; and/or
 - c. History of human immunodeficiency virus (HIV) infection or acute or chronic active hepatitis B or C infection, or presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring intravenous (IV) antimicrobials for management; and/or
 - d. Acute graft vs. host disease (GVHD) or receiving immunosuppressive therapy; **AND**
- 9. Member has not previously received treatment with chimeric antigen receptor (CAR) T-cell immunotherapy or other genetically modified T-cell therapy (e.g., Abecma®, Breyanzi®, Carvykti®, Kymriah®, or Yescarta®), nor will any CAR T-cell immunotherapy or other genetically modified T-cell therapy be prescribed concurrently with Tecartus®; **AND**
- 10. Member is receiving as a one-time, single administration treatment; **AND**
- 11. Treatment will be administered at a facility certified under the Yescarta and Tecartus Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
- 12. Dose does not exceed 1×10^8 CAR-positive viable T cells.

Any requests for continued therapy will not be authorized, as Tecartus® is indicated to be dosed one time only.

Mantle Cell Lymphoma

Tecartus® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of relapsed or refractory mantle cell lymphoma (MCL); **AND**
2. Member has at least one measurable lesion; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has had up to 5 previous treatments for MCL, including **ALL** of the following:
 - a. Anthracycline (e.g., doxorubicin) or bendamustine-containing chemotherapy; **AND**
 - b. Anti-CD20 monoclonal antibody therapy (e.g., rituximab); **AND**
 - c. Bruton tyrosine kinase (BTK) inhibitor (e.g., Imbruvica®, Calquence®, Brukinsa®); **AND**
5. Member has adequate bone marrow reserve (*definitions below*); **AND**
6. Member has adequate renal, hepatic, pulmonary, and cardiac function (*definitions following criteria*); **AND**
7. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
8. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
9. Member does not have **ANY** of the following:
 - a. History of allogeneic stem cell transplantation; and/or
 - b. Autologous stem cell transplant within 6 weeks of planned Tecartus® infusion; and/or
 - c. History of human immunodeficiency virus (HIV) infection or acute or chronic active hepatitis B or C infection; and/or
 - d. Presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring intravenous (IV) antimicrobials for management; and/or
 - e. Autoimmune disease requiring immunosuppressive therapy; and/or
 - f. History of a seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or cerebral edema; **AND**
10. Member has not previously received treatment with chimeric antigen receptor (CAR) T-cell immunotherapy or other genetically modified T-cell therapy (e.g., Abecma®, Breyanzi®, Carvykti®, Kymriah®, or Yescarta®), nor will any CAR T-cell immunotherapy or other genetically modified T-cell therapy be prescribed concurrently with Tecartus®; **AND**
11. Member is receiving Tecartus® as a one-time, single administration treatment; **AND**
12. Treatment will be administered at a facility certified under the Yescarta and Tecartus Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
13. Dose does not exceed 2×10^8 CAR-positive viable T cells.

Any requests for continued therapy will not be authorized, as Tecartus® is indicated to be dosed one time only.

Definitions

Definitions of what constitutes adequate (when referring to measures like renal function, bone marrow reserve, etc.) are defined within the individual clinical trials. For the indications and criteria above, the following definitions apply.

	Acute Lymphoblastic Leukemia ClinicalTrials.gov identifier NCT02614066 ⁸	Mantle Cell Lymphoma ClinicalTrials.gov identifier NCT02601313 ⁹
Adequate bone marrow reserve	Must meet all: 1. Platelet count > 50,000/ μ L 2. Absolute neutrophil count \geq 500/ μ L 3. Absolute lymphocyte count \geq 100/ μ L	Must meet all: 1. Platelet count \geq 75,000/uL 2. Absolute neutrophil count \geq 1,000/uL 3. Absolute lymphocyte count \geq 100/uL
Adequate renal, hepatic, cardiac, and pulmonary function	Must meet all: 1. Creatinine clearance (as estimated by Cockcroft Gault) \geq 60 cc/min 2. Serum ALT/AST \leq 2.5 x upper limit of normal 3. Total bilirubin \leq 1.5 mg/dL (except in members with Gilbert's syndrome) 4. Left ventricular ejection fraction \geq 50%, no evidence of pericardial effusion as determined by an echocardiogram (ECHO), no NYHA class III or class IV functional classification, and no clinically significant arrhythmias 5. No clinically significant pleural effusion, & a baseline oxygen saturation > 92% room air	Must meet all: 1. Creatinine clearance (as estimated by Cockcroft Gault) \geq 60 cc/min; 2. Serum ALT/AST \leq 2.5 x upper limit of normal (ULN); 3. Total bilirubin \leq 1.5 mg/dL (except in members with Gilbert's syndrome); 4. Cardiac ejection fraction \geq 50%, no evidence of pericardial effusion as determined by an echocardiogram (ECHO), and no clinically significant electrocardiogram (ECG) findings; 5. No clinically significant pleural effusion, and a baseline oxygen saturation > 92% on room air.
CNS-3 disease	Detectable cerebrospinal blast cells in a sample of CSF with \geq 5 WBCs per mm^3 , <i>with or without</i> neurological changes	n/a
CNS-2 disease	Detectable cerebrospinal blast cells in a sample of CSF with <5 WBCs per mm^3 <i>with</i> neurological changes	n/a

Approval Duration and Quantity Limits

	Initial Authorization		Subsequent Authorization
	Mantle cell lymphoma	Acute lymphocytic leukemia	
Approval Duration	One course of treatment per lifetime	One course of treatment per lifetime	Not applicable
Quantity Limits	Maximum 2×10^8 CAR-positive T cells per kilogram (kg) body weight	Maximum 1×10^8 CAR-positive T cells per kilogram (kg) body weight	

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J3262	Injection, tocilizumab, 1 mg [Actemra] <i>(if required to manage cytokine release syndrome or neurologic toxicities)</i>
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

ICD-10	Description
C83.10 – C83.19	Mantle cell lymphoma (relapsed or refractory)
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse

NDC	Labeler	Dosage	Pkg Size	Pkg Qty	Units /Pkg
71287-0219-01	Kite Pharma, Inc. (71287)	MCL: per treatment dose	1	EA	1
71287-0220-01	Kite Pharma, Inc. (71287)	ALL: per treatment dose	1	EA	1

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

¹ Tecartus® prescribing information (06/2024). Kite Pharma, Inc.: Santa Monica, CA. Available online: www.tecartushcp.com. Accessed November 4, 2024.

² Terwilliger T, Abdul-Hay M. Acute Lymphoblastic Leukemia: A Comprehensive Review and 2017 Update. *Blood Cancer J* 2017;7 (6):e577.

³ Freedman AS, Aster JC. Mantle cell lymphoma: Epidemiology, pathobiology, clinical manifestations, diagnosis, and prognosis. Rosmarin AG, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed December 20, 2024.

⁴ National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

⁵ National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

⁶ NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

- Acute Lymphoblastic Leukemia (v.2.2024 – July 19, 2024)
- B-Cell Lymphomas (v.3.2024 – August 26, 2024)

⁷ Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. *Am J Clin Oncol*. 1982;5:649-655. PMID 7165009.

⁸ A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-X19 (brexucabtagene autoleucel) in Adult Subjects With Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia (r/r ALL) (ZUMA-3). ClinicalTrials.gov identifier: NCT02614066. Updated September 28, 2022. clinicaltrials.gov/ct2/show/NCT02614066. Accessed December 20, 2022.

⁹ A Phase 2 Multicenter Study to Evaluate the Efficacy of KTE-X19 (brexucabtagene autoleucel) in Participants With Relapsed/Refractory Mantle Cell Lymphoma (ZUMA-2). ClinicalTrials.gov identifier: NCT02601313. Updated May 24, 2022. clinicaltrials.gov/ct2/show/NCT02601313. Accessed December 20, 2022.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
01/17/2025	CAC	Annual review. Updated boxed warning to include information regarding T cell malignancies. Updated NCCN Guidelines. Added J3262 [tocilizumab] to Coding and Product Information (may be used to treat cytokine release syndrome or neurologic toxicities.	5

Signature
William (Bill) Jagiello, DO




Change Date	Changed By	Description of Change	Version
01/19/2024	CAC	Annual review. Updated references.	4

Signature
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Change Date	Changed By	Description of Change	Version
01/20/2023	CAC	<ul style="list-style-type: none"> • ACL: Added criteria in diagnosis for Ph+ disease: documentation of failure/inadequate response to ≥ 2 tyrosine kinase inhibitors. • MCL: Added criteria, member has not had an autologous stem cell transplant within 6 weeks of planned Tecartus[®] infusion. • ALL and MCL: Added definitions for “adequate bone marrow reserve, renal, hepatic, pulmonary, and cardiac function.” Added Carvykti[®] to list of other CAR T therapies. 	3

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Change Date	Changed By	Description of Change	Version
01/21/2022	CAC	Revised criteria. Formatting changes.	2

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Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC	Criteria implementation.	1

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CAC = Medicaid Clinical Advisory Committee