

Medical Policy:

Tecartus (brexucabtagene autoleucl)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.318	January 2, 2024	January 1, 2021

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Brexucabtagene autoleucl is a chimeric antigen receptor (CAR) T-cell gene therapy. It is CD19-directed immunotherapy that works by using a patient's own genetically altered immune cells to kill B-cell cancer cells in the blood.

Brexucabtagene autoleucl is indicated for use in adult patients with mantle cell lymphoma who have not responded to or who have relapsed following other therapy.

Length of Authorization

Coverage will be provided for 90 days (1 dose)

Dosing Limits [Medical Benefit]

Max dose (per dose and over time):

Mantel cell lymphoma: 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

Acute Lymphoblastic Leukemia: 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.

Guideline

1. Relapsed or refractory mantle cell lymphoma (MCL) †

- A. Tecartus is prescribed by or in consultation with an oncologist; **AND**
- B. Patient is 18 years of age and older; **AND**
- C. Patient has disease that has relapsed or refractory to all other treatment options; **AND**
- D. 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 capsules and tablets).
- E. Patient did not receive prior allogeneic hematopoietic stem cell transplantation (HSCT); or CAR-T Therapy
*Note: Examples of CAR-T therapy include Tecartus, Breyanzi (lisocabtagene maraleucl intravenous infusion), Kymriah (tisagenlecleucl intravenous infusion), Yescarta (axicabtagene intravenous infusion) and Abecma (idecabtagene vicleucl intravenous infusion). **AND***
- F. Patient has an ECOG performance status of 0-1; **AND**
- G. Patient has CD19-positive disease; **AND**
- H. Patient must not be currently pregnant and sexually-active females of reproductive potential should have pregnancy status verified through a pregnancy test; **AND**
- I. Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
- J. Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during Tecartus treatment, and will not receive live vaccines until immune recovery following treatment; **AND**
- K. Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- L. Prophylaxis for infection has been followed according to local guidelines; **AND**
- M. Patient will be using Tecartus in conjunction with lymphodepleting chemotherapy cyclophosphamide 500 mg/m² intravenously and fludarabine 30 mg/m² intravenously on each of the fifth, fourth, and third days before infusion of Tecartus; **AND**
- N. Healthcare facility has enrolled in the Tecartus REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
- O. Patient will be using Tecartus at a treatment center that is certified to administer Tecartus; **AND**
- P. Patient will be monitored for signs and symptoms of Cytokine Release Syndrome (CRS) for at least 7 days after treatment with Tecartus and will be counselled to seek immediate medical attention should signs and symptoms of CRS or a neurological event occur at any time; **AND**
- Q. Patient will stay within proximity of the Tecartus infusion center for at least 4 weeks following infusion.

2. Acute Lymphoblastic Leukemia †

- 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 plan to receive lymphodepleting chemotherapy prior to Tecartus infusion; **AND**
- E. Patient has not been previously treated with CAR-T therapy; **AND**

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).

F. Tecartus is prescribed by or in consultation with an oncologist.

† FDA Approved Indication(s)

Applicable Procedure Codes

Code	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
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose; 1 billable unit = 200 million autologous anti-cd19 car positive viable t cells

Applicable NDCs

Code	Description
71287-0219-xx	Tecartus™ (brexucabtagene autoleucel) 68ml intravenous solution
71287-0220-xx	Tecartus suspension for intravenous infusion; 1 infusion bag (~68 mL)

ICD-10 Diagnoses

Code	Description
C83.10	Mantle cell lymphoma
C83.11	Mantle cell lymphoma, lymph nodes of head, face, and neck
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites
C83.50	Lymphoblastic (diffuse) lymphoma, unspecified site
C83.51	Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck
C83.52	Lymphoblastic (diffuse) lymphoma, intrathoracic lymph nodes
C83.53	Lymphoblastic (diffuse) lymphoma, intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma, lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma, lymph nodes of inguinal region and lower limb
C83.56	Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes
C83.57	Lymphoblastic (diffuse) lymphoma, spleen
C83.58	Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites
C83.59	Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: Updated NDC's
EmblemHealth & ConnectiCare	5/10/2023	<p>Corrected typographical error: Dosage Limit: Mantel Cell Lymphoma: Removed "Up to 2 × 10⁸ CAR-positive viable T cells per kg body weight, with a maximum of 2 × 10⁸ CAR-positive viable T cells"</p> <p>Added "The target dose is 2 × 10⁶ CAR-positive viable T cells per kg body weight, with a maximum of 2 × 10⁸ CAR-positive viable T cells"</p> <p>Dosage for Acute Lymphoblastic Leukemia: Removed "up to 1 × 10⁸ chimeric antigen receptor (CAR)-positive viable T-cells administered intravenously" added ": The target dose is 1 × 10⁶ CAR-positive viable T cells per kg body weight, with a maximum of 1 × 10⁸ CAR-positive viable T cells." For clarity</p>
EmblemHealth & ConnectiCare	4/21/2023	<p>Annual Review:</p> <p>Added Acute Lymphoblastic Leukemia indication and criteria and dosing MCL- Added: B) Patient has previously received the following (i and ii):</p> <p>i. Chemoimmunotherapy; AND</p> <p>Note: Examples of chemoimmunotherapy include bendamustine + rituximab, DHAP (dexamethasone, cisplatin, cytarabine) + rituximab, DHAX (dexamethasone, cytarabine, oxaliplatin) + rituximab.</p> <p>ii. A Bruton tyrosine kinase inhibitor; AND</p> <p>Note: Bruton tyrosine kinase inhibitors include Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib capsules), and Imbruvica (ibrutinib capsules and tablets).</p> <p>MCL-Added: or prior Car-T therapy</p> <p>Added code Q2053, C83.50-C91.02</p>
EmblemHealth & ConnectiCare	1/13/2023	Transfer to New Template
EmblemHealth & ConnectiCare	11/19/2021	Updated Length of Authorization from 14 days to 90 days
EmblemHealth & ConnectiCare	1/1/2021	Updated C-code C9073
EmblemHealth & ConnectiCare	9/2/2020	New Policy

References

1. TECARTUS™ (brexucabtagene autoleucel). Prescribing information. Kite Pharma, Inc; 2020