Medical Policy:

Tecartus (brexucabtagene autoleucel)

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

Definitions

Brexucabtagene autoleucel 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 autoleucel 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 maraleucel intravenous infusion), Kymriah (tisagenlecleucel intravenous infusion), Yescarta (axicabtagene intravenous infusion) and Abecma (idecabtagene vicleucel 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	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" 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" Dosage for Acute Lymphoblastic Leukemia: Removed "up to 1 x 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
EmblemHealth & ConnectiCare	4/21/2023	Annual Review: Added Acute Lymphoblastic Leukemia indication and criteria and dosing MCL- Added: B) 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). MCL-Added: or prior Car-T therapy Added code Q2053, C83.50-C91.02
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