Medical Policy:

Tecartus (brexucabtagene autoleucel)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.318	March 6, 2025	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 one treatment course (1 dose of Tecartus) and may not be renewed.

Dosing Limits [Medical Benefit]

Quantity Limit (max daily dose) [NDC Unit]:

- 1 infusion bag of up to 200 million autologous anti-CD19 CAR-positive viable T cells

Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit (1 infusion of up to 200 million autologous anti-CD19 CAR-positive viable T cells)

Guideline

I. Initial Approval Criteria

****For Medicare members: Tecartus- please refer to our separate LCD/NCD Medicare criteria**

1. Patient is at least 18 years of age, unless otherwise specified; **AND**
2. Healthcare facility must be enrolled in and comply with the requirements of the YESCARTA & TECARTUS REMS Program; **AND**
3. Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
4. Prophylaxis for infection will be followed according to local guidelines; **AND**
5. Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during brexucabtagene autoleucel treatment and until immune recovery following treatment; **AND**
6. 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**
7. Prophylaxis for infection will be followed according to local guidelines; AND
8. Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during brexucabtagene autoleucel treatment and until immune recovery following treatment; **AND**
9. 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**

A. **Mantle Cell Lymphoma †**

i. Patient has relapsed or refractory disease; **AND**

ii. Used as subsequent therapy after prior covalent Bruton Tyrosine Kinase Inhibitor (BTKi) therapy; **AND**

a. Patient had no response or progressive disease following second-line therapy with covalent BTKi or other continuous treatment regimens (i.e., lenalidomide and rituximab); **OR**

b. Patient had partial response, no response, or progressive disease following second-line therapy with fixed-duration regimens; **OR**

c. Patient has relapsed or progressive disease that is in second or greater relapse

B. **B-Cell Precursor Acute Lymphoblastic Leukemia (ALL) †**

i. Patient has relapsed or refractory disease; **AND**

ii. Patient has not received other anti-CD19 therapy, (e.g., blinatumomab, tafasitamab, loncastuximab tesirine, etc.) OR patient previously received other anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**

a. Patient has Philadelphia chromosome (Ph)-positive disease; **AND**

i. Previous therapy has included tyrosine kinase inhibitors (TKIs) (e.g., bosutinib, dasatinib, imatinib, nilotinib, or ponatinib); **OR**

b. Patient has Philadelphia chromosome (Ph)-negative disease

† 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
C91.02	Acute lymphoblastic leukemia, in relapse

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/6/2025	Annual Review: Separated initial approval criteria and individual diagnosis requirements Length of authorization - Coverage will be provided for one treatment course (1 dose of Tecartus) and may not be renewed. Removed coverage will be provided for 90 days (1 dose) Updated dosing limits. Addition of ****For Medicare members: Kymriah- please refer to our separate LCD/NCD Medicare criteria**

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; 2024