Medical Policy:

Breyanzi® (lisocabtagene maraleucel)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.324	March 5, 2025	April 5, 2021

Definitions

Breyanzi, a CD19-directed genetically modified autologous T-cell immunotherapy, is indicated for the treatment of adults with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

Length of Authorization

Coverage will be provided for one treatment course (1 dose of Breyanzi) and may not be renewed.

Dosing Limits [Medical Benefit]

Quantity Limitations:

Sufficient quantity will be provided for one-time treatment:

- 1 carton (1 to 4 vials) of up to 110 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 110 million autologous anti-cd19 CAR-positive viable T-cells)

Guideline

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

I. INITIAL APPROVAL CRITERIA

1. **B-Cell Lymphoma**
   - A. Patient meets ONE of the following (i or ii):
     - i. Patient meets BOTH of the following (a and b):
       - a. Patient has one of the following diagnoses (1, 2, 3, 4, 5, 6, 7, 8, 9, or 10):
         - (1) Large B-cell lymphoma; **OR**
         - (2) Diffuse large B-cell lymphoma, not otherwise specified
           - (i) May include DLBCL arising from indolent lymphoma; **OR**
         - (3) High-grade B-cell lymphoma; **OR**
         - (4) Primary mediastinal large B-cell lymphoma; **OR**
         - (5) Follicular lymphoma grade 3B; **OR**
         - (6) Human immunodeficiency virus (HIV)-related diffuse large B-cell lymphoma;**OR**
         - (7) Human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma; **OR**
         - (8) Primary effusion lymphoma; **OR**
         - (9) Post-transplant lymphoproliferative disorders; **OR**
         - (10) Mantle cell lymphoma; **AND**
       - b. Patient has received at least one line of systemic therapy; **OR**
     - ii. Patient meets BOTH of the following (a and b):
       - a. Patient has ONE of the following diagnoses [(1) or (2)]:
         - (1) Transformed indolent lymphoma to diffuse large B-cell lymphoma; **OR**
         - (2) Classic follicular lymphoma; AND
       - b. Patient has received at least two lines of systemic therapy; **AND**
   - B. Patient is ≥ 18 years of age; **AND**
   - C. The medication is prescribed by or in consultation with an oncologist; **AND**
   - D. The administering facility has been certified to administer Breyanzi and is enrolled in Breyanzi REMS program; **AND**
   - E. Patient has received lymphodepleting chemotherapy prior to infusion of Breyanzi; **AND**
   - F. Patient has not been previously treated with CAR-T therapy;
     Note; Current FDA-approved CAR-T therapies include Breyanzi, Kymriah® (tisagenlecleucel suspension for intravenous infusion), Tecartus™ (brexucabtagene suspension for intravenous infusion), and Yescarta® (axicabtagene suspension for intravenous infusion); **AND**
   - H. The requested use is supported by FDA-approved prescribing information OR the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

2. **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.** Approve a single dose if the patient meets ALL of the following :
   - A. Patient is ≥ 18 years of age; **AND**
   - B. Patient meets ONE of the following (i **or** ii):
     - i. Patient meets BOTH of the following (a **and** b):
       - a. Patient has received a Bruton tyrosine kinase inhibitor; **AND**
         Note: Examples of Bruton tyrosine kinase inhibitors include Imbruvica (ibrutinib capsules and tablets), Calquence (acalabrutinib capsules and tablets), and Brukinsa (zanubrutinib capsule).
       - b. Patient has received Venclexta (venetoclax tablets); **OR**
     - ii. Patient meets BOTH of the following (a **and** b):
       - a. Patient has histologic transformation to diffuse large B-cell lymphoma; **AND**
       - b. Patient meets ONE of the following [(1), (2), **and** (3)]:

(1) Patient has del(17p)/TP53 mutation positive disease; **OR**
(2) Patient is chemotherapy refractory; **OR**
(3) Patient is unable to receive chemoimmunotherapy; **AND**
Note: Examples of chemoimmunotherapy include dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin, rituximab) and RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone).

C. Patient has received or plans to receive lymphodepleting chemotherapy prior to infusion of Breyanzi; **AND**
D. Patient has not been previously treated with CAR-T therapy; **AND**
Note: Examples of CAR-T therapy includes Breyanzi, Kymriah (tisagenlecleucel intravenous infusion), Tecartus (brexucabtagene intravenous infusion), and Yescarta (axicabtagene intravenous infusion).
E. The medication is prescribed by or in consultation with an oncologist.

Dosing/Administration

Indication	Dose
B-Cell Lymphomas and PediatricAggressive Mature B-Cell Lymphomas	**Lymphodepleting chemotherapy:** • Administer cyclophosphamide 300 mg/m^2 and fludarabine 30 mg/m^2 intravenously daily for three days. **Breyanzi infusion for relapsed/refractory disease after receiving at least ONE line of therapy:** • Infuse 2 to 7 days after completion of lymphodepleting chemotherapy. • A single dose of Breyanzi contains 90 to 110 × 10^6 CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose vials. **Breyanzi infusion for relapsed/refractory Follicular Lymphoma Grade 1, 2, or 3a OR Mantle Cell Lymphoma after receiving at least TWO lines of therapy** • Infuse 2 to 7 days after completion of lymphodepleting chemotherapy. • A single dose of Breyanzi contains 90 to 110 × 10^6 CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose vials. **Breyanzi infusion for relapsed/refractory disease after receiving at least TWO lines of therapy** *(Note: Does NOT apply to Follicular Lymphoma Grade 1, 2, or 3a OR Mantle Cell Lymphoma)* • Infuse 2 to 7 days after completion of lymphodepleting chemotherapy. • A single dose of Breyanzi contains 50 to 110 × 10^6 CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose vials.
CLL/SLL	**Lymphodepleting chemotherapy:** • Administer cyclophosphamide 300 mg/m^2 and fludarabine 30 mg/m^2 intravenously daily for three days. **Breyanzi infusion for relapsed/refractory disease after receiving at least TWO lines of therapy:** • Infuse 2 to 7 days after completion of lymphodepleting chemotherapy. • A single dose of Breyanzi contains 90 to 110 × 10^6 CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose vials.

For autologous use only. For intravenous use only.
• Breyanzi is prepared from the patient's T-cells, which are obtained via a standard leukapheresis procedure.
• One treatment course consists of lymphodepleting chemotherapy followed by a single infusion of Breyanzi.
• Confirm Breyanzi availability prior to starting the lymphodepleting regimen.
• Confirm the patient's identity with the patient identifiers on the shipper and the respective Certificate of Release for

Infusion (RFI Certificate) prior to infusion.
• Delay the infusion of Breyanzi if the patient has unresolved serious adverse events from preceding chemotherapies, active uncontrolled infection, or active graft-versus-host disease (GVHD).

Premedication:
• Premedicate with 650 mg acetaminophen and 25-50 mg diphenhydramine (or another H1-antihistamine) 30-60 minutes prior to treatment with Breyanzi. Avoid prophylactic use of systemic corticosteroids, as they may interfere with the activity of Breyanzi.

Monitoring after infusion:
• Monitor patients daily at a REMS-certified healthcare facility for at least 7 days following Breyanzi infusion for signs and symptoms of CRS and neurologic toxicities.
• Instruct patients to remain within proximity of the certified healthcare facility for at least 4 weeks following infusion.
• Instruct patients to refrain from driving or hazardous activities for at least 8 weeks following infusion.

Limitations/Exclusions:

1. Breyanzi is not indicated for the treatment of patients with primary central nervous system lymphoma.

Applicable Procedure Codes

Code	Description
Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Applicable NDCs

Code	Description
73153-0900-01	Breyanzi (lisocabtagene maraleucel) suspension for intravenous infustion

ICD-10 Diagnoses

Code	Description
C82.40	Follicular lymphoma grade IIIb, unspecified site
C82.41	Follicular lymphoma grade IIIb, lymph nodes of head, face, and neck
C82.42	Follicular lymphoma grade IIIb, intrathoracic lymph nodes
C82.43	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes
C82.44	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb, intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb, spleen
C82.48	Follicular lymphoma grade IIIb, lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb, extranodal and solid organ sites
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes

C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C83.90	Non-follicular (diffuse) lymphoma, unspecified, unspecified site
C83.91	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of head, face, and neck
C83.92	Non-follicular (diffuse) lymphoma, unspecified, intrathoracic lymph nodes
C83.93	Non-follicular (diffuse) lymphoma, unspecified, intra-abdominal lymph nodes
C83.94	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of axilla and upper limb
C83.95	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C83.96	Non-follicular (diffuse) lymphoma, unspecified, intrapelvic lymph nodes
C83.97	Non-follicular (diffuse) lymphoma, unspecified, spleen
C83.98	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of multiple sites
C83.99	Non-follicular (diffuse) lymphoma, unspecified, extranodal and solid organ sites
C82.40	Follicular lymphoma grade IIIb, unspecified site
C82.41	Follicular lymphoma grade IIIb, lymph nodes of head, face, and neck
C82.42	Follicular lymphoma grade IIIb, intrathoracic lymph nodes
C82.43	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes
C82.44	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb, intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb, spleen
C82.48	Follicular lymphoma grade IIIb, lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb, extranodal and solid organ sites
C82.50	Diffuse follicle center lymphoma, unspecified site
C82.51	Diffuse follicle center lymphoma, lymph nodes of head, face, and neck
C82.52	Diffuse follicle center lymphoma, intrathoracic lymph nodes
C82.53	Diffuse follicle center lymphoma, intra-abdominal lymph nodes
C82.54	Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb
C82.55	Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.56	Diffuse follicle center lymphoma, intrapelvic lymph nodes
C82.57	Diffuse follicle center lymphoma, spleen
C82.58	Diffuse follicle center lymphoma, lymph nodes of multiple sites
C82.59	Diffuse follicle center lymphoma, extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face, and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes

C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C85.80	Other specified types of non-Hodgkin lymphoma, unspecified site
C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face and neck
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region of lower limb
C85.86 O	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87	Other specified types of non-Hodgkin lymphoma, spleen
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
C85.80	Other specified types of non-Hodgkin lymphoma, unspecified site

Revision History

<table>
<tr><th>Company(ies)</th><th>DATE</th><th>REVISION</th></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>3/5/2025</td><td>Addition of “may not be renewed” to length of authorization.
Removed Sufficient quantity will be provided for one-time treatment:
1. Dosing is based on the number of chimeric antigen receptor (CAR)-positive viable T cells. 2. A single dose of BREYANZI contains 50 to 110 × 106 CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose 5 mL vials 3. Each mL contains 1.5 × 106 to 70 × 106 CAR-positive viable T cells. 4. The infusion volume is calculated based on the concentration of cryopreserved drug product CAR-positive viable T cells concentration. The volume may differ for each component infused. Replaced with 1 carton (1 to 4 vials) of up to 110 million autologous anti-CD19 CAR-positive viable T-cells.

Addition of Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma: Added new condition of approval that the patient has histologic transformation to diffuse large B-cell lymphoma and the patient has del(17p)/TP53 mutation or is chemotherapy refractory or unable to receive chemoimmunotherapy. Revised the dose to 90 to 110 x 10^6 CAR-positive viable T-cells.
Addition of dosing/administration table
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<tr><td>EmblemHealth & ConnectiCare</td><td>7/1/2024</td><td>Revision: B-Cell Lymphoma Initial Criteria: Modified the following Statement “Acquired immunodeficiency syndrome (AIDS)-related diffuse large B-cell lymphoma;” to read: “ Human immunodeficiency virus (HIV)-related diffuse large B-cell lymphoma;OR “
Added: “Mantle cell lymphoma; AND
Patient has received at least one line of systemic therapy; OR
Patient meets BOTH of the following (a and b):
b. Patient has ONE of the following diagnoses [(1) or (2)]:
(1) Transformed indolent lymphoma to diffuse large B-cell lymphoma; OR
(2) Classic follicular lymphoma; AND
c. Patient has received at least two lines of systemic therapy; AND”
Removed the following wording: “Patient meets ONE of the following:
ii. refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; OR
iii. refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; OR
iv. relapsed or refractory disease after two or more lines of systemic therapy; AND”
Added all Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma criteria</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>4/8/2024</td><td>Added Statement: **For Medicare members: Breyanzi- please refer to our separate LCD/NCD Medicare criteria</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>3/28/2024</td><td>Annual Review: Updated dosing limits</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>7/24/2023</td><td>Annual Review:
B-Cell Lymphoma: Initial Criteria: Added: “Acquired immunodeficiency syndrome (AIDS)-related diffuse large B-cell lymphoma; OR
Human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma; OR
Primary effusion lymphoma; OR
Post-transplant lymphoproliferative disorders; AND”
Removed:
“Patient has a relapsed or refractory disease, defined as progression after 2 or more lines of systemic therapy; AND”
Added ”Patient meets ONE of the following:
i. refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; OR
ii. refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; OR
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Removed ICD-10 Z51.12; Added ICD-10 codes:
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EmblemHealth & ConnectiCare	4/6/2022	Transferred policy to new template, updated procedure code.	

EmblemHealth & ConnectiCare	4/5/2021	New Policy

References

1. Breyanzi ® intravenous suspension [package insert]. Bothell, WA. Juno Therapeutics, Inc. Updated February 9, 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=594bb413-af3b-4b97-afb3-bfe2b174f2ed. Accessed February 26, 2021.
2. Breyanzi ® intravenous suspension. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: https://www.micromedexsolutions.com. Updated February 12, 2021. Accessed February 26, 2021.