



## Breyanzi® (lisocabtagene maraleucel) (Intravenous)

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### I. Length of Authorization

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

### II. Dosing Limits

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

- 1 carton (1 to 4 vials) of up to 110 million autologous anti-CD19 CAR-positive viable T-cells

#### B. 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)

### III. Initial Approval Criteria <sup>1</sup>

Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e. genetic and mutational testing) supporting initiation when applicable. Medical records may be submitted via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **AND**
- Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**

- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during lisocabtagene maraleucel treatment and until immune recovery following treatment; **AND**
- 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**
- Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
- Healthcare facility must be enrolled in and comply with the requirements of the BREYANZI REMS Program; **AND**
- Patient has not received prior CAR-T therapy; **AND**
- Patient has not received other anti-CD19 therapy, (e.g., tafasitamab, blinatumomab, loncastuximab tesirine, etc.) OR patient previously received other anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy while awaiting manufacture); **AND**
- Patient does not have primary central nervous system lymphoma; **AND**

#### **B-Cell Lymphomas † ‡ Φ 1,2,7,9-11**

- Patient has diffuse large B cell lymphoma (DLBCL), high-grade B-cell lymphoma, primary mediastinal B-cell lymphoma (PMBCL), or follicular lymphoma (FL) grade 3b; **AND**
  - Patient received previous treatment with an anthracycline and anti-CD20 agent; **AND**
    - Used for primary refractory disease (partial response, no response, or progression) or relapsed disease within 12 months after completion of first-line therapy; **OR**
    - Used as second-line therapy for relapsed or refractory disease >12 months after completion of first-line therapy if no intention to proceed to transplant; **AND**
      - Patient is not eligible for HSCT due to one of the following: age ≥ 70 years, adjusted diffusing capacity of the lung for carbon monoxide (DLCO) ≤ 60%, LVEF < 50%, CrCl < 60 mL/min, AST or ALT > 2 × ULN, or ECOG 2; **OR**
    - Used as additional therapy for relapsed or refractory disease >12 months after completion of first-line therapy and a partial response following second-line therapy (*Note: For DLBCL, FL grade 3b, or PMBCL, patient must also have no intention to proceed to transplant*); **OR**
    - Used for treatment of disease that is in second or greater relapse in patients with partial response, no response, or progressive disease following therapy for relapsed or refractory disease; **OR**
- Patient has histologic transformation of an indolent lymphoma (follicular lymphoma or marginal zone lymphoma) to DLBCL; **AND**

- Patient received previous treatment with an anthracycline and anti-CD20 agent; **AND**
  - Disease is refractory to first-line chemoimmunotherapy or has relapsed within 12 months of first-line chemoimmunotherapy; **AND**
    - Patient is a candidate for autologous hematopoietic stem cell transplant (HSCT); **OR**
  - Disease is relapsed or refractory after first-line chemoimmunotherapy and patient is NOT eligible for HSCT; **AND**
    - Patient is not eligible for HSCT due to one of the following: age  $\geq 70$  years, adjusted diffusing capacity of the lung for carbon monoxide (DLCO)  $\leq 60\%$ , LVEF  $< 50\%$ , CrCl  $< 60\text{mL/min}$ , AST or ALT  $> 2 \times \text{ULN}$ , or ECOG  $\geq 2$ ; **OR**
  - Patient received at least two (2) prior lines of chemoimmunotherapy for indolent or transformed disease

#### Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (CLL/SLL) † Φ <sup>1,7,8,15</sup>

- Used for relapsed or refractory disease; **AND**
- Patient has received a Bruton tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, pirtobrutinib, zanubrutinib, etc.) **AND** a B-cell lymphoma 2 (BCL-2) inhibitor (e.g., venetoclax, etc.); **AND**
  - Patient has high-risk features defined as having complex cytogenetic abnormalities ( $>3$  chromosomal abnormalities), del (17p), mutated TP53, or unmutated immunoglobulin heavy-chain variable region **AND** failed  $\geq 2$  prior lines of therapy; **OR**
  - Patient has standard-risk features **AND** has failed  $\geq 3$  prior lines of therapy

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

#### IV. Renewal Criteria <sup>1</sup>

Coverage cannot be renewed.

#### V. Dosage/Administration <sup>1</sup>

Indication	Dose
B-Cell Lymphomas	<b><u>Lymphodepleting chemotherapy:</u></b> <ul style="list-style-type: none"> <li>• Administer cyclophosphamide 300 mg/m<sup>2</sup> and fludarabine 30 mg/m<sup>2</sup> intravenously daily for three days.</li> </ul>

	<p><b><u>Breyanzi infusion for relapsed/refractory disease after receiving at least ONE line of therapy:</u></b></p> <ul style="list-style-type: none"> <li>• Infuse 2 to 7 days after completion of lymphodepleting chemotherapy.</li> <li>• A single dose of Breyanzi contains 90 to <math>110 \times 10^6</math> 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.</li> </ul> <p><b><u>Breyanzi infusion for relapsed/refractory disease after receiving at least TWO lines of therapy:</u></b></p> <ul style="list-style-type: none"> <li>• Infuse 2 to 7 days after completion of lymphodepleting chemotherapy.</li> <li>• A single dose of Breyanzi contains 50 to <math>110 \times 10^6</math> 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.</li> </ul>
CLL/SLL	<p><b><u>Lymphodepleting chemotherapy:</u></b></p> <ul style="list-style-type: none"> <li>• Administer cyclophosphamide 300 mg/m<sup>2</sup> and fludarabine 30 mg/m<sup>2</sup> intravenously daily for three days.</li> </ul> <p><b><u>Breyanzi infusion for relapsed/refractory disease after receiving at least TWO lines of therapy:</u></b></p> <ul style="list-style-type: none"> <li>• Infuse 2 to 7 days after completion of lymphodepleting chemotherapy.</li> <li>• A single dose of Breyanzi contains 90 to <math>110 \times 10^6</math> 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.</li> </ul>
<p><b>For autologous use only. For intravenous use only.</b></p> <ul style="list-style-type: none"> <li>• Breyanzi is prepared from the patient's T-cells, which are obtained via a standard leukapheresis procedure</li> <li>• One treatment course consists of lymphodepleting chemotherapy followed by a single infusion of Breyanzi.</li> <li>• Confirm Breyanzi availability prior to starting the lymphodepleting regimen.</li> <li>• 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.</li> <li>• 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).</li> </ul>	
<p><b><u>Premedication:</u></b></p> <ul style="list-style-type: none"> <li>• 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.</li> </ul>	
<p><b><u>Monitoring after infusion:</u></b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Instruct patients to remain within proximity of the certified healthcare facility for at least 4 weeks following infusion.</li> <li>• Instruct patients to refrain from driving or hazardous activities for 8 weeks following infusion.</li> </ul>	
<ul style="list-style-type: none"> <li>• Store vials in the vapor phase of liquid nitrogen (less than or equal to minus 130°C). Thaw prior to infusion.</li> <li>• In case of manufacturing failure, a second manufacturing may be attempted.</li> <li>• Additional bridging chemotherapy (not the lymphodepletion) may be necessary while the patient awaits the product.</li> <li>• Ensure that 2 doses of tocilizumab and emergency equipment are available prior to infusion and during the recovery period.</li> <li>• Breyanzi contains human blood cells that are genetically modified with replication incompetent self-inactivating lentiviral vector. Follow universal precautions and local biosafety guidelines for handling and disposal to avoid potential transmission of infectious diseases.</li> </ul>	

## VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

- Breyanzi suspension for intravenous infusion [Each vial contains between  $6.9 \times 10^6$  and  $322 \times 10^6$  CAR-positive viable T cells in 4.6 mL cell suspension (between  $1.5 \times 10^6$  and  $70 \times 10^6$  CAR-positive viable T cells/mL)]: 73153-0900-xx

## VII. References (STANDARD)

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8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 3.2024. National Comprehensive Cancer Network, 2024. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed April 2024.
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## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 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
C83.30	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 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
C85.10	Unspecified B-cell lymphoma, unspecified site
C85.11	Unspecified B-cell lymphoma, lymph nodes of head, face, and neck
C85.12	Unspecified B-cell lymphoma, intrathoracic lymph nodes
C85.13	Unspecified B-cell lymphoma, intra-abdominal lymph nodes
C85.14	Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb
C85.15	Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.16	Unspecified B-cell lymphoma, intrapelvic lymph nodes
C85.17	Unspecified B-cell lymphoma, spleen
C85.18	Unspecified B-cell lymphoma, lymph nodes of multiple sites
C85.19	Unspecified B-cell 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

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC