TRUECARE

# PHARMACY POLICY STATEMENT
## Mississippi Medicaid

| DRUG NAME | Breyanzi (lisocabtagene maraleucel) |
|---|---|
| BENEFIT TYPE | Medical |
| STATUS | Prior Authorization Required |

Breyanzi, approved by the FDA in 2021, is a CD19-directed chimeric antigen receptor (CAR)T-cell therapy for the treatment of relapsed or refractory large B-cell lymphoma. It has accelerated approval status for relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL), follicular lymphoma (FL), and mantle cell lymphoma (MCL). Lymphoma is a cancer of the lymphatic system and white blood cells.

Breyanzi (lisocabtagene maraleucel) will be considered for coverage when the following criteria are met:

## Large B-Cell Lymphoma (LBCL)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Healthcare facility/provider has enrolled in the Breyanzi REMS; AND
3. Member has a documented diagnosis of large B-cell lymphoma including any of the following:
   a) Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma)
   b) High grade B-cell lymphoma (HGBCL)
   c) Primary mediastinal large B-cell lymphoma (PMBCL)
   d) Follicular lymphoma (FL) grade 3B
   e) DLBCL arising from follicular lymphoma (transformation FL; TFL)
   f) Intravascular LBCL
   g) DLBCL associated with chronic inflammation
   h) Fibrin-associated DLBCL
   i) EBV-positive DLBCL, NOS
   j) T-cell/histiocyte-rich LBCL; AND
4. Member has been treated with first line therapy containing an anthracycline and rituximab (or another CD20-targeted agent); AND
5. Member meets one of the following:
   a) Relapsed or refractory disease after two or more lines of systemic therapy
   b) Refractory disease to first-line chemoimmunotherapy (primary refractory) or relapse within 12 months of first-line chemoimmunotherapy
   c) Refractory disease to first-line chemoimmunotherapy (primary refractory) or relapse after first-line chemoimmunotherapy and ineligible for hematopoietic stem cell transplant (HSCT) due to comorbidities or age; AND
6. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
7. Member does NOT have any of the following:
   a) Primary central nervous system (CNS) lymphoma
   b) Prior CAR T-cell or other genetically-modified T-cell therapy; AND

8. Member has been or will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
9. **Dosage allowed/Quantity limit:**
   After 2 or more lines of therapy: A single dose of 50 to 110 × $10^6$ CAR-positive viable T cells
   After 1 line of therapy: A single dose of 90 to 110 × $10^6$ CAR-positive viable T cells

***If all the above requirements are met, the medication will be approved for 3 months.***

For **reauthorization**:
1. Breyanzi will not be reauthorized for continued therapy.

## Mantle Cell Lymphoma (MCL)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Healthcare facility/provider has enrolled in the Breyanzi REMS; AND
3. Member has a documented diagnosis of relapsed or refractory MCL; AND
4. Member has been treated with 2 or more prior lines of systemic therapy including ALL of the following:
   a) Alkylating agent
   b) CD20-targeted drug (e.g., rituximab)
   c) Covalent Bruton tyrosine kinase inhibitor (BTKi) (i.e., ibrutinib, acalabrutinib, or zanubrutinib); AND
5. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
6. Member does NOT have any of the following:
   a) Primary central nervous system (CNS) lymphoma
   b) Prior CAR T-cell or other genetically-modified T-cell therapy; AND
7. Member has been or will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
8. **Dosage allowed/Quantity limit:** A single dose of 90 to 110 × $10^6$ CAR-positive viable T cells

***If all the above requirements are met, the medication will be approved for 3 months.***

For **reauthorization**:
1. Breyanzi will not be reauthorized for continued therapy.

## Follicular Lymphoma (FL)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Healthcare facility/provider has enrolled in the Breyanzi REMS; AND
3. Member has a documented diagnosis of relapsed or refractory FL (grade 1, 2, or 3a [see LBCL section above for grade 3B]); AND
4. Member has been treated with 2 or more prior lines of systemic therapy, including an alkylating agent and CD20-targeted drug (e.g., rituximab); AND
5. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
6. Member does NOT have any of the following:
   a) Primary central nervous system (CNS) lymphoma
   b) Prior CAR T-cell or other genetically-modified T-cell therapy; AND
7. Member has been or will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
8. **Dosage allowed/Quantity limit:** A single dose of 90 to 110 × $10^6$ CAR-positive viable T cells

***If all the above requirements are met, the medication will be approved for 3 months.***

For **reauthorization**:
1. Breyanzi will not be reauthorized for continued therapy.

## Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Healthcare facility/provider has enrolled in the Breyanzi REMS; AND
3. Member has a documented diagnosis of relapsed or refractory CLL or SLL; AND
4. Member has been treated with 2 or more prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor (venetoclax); AND
5. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
6. Member does NOT have any of the following:
   a) Primary central nervous system (CNS) lymphoma
   b) Prior gene therapy; AND
7. Member has been or will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
8. **Dosage allowed/Quantity limit:** A single dose of 90 to 110 × $10^6$ CAR-positive viable T cells

***If all the above requirements are met, the medication will be approved for 3 months.***

For **reauthorization**:
1. Breyanzi will not be reauthorized for continued therapy.

## TrueCare considers Breyanzi (lisocabtagene maraleucel) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|---|---|
| **05/20/2021** | New policy for Breyanzi created. |
| **07/27/2022** | Updates to include 2nd line use in accordance with recent labeling changes and NCCN guidelines.<br>Updated billing code. |
| **12/12/2024** | Updated refs. Changed has been screened to has been or will be screened.<br>Added new sections for MCL, FL, and CLL/SLL (label update).<br>LBCL: Added more subtypes that would qualify (per NCCN). |

References:


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