CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Ohio 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); AND
9. The requesting physician attests to providing clinical outcome information within the Audaire Health™ provider portal as requested by CareSource.
10. **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); AND
8. The requesting physician attests to providing clinical outcome information within the Audaire Health™ provider portal as requested by CareSource.
9. **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); AND
8. The requesting physician attests to providing clinical outcome information within the Audaire Health™ provider portal as requested by CareSource.
9. **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); AND
8. The requesting physician attests to providing clinical outcome information within the Audaire Health™ provider portal as requested by CareSource.
9. **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.

CareSource 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. Updated billing code.
12/12/2024	Updated refs. Changed has been screened to has been or will be screened. Added new sections for MCL, FL, and CLL/SLL (label update). LBCL: Added more subtypes that would qualify (per NCCN).

06/05/2025	Added Audaire Health statement. ODM approved on 07/15/25.

References:

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