CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Breyanzi (lisocabtagene maraleucel)
BILLING CODE	Q2054
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Inpatient/Outpatient
STATUS	Prior Authorization Required

Breyanzi is a CD19-directed chimeric antigen receptor (CAR)T-cell therapy initially approved by the FDA in February 2021 for the treatment of relapsed or refractory large B-cell lymphoma after 2 or more lines of systemic therapy. Lymphoma is a cancer of the lymphatic system and white blood cells. Competitor CAR-T products include Kymriah and Yescarta. As of June 2022, Breyanzi is also indicated after just 1 line of therapy when certain qualifications are met.

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 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
   c) Primary mediastinal large B-cell lymphoma
   d) Follicular lymphoma grade 3B; 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 cell transplant (HCT) 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 (e.g. Yescarta, Kymriah);
8. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
9. **Dosage allowed/Quantity limit:**
   Relapsed or refractory after 2 or more lines of therapy: A single dose of 50 to 110 × 10^6 CAR-positive viable T cells

Relapsed or refractory 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.

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.

References:

1. Breyanzi (lisocabtagene maraleuce) [package insert]. Bothell, WA; Juno Therapeutics, Inc.; 2022.
2. National Comprehensive Cancer Network. B-Cell Lymphomas (Version 5.2021). https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed July 27, 2022.
3. Abramson JS, Palomba ML, Gordon LI, et al. Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL 001): a multicentre seamless design study. *Lancet*. 2020;396(10254):839-852. doi:10.1016/S0140-6736(20)31366-0
4. Abramson JS. Anti-CD19 CAR T-Cell Therapy for B-Cell Non-Hodgkin Lymphoma. *Transfus Med Rev*. 2020;34(1):29-33. doi:10.1016/j.tmrv.2019.08.003
5. Kamdar M, Solomon SR, Arnason J, et al. Lisocabtagene maraleucel versus standard of care with salvage chemotherapy followed by autologous stem cell transplantation as second-line treatment in patients with relapsed or refractory large B-cell lymphoma (TRANSFORM): results from an interim analysis of an open-label, randomised, phase 3 trial [published correction appears in Lancet. 2022 Jul 16;400(10347):160]. *Lancet*. 2022;399(10343):2294-2308. doi:10.1016/S0140-6736(22)00662-6
6. Sehgal A, Hoda D, Riedell PA, et al. Lisocabtagene maraleucel as second-line therapy in adults with relapsed or refractory large B-cell lymphoma who were not intended for haematopoietic stem cell transplantation (PILOT): an open-label, phase 2 study [published online ahead of print, 2022 Jul 12]. *Lancet Oncol*. 2022;S1470-2045(22)00339-4. doi:10.1016/S1470-2045(22)00339-4
7. Ernst M, Oeser A, Besiroglu B, et al. Chimeric antigen receptor (CAR) T-cell therapy for people with relapsed or refractory diffuse large B-cell lymphoma. *Cochrane Database Syst Rev*. 2021;9(9):CD013365. Published 2021 Sep 13. doi:10.1002/14651858.CD013365.pub2

Effective date: 01/01/2023
Revised date: 07/27/2022