



## PHARMACY POLICY STATEMENT

### HAP CareSource™ Marketplace

<b>DRUG NAME</b>	<b>Breyanzi (lisocabtagene maraleucel)</b>
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<sup>6</sup> CAR-positive viable T cells

Relapsed or refractory after 1 line of therapy: A single dose of 90 to 110 × 10<sup>6</sup> 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.

**HAP 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 2 <sup>nd</sup> 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](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.tmr.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

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Revised date: 07/27/2022