CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Breyanzi (lisocabtagene maraleucel)
BILLING CODE	J3490/J3590
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 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 products include Kymriah and Yescarta. Breyanzi was approved in February 2021.

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

Large B-Cell Lymphoma

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 relapsed or refractory 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 2 or more lines of systemic therapy, including treatment with an anthracycline and rituximab (or other CD20-targeted agent); 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 (e.g. Yescarta, Kymriah);
7. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
8. **Dosage allowed/Quantity limit:** 50 to 110 × 10^6 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

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.

References:

1. Breyanzi (lisocabtagene maraleuce) [package insert]. Bothell, WA; Juno Therapeutics, Inc.; Revised 02/2021.
2. National Comprehensive Cancer Network. B-Cell Lymphomas (Version 4.2021). https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed May 20, 2021.
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

Effective date: 10/01/2021
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