PHARMACY POLICY STATEMENT
North Carolina 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) (BCL)

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

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.