Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 24, 2021 October 14, 2022

BREYANZI® (lisocabtagene maraleucel)

LENGTH OF AUTHORIZATION: Date of service

REVIEW CRITERIA:

- Patient must be ≥18 years of age.
- Must have large B-cell lymphoma (LBCL) including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B who have:
    - Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; **OR**
    - Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; **OR**
    - Relapsed or refractory disease after two or more lines of systemic therapy.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/.
- A single dose of BREYANZI consists 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 5 mL vials. Each mL contains ≥ 1.5×10^6 to 70×10^6 CAR-positive viable T cells.
- Administer at a REMS-certified healthcare facility.

***** Because of the risk of Cytokine Release Syndrome and neurological toxicities, BREYANZI ® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BREYANZI REMS**.** Further information is available at www.BreyanziREMS.com or 1-888-423-5436).