



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 $\geq 1.5 \times 10^6$ to 70×10^6 CAR-positive viable T cells.
- Administer at a REMS-certified healthcare facility.