STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

Alex J. Mayer
Cabinet Secretary

Cynthia Beane, MSW, LCSW
Commissioner

Office of Pharmacy Services
Prior Authorization Criteria

BREYANZI® (lisocabtagene maraleucel)
Billed under: Q2054

BREYANZI is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of:

1) Patients ≥ 18 years of age with a diagnosis of 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 (FL) grade 3B, who have:
    a. refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; OR
    b. 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
    c. relapsed or refractory disease after two or more lines of systemic therapy.
2) Patients ≥ 18 years of age with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least two prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s)
3) Patients ≥ 18 years of age with relapsed or refractory FL who have received two or more prior lines of systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s)
4) Patients ≥ 18 years of age with relapsed or refractory mantle cell lymphoma (MCL) who have received at least two prior lines of systemic therapy, including a BTK inhibitor.

Limitations of Use: Breyanzi is not indicated for the treatment of patients with primary central nervous system (CNS) lymphoma.

Breyanzi is considered experimental/investigational for all other indications not listed above, including T-cell acute lymphoblastic leukemia (ALL) and Burkitt's Lymphoma/leukemia (e.g., patients with mature B-cell ALL) and therefore noncovered for any other indications than those listed above. There is insufficient evidence regarding its effectiveness and safety for any other indications.

Initial authorization requires review by the Medical Director and Breyanzi may be considered medically necessary only when being used for one of the approved indications and when all of the following criteria is met:

1. Must be prescribed by an Oncologist; **AND**
2. Supporting diagnostic documentation, identity of all prior treatments and response MUST be supplied; **AND**
3. Patient is ≥ 18 years of age with diagnosis of LBCL, including DLBCL not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and FL grade 3B; **AND** who have:

a. refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; **OR**
b. refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for HSCT due to comorbidities or age; **OR**
c. relapsed or refractory disease after two or more lines of systemic therapy; **OR**

4. Patient is ≥ 18 years of age with diagnosis of relapsed or refractory CLL or SLL who have received at least two prior lines of therapy, which MUST include a BTK inhibitor and a BCL-2 inhibitor; **OR**
5. Patient is ≥ 18 years of age with diagnosis of relapsed or refractory FL who have received two or more prior lines of systemic therapy; **OR**
6. Patient is ≥ 18 years of age with diagnosis of relapsed or refractory MCL who have received at least two prior lines of systemic therapy, which MUST include a BTK inhibitor; **AND**
7. No active or latent hepatitis B or active hepatitis C, human immunodeficiency virus (HIV) positive or any uncontrolled infection; **AND**
8. No presence of grade 2-4 acute or extensive chronic graft-versus-host disease (GVHD); **AND**
9. No active central nervous system involvement by malignancy; **AND**
10. No prior chimeric antigen receptor T-cell (CAR-T) or BCMA-targeted therapy ; **AND**
11. Karnofsky/Lansky score ≥ 50 or an Eastern Cooperative Oncology Group (ECOG) score of 0-1; **AND**
12. No live vaccination within six weeks prior to initiation of lymphodepleting chemotherapy, during Breyanzi treatment, and until immune recovery following treatment with Breyanzi.

Additional Requirements: Because of the risk of cytokine release syndrome (CRS) and neurological toxicities, Breyanzi is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BREYANZI REMS. The required components of the BREYANZI REMS are:

- Healthcare facilities that dispense and administer Breyanzi must be enrolled and comply with the REMS requirements. REMS certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available on-site for each patient for immediate administration within two hours after Breyanzi infusion, if needed for treatment of CRS.

Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer Breyanzi are trained in the management of CRS and neurological toxicities.

Monitor patients daily for at least seven days at the REMS-certified healthcare facility following infusion for signs and symptoms of CRS and neurologic toxicities. The product labeling gives specific treatment recommendations for the different grades of CRS and neurologic toxicity. Instruct patients to remain within a two hour proximity of the REMS certified healthcare facility for at least four weeks following infusion. Patients should be advised to refrain from driving or operating heavy machines until at least eight weeks after Breyanzi administration.

Authorization approval will be for 60 days to allow for a one-time infusion of therapy.

As additional indications may be approved by the FDA, expansion of the covered indications will be considered.

References:

Government Agency, Medical Society, and Other Authoritative Publications:

1. LexiComp Clinical Reference (Revised 3/6/2019)
2. Breyanzi [package insert]. Bothell, WA: Juno Therapeutics Inc.; 2024. https://packageinserts.bms.com/pi/pi_breyanzi.pdf (Accessed 12/18/2024)
3. REMS: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=405 (Accessed 12/15/2024)
4. UpToDate Clinical article “Diffuse large B cell lymphoma (DLBCL): Suspected first relapse or refractory disease in patients who are medically fit” (Accessed 12/13/2024)
5. Larson MD, R.A., Lowenberg MD, B., & Rosmarin MD, A.G. (2022). Treatment of relapsed or refractory acute lymphoblastic leukemia in adults. *UpToDate*. https://www.uptodate.com/contents/treatment-of-relapsed-or-refractory-acute-lymphoblastic-leukemia-in-adults?search=Treatment%20of%20relapsed%20or%20refractory%20acute%20lymphoblasti

c%20leukemia%20in%20adults&source=search_result&selectedTitle=1%7E150&usage_type=default&display_rank=1 (Accessed 12/13/2024)
6. National Comprehensive Cancer Network (NCCN) Guidelines – Treatment by Cancer Type https://www.nccn.org/guidelines/category_1 :
   a. (Acute Lymphoblastic Leukemia) NCCN Guidelines Version 4.2023 (Revised 2/5/2024)
   b. (Multiple Myeloma) NCCN Guidelines Version 2.2024 (Revised 11/1/2023)
   c. (B-Cell Lymphomas) NCCN Guidelines Version 1.2024 (Revised 1/18/2024)
7. Leukemia and Lymphoma Society Website https://www.lls.org/leukemia/acute-lymphoblastic-leukemia/treatment (Accessed 2/26/2024)
8. Beinfeld MT, Rucker JA, Jenkins NB, de Breed LA, Chambers JD. Variation in Medicaid and commercial coverage of cell and gene therapies. Health Policy Open. 2023 Oct 13;5:100103. doi: 10.1016/j.hpopen.2023.100103. PMID: 38023441; PMCID: PMC10660088. (Accessed 12/17/24)

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member according to BMS coverage and policy guidelines.