MEDICAL COVERAGE POLICY	
SERVICE:	**Lisocabtagene Maraleucel (Breyanzi®)**
Policy Number:	**291**
Effective Date:	**09/01/2025**
Last Review:	**07/23/2025**
Next Review:	**07/23/2026**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

SERVICE: Lisocabtagene Maraleucel (Breyanzi®)

PRIOR AUTHORIZATION:

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details.

For Medicare plans, please refer to Medicare NCD 110.24 Chimeric Antigen Receptor (CAR) T-cell Therapy

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). Texas Mandate HB154 is applicable for Medicaid plans.

Baylor Scott & White Health Plan (BSWHP) may consider lisocabtagene maraleucel (Breyanzi®) medically necessary when documentation is submitted showing ALL of the following criteria are met:

Universal Criteria Applied To All Requests

1. Member is 18 years or older; **AND**
2. Lisocabtagene is prescribed by or in consultation with a board-certified hematologist or oncologist; **AND**
3. Lisocabtagene will be dosed and administered according to FDA approved labeling; **AND**
4. Lisocabtagene will be used as monotherapy; **AND**
5. Provider attests all Risk Evaluation and Mitigation Strategy (REMS) program requirements are met; **AND**
6. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
7. Member has adequate bone marrow, renal, hepatic, pulmonary, and cardiac function; **AND**
8. Member has been assessed by a hematologist/oncologist to be an appropriate candidate for apheresis; **AND**
9. Member has documentation of CD-19 tumor expression; **AND**
10. Member has had no prior treatment with CAR T-cell immunotherapy (e.g., axicabtagene, tisagenlecleucel, brexucabtagene); **AND**
11. If the member has received prior treatment with anti-CD19 therapy (e.g., tafasitamab, loncastuximab) the member's repeat biopsy indicates CD-19 positive disease; **AND**
12. Member does NOT have any of the following:

a. Primary central nervous system (CNS) malignancy
b. Active hepatitis B (HBs AG-positive), active hepatitis C, HIV infection, or uncontrolled infection
c. History of CNS disorders (ex. seizure disorder, cerebrovascular ischemia)
d. Active inflammatory disorder requiring systemic immunosuppression
e. Richter transformation
f. Active graft versus host disease (GVHD)
g. Allogeneic hematopoietic stem-cell transplantation in the preceding 84 days before leukapheresis
h. Unmanaged venous thrombosis or embolism
i. Pregnant

Indication Specific Criteria

Large B-cell lymphoma (LBCL) specific criteria:

1. Member meets all universal criteria; **AND**
2. Member has a diagnosis of Large B-cell lymphoma [i.e., 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]; **AND**
3. Member has one of the following:
   a. Relapsed or refractory disease after two or more prior lines of systemic therapy
   b. Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy
   c. Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) specific criteria:

1. Member meets all universal criteria; **AND**
2. Member has a diagnosis of relapsed or refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma; **AND**
3. Member has received two or more prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor (i.e., ibrutinib, acalabrutinib, zanubrutinib, or pirtobrutinib) and a B-cell lymphoma 2 (BCL-2) inhibitor (i.e., venetoclax)

Mantle Cell Lymphoma (MCL) specific criteria:

1. Member meets all universal criteria; **AND**
2. Member has a diagnosis of relapsed or refractory Mantle Cell Lymphoma confirmed with cyclin D1 expression or evidence of t(11;14) by cytogenetics, fluorescence in situ hybridization (FISH), or polymerase chain reaction (PCR); **AND**

3. Member has received two or more prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor (i.e., ibrutinib, acalabrutinib, zanubrutinib, or pirtobrutinib)

Follicular Lymphoma (FL) specific criteria:

1. Member meets all universal criteria; **AND**
2. Member has histologically confirmed relapsed or refractory Follicular Lymphoma grade 1, 2, or 3a; **AND**
3. Member has received two or more prior lines of systemic therapy, including a CD-20 antibody (e.g., obinutuzumab, rituximab) and an alkylator (e.g., bendamustine, cyclophosphamide)

BSWHP considers only ONE treatment per lifetime is medically necessary as repeat administration of lisocabtagene maraleucel (Breyanzi®) is experimental and investigational because the effectiveness of this strategy has not been established.

BSWHP considers lisocabtagene maraleucel (Breyanzi®) for the treatment of all other indications to be experimental and investigational because the effectiveness of this strategy has not been established.

All requests will be reviewed by a clinical pharmacist and medical director.

BACKGROUND:

The U. S. Food and Drug Administration (FDA) granted approval for lisocabtagene maraleucel (Breyanzi®) on February 5, 2021 for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, 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. The boxed warning includes the clarification that lisocabtagene maraleucel is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) because of the risk of cytokine release syndrome (CRS) and neurological toxicities.

Lisocabtagene is a CD19-directed genetically modified autologous T-cell immunotherapy in which a patient's T-cells are reprogrammed with a transgene encoding a chimeric antigen receptor (CAR) to identify and eliminate CD19-expressing cells (malignant and normal). Lisocabtagene has a defined composition of CD8-and CD4-positive CAR T-cells. CAR is comprised of an FMC63 monoclonal antibody-derived single chain variable fragment (scFv), IgG4 hinge region, CD28 transmembrane domain, 4-1BB (CD137) costimulatory domain, and CD3 zeta activation domain. CD3 zeta signaling initiates activation and antitumor activity, while 4-1BB (CD137) signaling enhances T-cell expansion. CAR binding to CD19 (expressed on cell surfaces) induces activation and proliferation of CAR T-cells, release of pro-inflammatory cytokines, and results in cytotoxic destruction of target cells. Lisocabtagene is prepared from the patient's T-cells, which are obtained via leukapheresis.

The FDA approval of lisocabtagene is based on data from the TRANSCEND (NCT02631044) open-

label, multicenter, single-arm Phase I trial involving 299 patients, 204 receiving treatment in the intended dose range, of whom 192 were evaluable for efficacy. Results showed that 54% of those taking lisocabtagene had a complete response, with another 19% having a partial response. Among the complete responders, 65% had remission lasting at least 6 months and 62% had remission lasting at least 9 months. With respect to safety, the most common grade 3 or higher adverse effects were neutropenia (76%) and thrombocytopenia (39%). Serious adverse reactions occurred in 46% of patients.

Large B-cell Lymphoma

The FDA updated approval of lisocabtagene to include treatment for adult patients with relapsed or refractory Large B-Cell Lymphoma (LBCL) after first-line chemoimmunotherapy based on a randomized, open-label, multicenter trial (TRANSFORM; NCT03575351). The estimated 1-year event free survival was 45% in the lisocabtagene arm and 24% in the standard therapy arm. 66% of lisocabtagene maraleucel arm achieved complete response vs 39% in the standard therapy arm.

Lisocabtagene was evaluated in a single-arm, open-label, multicenter trial (PILOT; NCT03483103) in transplant-ineligible patients with relapsed or refractory LBCL after one line of chemoimmunotherapy. Overall response rate was 80% with lisocabtagene with 54% complete response.

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

The U. S. Food and Drug Administration (FDA) granted approval for lisocabtagene on March 21, 2024 for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after two or more prior lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor and a B-cell lymphoma-2 (BCL-2) inhibitor.

The FDA approval of lisocabtagene is based on data from the TRANSCEND CLL 004 (NCT03331198) open-label, multicenter, single-arm, Phase 1-2 trial involving 117 patients. Patients had received and had treatment failure on a previous BTK inhibitor. The primary efficacy analysis was conducted on a subset of patients who had also experienced venetoclax failure (n=70) and were treated with dose level 2 (n=49). In the primary efficacy analysis, the rate of complete response or remission (including with incomplete marrow recovery) was statistically significant at 18% (n=9; 95% CI 9-32; p=0.0006). In patients treated with lisocabtagene maraleucel, grade 3 cytokine release syndrome was reported in ten (9%) of 117 (with no grade 4 or 5 events) and grade 3 neurological events were reported in 21 (18%; one [1%] grade 4, no grade 5 events). Among 51 deaths on the study, 43 occurred after lisocabtagene maraleucel infusion, of which five were due to treatment-emergent adverse events (within 90 days of lisocabtagene maraleucel infusion). One death was related to lisocabtagene maraleucel (macrophage activation syndrome-haemophagocytic lymphohistiocytosis).

Follicular Lymphoma

The U. S. Food and Drug Administration (FDA) granted approval for lisocabtagene on May 15, 2024 for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after

two or more prior lines of systemic therapy including, including an anti-CD20 antibody and an alkylating agent.

The FDA approval of lisocabtagene is based on data from the TRANSCEND-FL (NCT 04245839) open-label, multicenter, single-arm, Phase 2 trial involving 130 patients. The primary efficacy population included 94 patients with PET-positive disease at baseline or after bridging therapy, received conforming product in the intended dose range, and had at least 9 months of follow up from first response. The main efficacy outcome measures were overall response rate (ORR), defined as the percentage of patients with a best overall response (BOR) of complete response or partial response after lisocabtagene infusion, and duration of response (DOR) as determined by an independent review committee. The ORR was 95.7% (95% CI: 89.5, 98.8). After a median follow up of 16.8 months (95% CI: 16.3, 17.0), the median DOR was not reached (NR) (95% CI: 18.04, NR). The most common nonlaboratory adverse reactions (≥20%) were cytokine release syndrome (CRS), headache, musculoskeletal pain, fatigue, constipation, and fever.

Mantle Cell Lymphoma

The U. S. Food and Drug Administration (FDA) granted approval for lisocabtagene on May 30, 2024 for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more prior lines of systemic therapy, including a Bruton tyrosine kinase inhibitor (BTKi).

The FDA approval of lisocabtagene is based on data from the TRANSCEND-MCL (NCT 02631044) open-label, multicenter, single-arm, Phase 1 trial involving 88 patients. Patients had received at least two prior lines of therapy including a Bruton tyrosine kinase inhibitor, an alkylating agent, and an anti-CD20 agent. The primary efficacy analysis included a total of 68 patients with MCL who received at least 2 prior lines of therapy including a BTKi, had PET-positive disease at study baseline or after bridging therapy, received conforming product in the intended dose range, and had at least 6 months of follow-up from the date of first response. The main efficacy outcome measure was overall response rate (ORR), defined as percentage of patients with best overall response (BOR) of either complete response (CR) or partial response (PR) after lisocabtagene infusion, as determined by an independent review committee (IRC) using 2014 Lugano classification. Other efficacy measures included complete response rate (CRR) and duration of response (DOR), as determined by IRC. The ORR was 85.3% (95% CI: 74.6, 92.7) and the CRR was 67.6% (95% CI: 55.2, 78.5). After a median follow-up of 22.2 months (95% CI: 16.7, 22.8), the median DOR was 13.3 months (95% CI: 6.0, 23.3). The most common nonlaboratory adverse reactions (≥ 20%) were cytokine release syndrome (CRS), fatigue, musculoskeletal pain, encephalopathy, edema, headache, and decreased appetite.

CODES:

Important note: *Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.*

CPT Codes:	0540T - Chimeric antigen receptor T cell (CAR-T) therapy; CAR-T cell administration, autologous 96409 - Chemotherapy administration; intravenous, push technique, single or initial substance/drug 96413 - Chemotherapy administration; intravenous infusion technique; up to 1 hour, single or initial substance/drug
HCPCS Codes:	Q2054 Lisocabtagene maraleucel, up to 110 million autologous anti-CD19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
ICD10 codes:	C82.00 - C82.69, C82.80 – C82.99 Follicular lymphoma C83.00 – C83.09 Small cell B-cell lymphoma C83.10 – C83.19 Mantle cell lymphoma C83.30 - C83.39 Diffuse large B-cell lymphoma C83.90 - C83.99 Non-follicular (diffuse) lymphoma C85.20 - C85.29 Mediastinal (thymic) large B-cell lymphoma C91.10 Chronic lymphocytic leukemia of B-cell type not having achieved remission C91.12 Chronic lymphocytic leukemia of B-cell type in relapse
ICD10 Not covered:	

POLICY HISTORY:

Status	Date	Action
New	04/22/2021	New policy
Updated	05/27/2021	Removed Oncology Analytics line, added apheresis criteria
Updated	07/22/2021	Added clinician reviewer criteria
Updated	06/23/2022	Added NCD information
Updated	10/27/2022	Removed language with CMS LCD since NCD applies. Updated HCPCS code. Added new criteria for relapsed/refractory disease after first-line chemoimmunotherapy. Removed Texas Mandate HB1584 language from main policy section as the policy is compliant. Minor formatting update.
Reviewed	10/09/2023	Applied new layout and format.

Updated	08/12/2024	Added three new indications, updated treatment center to REMS, updated layout (dividing criteria into "universal criteria" and "indication specific criteria"), added additional exclusion criteria (13d-i), modified universal criteria (8), updated background to include CLL/MCL/FL, updated ICD10 codes (C82.00 – C82.69, C82.80 – C82.99, C83.00 – C83.09, C83.10 – C83.19, C91.10, C91.12)
Updated	07/23/2025	Updated beginning note to align with standard language, Updated formatting of age requirement, Updated to standard language for dosing and administration, Updated to standard language for monotherapy criteria, Updated formatting of REMS requirement, Updated to standard language for indication and prescriber, Updated formatting of no prior treatment with CAR T-cell immunotherapy requirement, Updated formatting for exclusion criteria, Updated lifetime treatment and experimental and investigational language. Background section simplified.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available, and they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

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***Note**:*
Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.