Breyanzi (lisocabtagene maraleucel)
PAM – 039

Iowa Medicaid Program	Prior Authorization	**Effective Date**	10/01/2021
Revision Number	5	**Last Reviewed**	10/17/2025
Reviewed By	Medicaid Medical Director	**Next Review**	10/16/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	10/15/2021

Overview

Medication: [1]	lisocabtagene maraleucel
Brand Name:	Breyanzi®
Pharmacologic Category:	Antineoplastics; Genetically modified autologous T cell immunotherapy, CD19-directed

FDA-Approved Indication(s):

1. Adult patients with **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 (PMBCL), and follicular lymphoma 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, 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.
   - Limitations of Use: Breyanzi is not indicated for the treatment of patients with primary central nervous system (CNS) lymphoma.
2. Adult patients with **relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)** who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.
   - Accelerated Approval: 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. Adult patients with **relapsed or refractory follicular lymphoma (FL)** who have received 2 or more prior lines of systemic therapy.
   - Accelerated Approval: 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. Adult patients with **relapsed or refractory mantle cell lymphoma (MCL)** who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.

How Supplied:	Genetically modified autologous T cells supplied in vials as separate frozen suspensions of each CD8 component and CD4 component. Each CD8 or CD4 component is packed in a carton containing up to 4 vials, depending upon the concentration of the cryopreserved drug product CAR-positive viable T cells.

Dosage and Administration:

Indication	Breyanzi® Dose Range
LBCL after 2 or more lines of therapy	50 to 110 x 10^6 CAR-positive viable T cells
LBCL after 1 line of therapy	90 to 110 x 10^6 CAR-positive viable T cells
CLL or SLL	
FL	
MCL	

CLL - chronic lymphocytic leukemia FL – follicular lymphoma LBCL - large B-cell lymphoma
MCL – mantle cell lymphoma SLL – small lymphocytic lymphoma

Benefit Category: Medical

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, AND SECONDARY HEMATOLOGICAL MALIGNANCIES

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving Breyanzi®. Do not administer Breyanzi® to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab with or without corticosteroids.
- Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving Breyanzi®, including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment. Provide supportive care and/or corticosteroids as needed.
- T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including Breyanzi®.

POST-INFUSION MONITORING

- Monitor patients at least daily for seven days following Breyanzi® infusion for signs and symptoms of CRS and neurologic toxicities.
- Instruct patients to remain within proximity of a healthcare facility for at least two weeks following infusion.
- Advise patients to avoid driving for at least 2 weeks following infusion.

Descriptive Narrative

Diffuse Large B-Cell Lymphoma (DLBCL)

Diffuse large B-cell lymphoma (DLBCL) is the most common histologic subtype of non-Hodgkin lymphoma (NHL) accounting for approximately 25 percent of NHL cases in the developed world. In the United States, the incidence of DLBCL is approximately 7 cases per 100,000 persons per year. Incidence varies by ethnicity, with White Americans having higher rates than Black, Asian, and American Indian or Alaska Native individuals, in order of decreasing incidence. Like most other NHLs, there is a male predominance with approximately 55 percent of cases occurring in men. Incidence increases with age; the median age at presentation is 64 years for patients as a whole but appears to be younger for Black compared with White Americans.[2]

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)

Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) is a mature B cell neoplasm characterized by a progressive accumulation of monoclonal B lymphocytes. CLL is considered to be identical (i.e., one disease with different manifestations) to the non-Hodgkin lymphoma SLL (the malignant cells seen in CLL and SLL have identical pathologic and immunophenotypic features). The term CLL is used when the disease manifests primarily in the blood, whereas the term SLL is used when involvement is primarily nodal.

CLL/SLL is the most prevalent leukemia in adults in Western countries, accounting for approximately 25 to 35 percent of all leukemias in the United States. CLL/SLL is more common in men, with a male to female ratio of approximately 1.2:1 to 1.8:1. The incidence rates among males and females in the United States are approximately 6.75 and 3.65 cases per 100,000 population per year, respectively. An estimated 20,700 new cases of CLL/SLL are diagnosed annually in the United States: 12,690 in males and 8010 in females. CLL/SLL is considered to be mainly a disease of older adults, with a median age at diagnosis of approximately 70 years.[3]

Follicular Lymphoma (FL)

Follicular lymphoma (FL) is the second most common subtype of NHL and is the most common of the clinically indolent NHLs (defined as those lymphomas in which survival of the untreated patient is measured in years). The vast majority of patients treated for FL will have an initial response to therapy, with 40 to 80 percent demonstrating a complete response, depending on the initial regimen used. However, conventional therapy for FL is not curative and most of these patients will ultimately develop progressive disease. In addition, less than 10 percent of patients treated with initial chemoimmunotherapy will not respond to treatment (i.e., refractory disease).[4]

In the United States as a whole, the estimated incidence of FL is 3.18 cases per 100,000 people. The incidence is stable over time, but varies, with the incidence in White populations being more than twice that in African and Asian populations. The incidence increases with age; FL most frequently presents in middle-aged individuals and the elderly; the median age at diagnosis is 65 years. Rarely, FL arises in children or adolescents.[5]

Mantle Cell Lymphoma (MCL)

Mantle cell lymphoma (MCL) is a mature B-cell non-Hodgkins lymphoma with a variable clinical course. MCL can involve lymph nodes and extranodal sites, such as the gastrointestinal tract or blood and bone marrow. The median age

at diagnosis is 68 years. In members with MCL, B-cells, a type of white blood cell that helps the body fight infection, transform into malignant cells. These cells form tumors in the mantle zone of the lymph nodes and quickly spread to other areas of the body.

Approximately three-quarters of patients with MCL are male, and White individuals are affected almost twice as frequently as Black individuals. MCL comprises about 3 to 7 percent of non-Hodgkin lymphomas in the United States and Europe, with an incidence of approximately 4 to 8 cases per million persons per year. Incidence increases with age and appears to be increasing overall in the United States.[6]

Definitions

- **CAR T-cell therapy:** A type of treatment in which a patient's T cells taken from a patient's blood are changed in the laboratory so they will attack cancer cells. Then the gene for a special receptor that binds to a certain protein on the patient's cancer cells is added to the T cells in the laboratory. The special receptor is called a chimeric antigen receptor (CAR). Large numbers of the CAR T cells are grown in the laboratory and given to the patient by infusion.
- **Chemotherapy:** The medical treatment of a disease, particularly cancer, with drugs or other chemicals.
- **Chemoimmunotherapy:** A treatment option for cancer that combines traditional chemotherapy with immunotherapy. This approach aims to increase the efficacy of cancer treatment by simultaneously targeting cancer cells through chemotherapy and boosting the immune system's ability to fight cancer through immunotherapy.[7]
- **Line of therapy:**
  - First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy, or a combination of these therapies.
  - Second-line therapy: Treatment given when the initial treatment (first-line therapy) is not effective or there is disease progression.
  - Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent (second-line therapy) treatments are not effective or there is disease progression.
- **Refractory disease:** illness or disease that does not respond to treatment.
- **Relapse or recurrence:** After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Guidelines

The National Comprehensive Cancer Network (NCCN) publishes guidelines for the prevention, diagnosis, and management of malignancies across the

continuum of care. The NCCN Guidelines® are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. The guidelines are developed and updated by 61 individual panels, comprising over 1,700 clinicians and oncology researchers from the 33 NCCN Member Institutions.

Guidelines are reviewed and updated on a continual basis to ensure that the recommendations take into account the most current evidence. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.[8,9]

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):[10]

- B-Cell Lymphomas (v.3.2024 – August 26, 2024)
- Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (v.3.2024 – March 26, 2024)

NCCN Guidelines® Recommendation(s) – B-Cell Lymphomas
(1) Diffuse Large B-Cell Lymphoma – Suggested Treatment Regimens a. Second-line Therapy i. No intention to proceed to transplant – Lisocabtagene maraleucel (CD19-directed): Category 2A, Preferred Regimen ii. Relapsed disease < 12 months or primary refractory disease – Lisocabtagene maraleucel (CD19-directed): Category 1 b. Third-Line and Subsequent Therapy i. Lisocabtagene maraleucel (CD19-directed): Category 2A, Preferred Regimen
(2) Classic Follicular Lymphoma – Suggested Treatment Regimens a. Third-Line and Subsequent Therapy i. Subsequent systemic therapy options include second-line therapy regimens that were not previously given. ii. Lisocabtagene maraleucel (CD19-directed): Category 2A, Preferred Regimen (3) Histologic Transformation of Indolent Lymphomas to DLBCL – Suggested Treatment Regimens a. Lisocabtagene maraleucel (CD19-directed): Category 2A (4) Mantle Cell Lymphoma – Suggested Treatment Regimens a. Second-Line and Subsequent Therapy i. Lisocabtagene maraleucel (CD19-directed): Category 2A, Useful in Certain Circumstances

NCCN Guidelines® Recommendation(s) – Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
(1) CLL/SLL **without** del(18p)/*TP53* Mutation: Suggested Treatment Regimens a. Therapy for Relapsed or Refractory Disease after Prior BTKi- and Venetoclax-Based Regimens i. Lisocabtagene maraleucel (CD19-directed): Category 2A (2) CLL/SLL **with** del(18p)/*TP53* Mutation: Suggested Treatment Regimens a. Therapy for Relapsed or Refractory Disease after Prior BTKi- and Venetoclax-Based Regimens i. Lisocabtagene maraleucel (CD19-directed): Category 2A

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale [11]

Developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group, and published in 1982, the ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). It is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient, and to determine appropriate treatment and prognosis.

Grade	**ECOG Performance Status** **[Synonyms: WHO/Zubrod score]**
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair.
5	Dead.

Criteria

Tocilizumab (Actemra®) may be required to manage cytokine release syndrome or neurologic toxicities. If tocilizumab therapy is required, may be approved for up to 4 doses of 800 mg each. HCPCS code J3262 suspends for claims review.

Prior authorization is required.

Large B-Cell Lymphoma (LBCL)

Breyanzi® is considered medically necessary when **ALL** of the following are met:

1. Member has a diagnosis of one of the following large B-cell lymphomas (LBCL):
    a. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified; **OR**
    b. DLBCL arising from indolent lymphoma; **OR**
    c. High-grade B-cell lymphoma; **OR**
    d. Primary mediastinal large B-cell lymphoma (PMBCL); **OR**
    e. Follicular lymphoma grade 3B; **OR**
    f. HIV related B-cell lymphomas (NCCN 2A): **OR**
    g. Monomorphic post-transplant lymphoproliferative (B-cell type) disorders (PTLD) (NCCN 2A); **AND**
2. Member is 18 years of age or older; **AND**
3. Request is for one of the following (a, b, or c):
    a. Member has refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy [which included an anti-CD20 monoclonal antibody (e.g., rituximab) and an anthracycline-containing chemotherapy regimen (e.g., doxorubicin)]; or,
    b. Member has 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; or
    c. Member has relapsed or refractory (r/r) disease after two or more lines of systemic therapy [which included an anti-CD20 monoclonal antibody (e.g., rituximab) and an anthracycline-containing chemotherapy regimen (e.g., doxorubicin)]; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1; **AND**
5. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
6. Member does **NOT** have primary central nervous system lymphoma; **AND**
7. Member has **NOT** received any previous treatment with chimeric antigen receptor (CAR) T-cell immunotherapy or other genetically modified T-cell therapy (e.g., Abecma®, Carvykti®, Kymriah®, Tecartus®, or Yescarta®), nor will CAR T therapy or other genetically modified T-cell therapy be administered concurrently with Breyanzi®; **AND**
8. Breyanzi® is given as a one-time, single administration treatment; **AND**
9. Request meets one of the following (a or b):
    a. Diagnosis of r/r LBCL after one line of therapy and dose does not exceed 90 to 110 x 10^6 CAR-positive viable T cells; or
    b. Diagnosis of r/r LBCL after two or more lines of therapy and dose does not exceed 50 to 110 x 10^6 CAR-positive viable T cells.

Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

Breyanzi® is considered medically necessary when **ALL** of the following are met:

1. Member has a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL); **AND**
2. Member is 18 years of age or older; **AND**
3. Member has received 2 or more prior lines of therapy, including **BOTH** of the following:
   a. One Bruton tyrosine kinase inhibitor (BTKi); **AND**
   b. One B-cell lymphoma 2 protein inhibitor (BCL2i) (e.g., Venclexta®); **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1; **AND**
5. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
6. Member does **NOT** have primary central nervous system lymphoma; **AND**
7. Member has **NOT** received any previous treatment with chimeric antigen receptor (CAR) T-cell immunotherapy or other genetically modified T-cell therapy (e.g., Abecma®, Carvykti®, Kymriah®, Tecartus®, or Yescarta®), nor will CAR T therapy or other genetically modified T-cell therapy be administered concurrently with Breyanzi®; **AND**
8. Breyanzi® is given as a one-time, single administration treatment; **AND**
9. Dose does not exceed 90 to 110 x 10^6 CAR-positive viable T cells.

Follicular Lymphoma (FL)

Breyanzi® is considered medically necessary when **ALL** of the following are met:

1. Member has a diagnosis of follicular lymphoma (FL) grade 1, 2, or 3a; **AND**
2. Member is 18 years of age or older; **AND**
3. Disease is relapsed/refractory after 2 or more lines of systemic therapy that includes a combination of an anti-CD20 monoclonal antibody (e.g., rituximab or Gazyva®) and an alkylating agent (e.g., bendamustine, cyclophosphamide, chlorambucil)*; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1; **AND**
5. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
6. Member does **NOT** have primary central nervous system lymphoma; **AND**
7. Member has **NOT** received any previous treatment with chimeric antigen receptor (CAR) T-cell immunotherapy or other genetically modified T-cell therapy (e.g., Abecma®, Carvykti®, Kymriah®, Tecartus®, or Yescarta®), nor will CAR T therapy or other genetically modified T-cell therapy be administered concurrently with Breyanzi®; **AND**
8. Breyanzi® is given as a one-time, single administration treatment; **AND**
9. Dose does not exceed 90 to 110 x 10^6 CAR-positive viable T cells.

** Prior authorization may be required.*

Mantle Cell Lymphoma (MCL)

Breyanzi® is considered medically necessary when **ALL** of the following are met:

1. Member has a diagnosis of mantle cell lymphoma (MCL); **AND**
2. Member is 18 years of age or older; **AND**
3. Disease is relapsed/refractory after 2 or more lines of systemic therapy that includes all of the following (a, b, and c):
   a. Anti-CD20 monoclonal antibody therapy (e.g., rituximab); **AND**
   b. Bruton tyrosine kinase inhibitor (BTKi); **AND**
   c. Alkylating agent (e.g., bendamustine, cyclophosphamide, platinum [carboplatin, cisplatin, or oxaliplatin]); **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1; **AND**
5. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
6. Member does **NOT** have primary central nervous system lymphoma; **AND**
7. Member has **NOT** received any previous treatment with chimeric antigen receptor (CAR) T-cell immunotherapy or other genetically modified T-cell therapy (e.g., Abecma®, Carvykti®, Kymriah®, Tecartus®, or Yescarta®), nor will CAR T therapy or other genetically modified T-cell therapy be administered concurrently with Breyanzi®; **AND**
8. Breyanzi® is given as a one-time, single administration treatment; **AND**
9. Dose does not exceed 90 to 110 x 10^6 CAR-positive viable T cells.

Continued Therapy (all indications)

Continued therapy will not be authorized, as Breyanzi® is indicated to be dosed one time only.

Approval Duration and Quantity Limits

	Initial Authorization	**Subsequent Authorization**
Approval Duration	One course of treatment per lifetime	Not applicable
Quantity Limits	One-time dose, not to exceed 110 x 10^6 CAR-positive T cells	

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J3262	Injection, tocilizumab, 1 mg [Actemra®: may be required to manage cytokine release syndrome or neurologic toxicities]
Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

ICD-10	Description
C82.40 – C82.49	Follicular lymphoma grade IIIb
C83.00 – C83.09	Small B-cell lymphoma
C83.10 – C83.19	Mantle cell lymphoma (relapsed or refractory)
C83.30 – C83.39	Diffuse large B-cell lymphoma
C83.90 – C83.99	Non-follicular (diffuse) lymphoma
C85.10 – C85.19	Unspecified B-cell lymphoma
C85.20 – C85.29	Mediastinal (thymic) large B-cell lymphoma
C91.10 – C91.12	Chronic lymphocytic leukemia of B-cell type

NDC	Labeler (and code)	Dosage	Pkg Size	Pkg Qty	Units /Pkg
73153-0901-08 (CD8)	Juno Therapeutics, Inc. (73153)	per treatment dose	1	EA	1
73153-0902-04 (CD4)	Juno Therapeutics, Inc. (73153)	per treatment dose	1	EA	1

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Breyanzi prescribing information (06/2025). Juno Therapeutics, Inc.: Bothell, WA. Available online: www.breyanzihcp.com. Accessed August 12, 2025.

[2] Aster JC, Herrera AF. Diffuse large B cell lymphoma and other large B cell lymphomas: Presentation, diagnosis, and classification. Rosmarin AG, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed June 9, 2025.

[3] Rai KR, Stilgenbauer S, Aster JC. Clinical features and diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed September 11, 2024.

[4] Freedman AS, Friedberg JW. Treatment of relapsed or refractory follicular lymphoma. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed March 5, 2025.

[5] Freedman AS, Aster JC. Clinical manifestations, pathologic features, diagnosis, and prognosis of follicular lymphoma. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed March 5, 2025.

[6] Freedman AS, Aster JC. Mantle cell lymphoma: Epidemiology, pathobiology, clinical manifestations, diagnosis, and prognosis. Rosmarin AG, MD, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed December 20, 2024.

[7] Sordo-Bahamonde C, Lorenzo-Herrero S, et al. Chemo-Immunotherapy: A New Trend in Cancer Treatment. Cancers (Basel). 2023 May 25;15(11):2912. PMID: 37296876.

[8] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[9] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[10] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

- B-Cell Lymphomas (v.3.2024 – August 26, 2024)
- Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (v.3.2024 – March 26, 2024)

[11] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

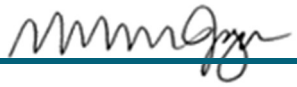
Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
10/17/2025	CAC	Annual review. Updated boxed warning to reflect removal of REMS requirement and added post-infusion monitoring requirements in a separate table (Overview section). Added information on follicular lymphoma to Descriptive Narrative. Updated criteria to remove requirement that Breyanzi® be administered at a REMS facility.	5
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/18/2024	CAC	Annual review. Updated NCCN Guidelines® and references. Updated Approval Duration and Quantity Limits to include information for new FDA-approved indications. Updated Coding and Product Information. 03/21/2024: FDA approved new indication – treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Criteria added, NCCN Guidelines reviewed 05/15/2024: FDA approved new indication – adult patients with relapsed or refractory follicular lymphoma (FL). Criteria added, NCCN Guidelines reviewed. 05/30/2024: FDA approved new indication – adult patients with relapsed or refractory mantle cell lymphoma (MCL). Criteria added, NCCN Guidelines reviewed.	4
Signature William (Bill) Jagiello, DO			

Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
10/20/2023	CAC	Annual review. Added warning regarding cytokine release syndrome and neurologic toxicities to Overview section. Updated DLBCL information in Descriptive Narrative. Added small list of definitions for various oncology terms. Updated NCCN Guidelines. Added paragraph before prior authorization criteria regarding tocilizumab (Actemra®) to manage CRS or neurological toxicities. Added dosing and therapy options into criteria. Added J3262 (Actemra®) to Coding and Product Information.	3
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
10/21/2022	CAC	New indications: 1. Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy. 2. Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemo-immunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age. Updated NCCN Guidelines.	2
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
10/15/2021	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee