Breyanzi (lisocabtagene maraleucel)
PAM – 039

Iowa Medicaid Program	Prior Authorization	**Effective Date**	10/01/2021
Revision Number	6	**Last Reviewed**	10/16/2026
Reviewed By	Medicaid Medical Director	**Next Review**	10/15/2027
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.
   - 2/20/2026: FDA converted from accelerated to traditional approval for this indication.
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.
5. Adult patients with **relapsed or refractory marginal zone lymphoma (MZL)** who have received at least 2 prior lines of systemic therapy.

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	
MZL	

CLL – chronic lymphocytic leukemia LBCL – large B-cell lymphoma MZL – marginal zone lymphoma
FL – follicular 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]

Marginal Zone Lymphoma (MZL)

The non-Hodgkin lymphoma subtype of marginal zone lymphoma represents a group of lymphomas that have been historically classified together because they appear to arise from post-germinal center marginal zone B cells and share a similar immunophenotype: typically positive for B cell markers CD19, CD20, and CD22, and negative for CD5, CD10, and usually CD23.

Several marginal zone lymphoma subtypes are recognized in the World Health Organization classification of lymphoid neoplasms:

- Extranodal marginal zone lymphoma of mucosa-associated lymphoid tissue (MALT lymphoma)
- Primary cutaneous marginal zone lymphoma
- Nodal marginal zone lymphoma
- Splenic marginal zone lymphoma

Extranodal marginal zone lymphoma (EMZL) arises in several epithelial tissues, including the stomach, salivary gland, lung, small bowel, thyroid, ocular adnexa, skin, and elsewhere. While it tends to remain localized to the tissue of origin for long periods of time, it is a clonal B cell neoplasm that frequently recurs locally and has potential for systematic spread and transformation to an aggressive B cell lymphoma.[7]

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.[8]
- **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

Clinical Practice Guidelines in Oncology document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes. The guidelines are developed and updated by 63 individual panels, comprising over 1,900 clinicians and oncology researchers from the 33 NCCN Member Institutions. The categories for recommendations are based on both the level of clinical evidence available and the degree of consensus within the NCCN Guidelines Panel.

The library of NCCN Guidelines® currently apply to more than 97 percent of people living with cancer or anyone at risk for a diagnosis of cancer in the United States. The guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management and are intended to assist all individuals who impact decision-making in cancer care, including physicians, nurses, pharmacists, payers, patients and their families, and others.

The NCCN Guidelines® provide recommendations based on the best evidence available at the time they are derived. Because new data are published

continuously, it is essential that the NCCN Guidelines also be continuously updated and revised* to reflect new data and clinical information that may add to or alter current clinical practice standards.[9,10]

The information referenced at the time of this policy writing/revision (note version number and effective date) is from the NCCN Guidelines® for:[11]

- B-Cell Lymphomas (v.4.2026 – May 20, 2026)
- Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (v.2.2026 – December 22, 2025)

* 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.

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale [12]

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 may be required to manage cytokine release syndrome or neurologic toxicities. If tocilizumab is required, may be approved for up to 4 doses. Tocilizumab is available from multiple manufacturers. Reference dosage in prescribing information of product utilized.

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 or 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 or 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 or 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 or 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.

Marginal Zone Lymphoma (MZL)

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

1. Member has a diagnosis of marginal zone lymphoma (MZL); **AND**
2. Member is 18 years of age or older; **AND**
3. Disease is relapsed/refractory after 2 or more lines of systemic therapy, including an anti-CD20 antibody and an alkylating agent; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 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
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
C88.4 – C88.41	Extranodal marginal zone 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

* outer carton NDC 73153-0900-01

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 (02/2026). Juno Therapeutics, Inc.: Bothell, WA. Available online: www.breyanzihcp.com. Accessed July 28, 2026.

[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 July 29, 2026.

[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 July 29, 2026.

[4] Freedman AS, Friedberg JW. Treatment of relapsed or refractory follicular lymphoma. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed July 29, 2026.

[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 July 29, 2026.

[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 August 12, 2026.

[7] Freedman AS, Aster JC. Clinical manifestations, pathological features, and diagnosis of extranodal marginal zone lymphoma of mucosa-associated lymphoid tissue (MALT). Rosmarin AG, MD, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed August 12, 2026.

[8] 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.

[9] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[10] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[11] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are continuously updated and revised to reflect new data and clinical information that may add to or alter current clinical practice standards. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced at the time of this revision (note version number and effective date):

- B-Cell Lymphomas (v.4.2026 – May 20, 2026)
- Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (v.3.2024 – March 26, 2024)

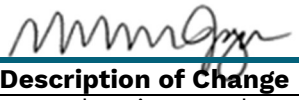
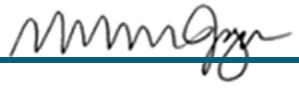
[12] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

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.

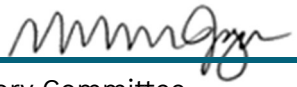
Criteria Change History

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
10/16/2026	CAC	Annual review. Updated references. Removed J3262 (Actemra) from Coding and Product Information section, as multiple biosimilars are now also available and carry the same indication to treat CRS. 12/04/2025: FDA approved new indication for marginal zone lymphoma. Added criteria, disease, and coding information to policy. Policy format update: Removed current NCCN Guidelines recommendations, as guidelines may change more frequently than the review cadence of this document. Will continue to reference NCCN when writing criteria, and include the specific version referenced at the time of the policy writing/revision.	6
Signature William (Bill) Jagiello, DO			
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			

Criteria Change History *(continued)*

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			
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