STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Kymriah (tisagenlecleucel)
PAM–010

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	01/01/2019
Revision Number:	7	**Last Rev Date:**	04/19/2024
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	04/18/2025
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	11/27/2017

Overview

Medication:[1]	tisagenlecleucel
Brand Name:	Kymriah®
Pharmacologic Category:	CD19-directed genetically modified autologous T-cell immunotherapy
FDA-Approved Indication(s):	1. Pediatric and young adults (up to 25 years of age) with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. 2. Adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. ► Limitation of Use: not indicated for treatment of patients with primary central nervous system lymphoma. 3. Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more 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).
How Supplied:	Supplied as a frozen suspension of genetically modified autologous T cells in an infusion bag(s) labeled for the specific recipient.
Dosage and Administration:	For autologous use only. For intravenous use only. Dosing is weight-based (per weight reported at the time of leukapheresis). 1. Pediatric and young adult r/r B-cell ALL (dose depends on patient body weight): • 50 kg or less: administer 0.2 to 5.0 x 10^6 CAR-positive viable T cells per kilogram • Above 50 kg: administer 0.1 to 2.5 x 10^8 CAR-positive viable T cells 2. Adult r/r DLBCL: administer 0.6 to 6.0 x 10^8 CAR-positive viable T cells 3. Adult r/r FL: administer 0.6 to 6.0 x 10^8 CAR-positive viable T cells
Benefit Category:	Medical

BOXED WARNING: Cytokine Release Syndrome (CRS) and Neurological Toxicities

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving Kymriah®. Do not administer Kymriah® to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.
- Neurological toxicities, which may be severe or life-threatening, can occur following treatment with Kymriah®, including concurrently with CRS. Monitor for neurological events after treatment with Kymriah®. Provide supportive care as needed.
- Kymriah® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIAH REMS.

Descriptive Narrative

Kymriah® is a CD19-directed genetically modified autologous T cell immunotherapy which involves reprogramming a patient's own T cells with a transgene encoding a chimeric antigen receptor (CAR) to identify and eliminate CD19-expressing malignant and normal cells.

The CAR is comprised of a murine single-chain antibody fragment which recognizes CD19 and is fused to intracellular signaling domains from 4-1BB (CD137) and CD3 zeta. The CD3 zeta component is critical for initiating T cell activation and antitumor activity, while 4-1BB enhances the expansion and persistence of Kymriah®. Upon binding to CD19-expressing cells, the CAR transmits a signal to promote T cell expansion, activation, target cell elimination, and persistence of the Kymriah® cells.

B Cell Lymphoblastic Leukemia/Lymphoma (B cell ALL/LBL)

The lymphoblastic neoplasms are classified on the basis of B cell versus T cell lineage:

- B cell lymphoblastic leukemia/lymphoma (B cell ALL/LBL)
- T cell lymphoblastic leukemia/lymphoma (T cell ALL/LBL).

Leukemia and lymphoma are overlapping clinical presentations of the same disease (i.e., B cell ALL/LBL); diagnosis and classification do not distinguish between these entities.

B cell ALL/LBL is primarily a disease of children, with 75 percent of cases occurring in children less than 6 years of age. The estimated annual incidence of ALL worldwide is 1 to 5 cases per 100,000 population, and more than two-thirds of cases of ALL are B cell phenotype.[2]

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.[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]

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. Also called chimeric antigen receptor T-cell therapy.

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

As new and emerging therapies are rapidly coming to market, oncology treatment recommendations and guidelines are constantly changing. To keep up with these changes, the National Comprehensive Cancer Network (NCCN) publishes guidelines which are developed and updated by 60 individual panels, comprising over 1,660 clinicians and oncology researchers from the 31 NCCN Member Institutions.[6]

The NCCN Clinical Practice Guidelines in Oncology (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 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.

The information referenced at the time of this policy writing/revision is from:

- NCCN Guidelines® for Acute Lymphoblastic Leukemia (Version 4.2023 – February 5, 2024)[7]
- NCCN Guidelines® for B-Cell Lymphomas (Version 1.2024 – January 18, 2024)[8]

Recommendation(s) for tisagenlecleucel (Kymriah®) in Acute Lymphoblastic Leukemia (B-ALL)
(1) Relapsed or Refractory Ph-positive B-ALL [a, b] A. Patients aged < 26 years and with refractory disease or ≥ 2 relapses and following therapy that has included 2 tyrosine kinase inhibitors i. Tisagenlecleucel: Category 2A, other recommended regimen (2) Relapsed or Refractory Ph-negative B-ALL [a, c, d] A. Patients aged < 26 years and with refractory disease or ≥ 2 relapses i. Tisagenlecleucel: Category 2A, preferred regimen [a] All regimens include CNS prophylaxis with systemic therapy (e.g., methotrexate, cytarabine) and/or IT therapy (e.g., IT methotrexate, IT cytarabine; triple IT therapy with methotrexate, cytarabine, corticosteroid). [b] The safety of relapsed/refractory regimens in adults ≥65 years or adults with substantial comorbidities has not been established. [c] For patients who develop hypersensitivity to E. coli-derived asparaginase, ERW-rywn can be substituted as a component of the multi-agent therapeutic regimen to complete the full treatment course. [d] For patients in late relapse (>3 years from initial diagnosis), consider treatment with the same induction regimen.

Recommendation(s) for tisagenlecleucel (Kymriah®) in B-cell lymphomas
(1) Classic Follicular Lymphoma A. Third line and subsequent therapy [a] i. Tisagenlecleucel (CD19 directed): Category 2A, preferred regimen (2) Diffuse Large B-Cell Lymphoma (DLBCL) [a] A. Third line and subsequent therapy i. Tisagenlecleucel (CD19 directed): Category 2A, preferred regimen (3) Histologic transformation of Indolent Lymphomas to DLBCL A. T-Cell Engager Therapy i. Tisagenlecleucel (CD19 directed); Category 2A, suggested treatment regimen [b] [a] Subsequent systemic therapy options include second-line therapy regimens that were not previously given. [b] Patients should have received at least one anthracycline-based regimen, unless contraindicated.

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).

Tools for Assessment of Patient Functional Levels

The Eastern Cooperative Oncology Group Performance Status (ECOG-PS) and the Karnofsky Performance Status (KPS) are widely used methods to assess the functional status of a patient. ECOG-PS describes a patient's functional status using a scale which ranges from 0 (healthy, no pain) to 5 (death). KPS, used in patients 16 years of age and older, describes a patient's functional status as a comprehensive 11-point scale correlating to percentage values ranging from 100 percent (no evidence of disease, no symptoms) to 0 percent (death).

For years, these two assessment methodologies have been important tools in clinical practice. In clinical trials, they are used as selection criteria (similar to processes for selection using age or gender) and for the stratification of subgroups in test patient cohorts. Both are used by doctors and researchers to assess how a patient's disease is progressing, assess how the disease affects the daily living abilities of the patient, and determine appropriate treatment and prognosis.[9,10] A third functional assessment tool, the Lansky Play – Performance Scale, may be utilized to assess the functional status of patients younger than 16 years of age.[11]

Performance Status Assessments					
Eastern Cooperative Oncology Group (ECOG) Performance Status		**Karnofsky Performance Status**		**Lansky Play – Performance Scale**	
Score	Description	Score	Description	Score	Description
0	Fully active, able to carry on all pre-disease performance without restriction.	100	Normal, no complaints, no evidence of disease.	100	Fully active, normal.
		90	Able to carry on normal activity, minor signs or symptoms of disease.	90	Minor restrictions in physically strenuous activity.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (light housework, office work).	80	Normal activity with effort, some signs or symptoms of disease.	80	Active, but tires more quickly.
		70	Cares for self, unable to carry on normal activity or do active work.	70	Both greater restriction of, and less time spent in, play activity.
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.	60	Requires occasional assistance but is able to care for most of his/her needs.	60	Up and around, but minimal active play; keeps busy with quieter activities.
		50	Requires considerable assistance and frequent medical care.	50	Gets dressed but lies around much of the day; no active play; able to participate in all quiet play and activities.
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.	40	Disabled, requires special care and assistance.	40	Mostly in bed, participates in quiet activities.
		30	Severely disabled, hospitalization indicated. Death not imminent.	30	In bed, needs assistance even for quiet play.
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair.	20	Very sick, hospitalization indicated. Death not imminent.	20	Often sleeping, play entirely limited to very passive activities.
		10	Moribund, fatal processes progressing rapidly.	10	No play, does not get out of bed.
5	Dead.	0	Dead.	0	Dead.

Criteria

Prior authorization is required.

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

B-Cell Acute Lymphoblastic Leukemia (ALL)

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

1. Confirmed diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL); **AND**
2. CD19 tumor expression is confirmed; **AND**
3. Disease is relapsed or refractory (r/r) as defined by **ONE** of the following:
    a. Second or later bone marrow relapse; **OR**
    b. Bone marrow relapse after allogeneic stem cell transplant; **OR**
    c. Primary refractory disease defined as failure to achieve complete response after two cycles of standard chemotherapy; **OR**
    d. Chemo-refractory after relapse defined as failure to achieve complete response after one cycle of standard chemotherapy for relapsed leukemia; **AND**
4. If the member is diagnosed with Philadelphia chromosome positive (Ph+) ALL: Kymriah is prescribed following therapy that has included two tyrosine kinase inhibitors (TKIs) (imatinib mesylate, dasatinib, nilotinib, bosutinib, ponatinib), unless TKI therapy is not tolerated or contraindicated*; **AND**
5. Member is 25 years of age or younger; **AND**
6. Member has a Karnofsky performance status (KPS) or Lansky performance score (LPS) of $\geq$ 50; **AND**
7. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
8. Member is **NOT** receiving therapy for a chronic condition, such as an autoimmune disease, that requires systemic steroids or immunosuppressive agents; **AND**
9. Member does **NOT** have an active infection requiring systemic therapy; **AND**
10. 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®, Breyanzi®, Tecartus®, or Yescarta®), nor will CAR T therapy or other genetically modified T-cell therapy be prescribed concurrently with Kymriah®; **AND**
11. Member is receiving Kymriah® as a one-time, single administration treatment; **AND**
12. Treatment will be administered at a facility that is certified under the Kymriah® Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
13. Dose does not exceed:
    a. Member weight $\leq$ 50 kg: 5×10^6 CAR-positive viable T cells per kilogram (kg); **OR**
    b. Member weight 50 kg or greater: 2.5×10^8 CAR-positive viable T cells.

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

* Imatinib mesylate (Gleevec®), dasatinib (Sprycel®), nilotinib (Tasigna®), bosutinib (Bosulif®), and ponatinib (Iclusig®) may require a separate pharmacy prior authorization (see Iowa Medicaid preferred drug list for more information).

Diffuse Large B-Cell Lymphoma

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

1. Histologically confirmed diagnosis of **ONE** of the following:
    a. Diffuse large B-cell lymphoma (DLBCL); **OR**
    b. High-grade B-cell lymphoma; **OR**
    c. DLBCL from follicular lymphoma (FL); **AND**
2. Disease is relapsing or remitting following treatment with one anthracycline-containing regimen (e.g., doxorubicin) and rituximab; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2; **AND**
5. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
6. Member is **NOT** receiving therapy for a chronic condition, such as an autoimmune disease, which requires systemic steroids or immunosuppressive agents; **AND**
7. Member does **NOT** have an active infection requiring systemic therapy; **AND**
8. Member does **NOT** have active central nervous system (CNS) lymphoma; **AND**
9. 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®, Breyanzi®, Tecartus®, or Yescarta®), nor will CAR T therapy or other genetically modified T-cell therapy be prescribed concurrently with Kymriah®; **AND**
10. Member is receiving Kymriah® as a one-time, single administration treatment; **AND**
11. Treatment will be administered at a facility that is certified under the Kymriah® Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
12. Dose does not exceed 6×10^8 CAR-positive viable T cells.

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

Follicular Lymphoma (FL)

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

1. Confirmed diagnosis of relapsed or refractory follicular lymphoma (grade 1, 2, or 3A) which meets at least **ONE** of the following:
    a. Refractory to a second or later line of systemic therapy (including an anti-CD20 antibody and an alkylating agent) or relapsed within 6 months after completion of a second or later line of systemic therapy; **AND/OR**
    b. Relapsed during anti-CD20 antibody maintenance (following at least two lines of therapies as above) or within 6 months after maintenance completion; **AND/OR**
    c. Relapsed following autologous hematopoietic stem cell transplant (HSCT); **AND**
2. Member is 18 years of age or older; **AND**
3. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**

4. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
5. Member does **NOT** have active CNS involvement by malignancy; **AND**
6. 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®, Breyanzi®, Tecartus®, or Yescarta®), nor will CAR T therapy or other genetically modified T-cell therapy be prescribed concurrently with Kymriah®; **AND**
7. Member is receiving Kymriah® as a one-time, single administration treatment; **AND**
8. Treatment will be administered at a facility that is certified under the Kymriah® Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
9. Dose does not exceed 6 x 10^8 CAR-positive viable T cells.

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

Approval Duration and Quantity Limits

Diagnosis	Quantity Limits	Duration
Acute lymphoblastic leukemia (ALL)	≤50 kg patient: limit of 5 x 10^6 CAR-positive viable T-cells per kilogram (kg) >50 kg patient: limit of 2.5 x 10^8 CAR-positive viable T cells	Limited to one course of treatment per lifetime.
Diffuse large B-cell lymphoma (DLBCL)	Limit of 6 x 10^8 CAR-positive viable T cells	
Follicular lymphoma (FL)	Limit of 6 x 10^8 CAR-positive viable 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)
Q2042	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

ICD-10	Description
C82.00-C82.09	Follicular lymphoma grade I
C82.10-C82.19	Follicular lymphoma grade II
C82.30-C82.39	Follicular lymphoma grade IIIa
C83.00-C83.09	Small cell B-cell lymphoma (relapsed or refractory)
C83.30-C83.39	Diffuse large B-cell lymphoma (relapsed or refractory)
C83.50-C83.59	Lymphoblastic (diffuse) lymphoma (relapsed or refractory)
C83.80-C83.89	Other non-follicular lymphoma (relapsed or refractory)
C83.90-C83.99	Non-follicular (diffuse) lymphoma (relapsed or refractory)
C85.10-C85.19	Unspecified B-cell lymphoma (relapsed or refractory)
C85.20-C85.29	Mediastinal (thymic) large B-cell lymphoma (relapsed or refractory)

ICD-10	Description
C85.80-C85.89	Other specified types of non-Hodgkin lymphoma (relapsed or refractory)
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse

NDC	Labeler	Dosage	Pkg Size	Pkg Qty	Units/ Pkg
00078-0846-19 (Pediatric ALL)	Novartis Pharmaceuticals	per treatment dose	1	EA	1
00078-0958-19 (DLBCL and FL)	Novartis Pharmaceuticals	per treatment dose	1	EA	1

Compliance

1. Should conflict exist between this 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] Kymriah prescribing information (05/2022). Novartis Pharmaceuticals Corporation: East Hanover, NJ. Available online at www.hcp.novartis.com/products/kymriah. Accessed March 12, 2024.

[2] Advani AS, Aster JC. Clinical manifestations, pathologic features, and diagnosis of B cell acute lymphoblastic leukemia/lymphoma. Rosmarin AG, MD, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed March 12, 2024.

[3] Freedman AS, Aster JC. Epidemiology, clinical manifestations, pathologic features, and diagnosis of diffuse large B cell lymphoma. Rosmarin AG, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed March 12, 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 February 10, 2024.

[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 February 10, 2024.

[6] National Comprehensive Cancer Network (NCCN). Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 11, 2023.

[7] Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Lymphoblastic Leukemia (v.4.2023 – February 5, 2024). Accessed March 12, 2024. 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 of the guidelines, go online to NCCN.org.

[8] Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas (v.1.2024 – January 18, 2024). Accessed March 12, 2024. 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 of the guidelines, go online to NCCN.org.

[9] 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.

[10] Péus D, Newcomb N, Hofer S. Appraisal of the Karnofsky Performance Status and proposal of a simple algorithmic system for its evaluation. *BMC Med Inform Decis Mak*. 2013;13:72. Published 2013 Jul 19. doi:10.1186/1472-6947-13-72.

[11] Lansky SB, Lisa MA, et al. The measurement of performance in childhood cancer patients. Cancer. 1987 Oct 1;60(7):1651-6. PMID 3621134.

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

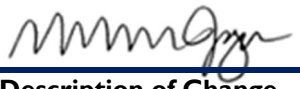
Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

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

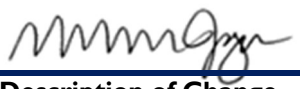
Change Date	Changed By	Description of Change	Version
04/19/2024	CAC	Annual review. Updated NCCN Guidelines. Updated references. Changed review cycle from July to April to align with other follicular lymphoma treatment (J9350, Lunsumio®). Criteria – B-cell ALL: changed Ph+ B-ALL criteria: [~~trial and inadequate response to at least~~ *following therapy that has included* two tyrosine kinase inhibitors ~~therapies~~] to align with version 1.2024 of guidelines.	7
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/21/2023	CAC	Annual review. Added "Guidelines" section to policy. Developed criteria for new indication of follicular lymphoma (FDA-approved 5/27/2022). Standardized CAR-T language in criteria for ALL and DLBCL.	6
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
04/15/2022	CAC	Criteria and approval updates.	5
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
01/21/2022	CAC	Updated descriptions and criteria.	4
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
01/15/2021	CAC	Annual review.	3
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/16/2020	Medical Director	All sections updated.	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/20/2017	Medical Director	Criteria development.	1
Signature C. David Smith, MD			

CAC = Medicaid Clinical Advisory Committee