



## Kymriah (tisagenlecleucel) PAM – 010

<b>Iowa Medicaid Program</b>	Prior Authorization	<b>Effective Date</b>	01/01/2019
<b>Revision Number</b>	9	<b>Last Reviewed</b>	04/17/2026
<b>Reviewed By</b>	Medicaid Medical Director	<b>Next Review</b>	04/16/2027
<b>Approved By</b>	Medicaid Clinical Advisory Committee	<b>Approved Date</b>	11/27/2017

### Overview

Medication: <sup>1</sup>	tisagenlecleucel
Brand Name:	Kymriah®
Pharmacologic Category:	Antineoplastics; CD19-directed genetically modified autologous T-cell immunotherapy
FDA-Approved Indication(s):	<ol style="list-style-type: none"> <li>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.</li> <li>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. <ul style="list-style-type: none"> <li>▶ <b>Limitation of Use:</b> Not indicated for treatment of patients with primary central nervous system lymphoma.</li> </ul> </li> <li>3. Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. <ul style="list-style-type: none"> <li>▶ <b>Accelerated Approval:</b> 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).</li> </ul> </li> </ol>
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:	<p>For autologous use only. For intravenous use only. Dosing is weight-based (per weight reported at the time of leukapheresis).</p> <ol style="list-style-type: none"> <li>1. Pediatric and young adult r/r B-cell ALL (dose depends on patient body weight): <ul style="list-style-type: none"> <li>• 50 kg or less: administer 0.2 to 5.0 x 10<sup>6</sup> CAR-positive viable T cells per kilogram body weight</li> <li>• Above 50 kg: administer 0.1 to 2.5 x 10<sup>8</sup> CAR-positive viable T cells</li> </ul> </li> <li>2. Adult r/r DLBCL: administer 0.6 to 6.0 x 10<sup>8</sup> CAR-positive viable T cells</li> <li>3. Adult r/r FL: administer 0.6 to 6.0 x 10<sup>8</sup> CAR-positive viable T cells</li> </ol>
Benefit Category:	Medical

#### BOXED WARNING: CYTOKINE RELEASE SYNDROME (CRS), NEUROLOGICAL TOXICITIES, and SECONDARY HEMATOLOGICAL MALIGNANCIES

- 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, including severe or life-threatening reactions, occurred following treatment with Kymriah®, including concurrently with CRS. Monitor for neurological events after treatment with Kymriah®. Provide supportive care and/or corticosteroids as needed.
- T cell malignancies have occurred following treatment of hematological malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including Kymriah®.

#### POST-INFUSION MONITORING

- Monitor patients daily during the first week following Kymriah® infusion for signs and symptoms of CRS and neurologic toxicities.
- Instruct patients to remain within proximity of a healthcare facility for at least 2 weeks following infusion.
- Advise patients to avoid driving for at least 2 weeks following infusion.

### 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.

#### B-Cell Lymphoblastic Leukemia/Lymphoma (B-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. 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).

B-cell ALL/LBL is primarily a disease of children, with 75 percent of cases occurring in children less than 6 years of age; there is a second peak of incidence in adults older than 60 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.<sup>2</sup>

#### Diffuse Large B-Cell Lymphoma (DLBCL)

Diffuse large B-cell lymphoma (DLBCL) is the most common histologic category of non-Hodgkin lymphoma (NHL), accounting for approximately one-quarter of cases of NHL 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 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.<sup>3</sup>

## Follicular Lymphoma (FL)

Follicular lymphoma (FL) is the second most common type of non-Hodgkin lymphoma (NHL). The vast majority of patients treated for FL will have an initial response to therapy, with 40 to above 80 percent demonstrating a complete response, depending on the initial regimen used. However, conventional therapy for FL is not curative, and most patients will ultimately develop progressive disease within 24 months of initial chemoimmunotherapy, and a small percentage will not respond to treatment (i.e., refractory disease).<sup>4</sup>

In the United States as a whole, FL accounts for approximately 35 percent of NHLs and has an estimated incidence of 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 older adults; the median age at diagnosis is 65 years. Rarely, FL arises in children or adolescents.<sup>5</sup>

## Definitions

- **CAR T-cell therapy:** Chimeric antigen receptor (CAR)-T cells are genetically modified autologous immunotherapy. The patient's own (autologous) T cells are collected from blood and modified ex vivo to express a tumor antigen-specific CAR. Following ex vivo expansion, the CAR-T cells are then reinfused back into the patient. As a result of this therapy, recognition of a specific tumor/cell surface antigen activates T cell response independently of major histocompatibility complex (MHC) recognition.<sup>6</sup>
- **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) 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.<sup>7,8</sup>

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):<sup>9</sup>

- Acute Lymphoblastic Leukemia (v.2.2025 – June 27, 2025)
- B-Cell Lymphomas (v.1.2026 – December 22, 2025)

\* To view the most recent and complete version of the guidelines, go online to [nccn.org](http://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.

<b>NCCN Guidelines® Recommendation(s) in Acute Lymphoblastic Leukemia (B-ALL)</b>
(1) Relapsed or Refractory Ph-positive B-ALL <sup>a, b</sup> a. Patients aged < 26 years and with refractory disease or ≥ 2 relapses and following therapy that has included 2 tyrosine kinase inhibitors (TKIs) i. Tisagenlecleucel: Category 2A, Other Recommended Regimen
(2) Relapsed or Refractory Ph-negative B-ALL <sup>a, c, d</sup> a. Patients aged < 26 years and with refractory disease or ≥ 2 relapses i. Tisagenlecleucel: Category 2A, Preferred Regimen
<sup>a</sup> All regimens include CNS prophylaxis with systemic therapy (e.g., methotrexate, cytarabine) and/or intrathecal therapy (IT) (e.g., IT methotrexate, IT cytarabine; triple IT therapy with methotrexate, cytarabine, corticosteroid).
<sup>b</sup> The safety of relapsed/refractory regimens in adults ≥65 years or adults with substantial comorbidities has not been established.
<sup>c</sup> 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.
<sup>d</sup> For patients in late relapse (>3 years from initial diagnosis), consider treatment with the same induction regimen.

<b>NCCN Guidelines® Recommendation(s) in B-Cell Lymphomas</b>	
(1) Classic Follicular Lymphoma	a. Third-line and subsequent therapy <sup>a</sup> i. Tisagenlecleucel (CD19 directed): Category 2A, Preferred Regimen
(2) ALK-Positive Large B-Cell Lymphomas (ALK + LBCL) <sup>b</sup>	a. Relapsed/Refractory Disease i. Tisagenlecleucel (if CD19-positive): Category 2A
(3) Diffuse Large B-Cell Lymphoma (DLBCL) <sup>a</sup>	a. Third-line and subsequent therapy i. Tisagenlecleucel (CD19 directed): Category 2A, Preferred Regimen
(4) Histologic Transformation of Indolent Lymphomas to DLBCL	a. T-cell Mediated Therapy i. Tisagenlecleucel (CD19 directed): Category 2A, Suggested Treatment Regimen <sup>c</sup>
<sup>a</sup> Second-line therapy regimens that were not previously given can also be used as options for third-line and subsequent therapy.	
<sup>b</sup> ALK-positive LBCL is a mature aggressive B-cell lymphoma characterized by large cells with plasmablastic differentiation and cytoplasmic expression of ALK, and lacking CD20 expression. Cytoplasmic ALK expression helps differentiate this entity from other aggressive CD20-negative LBCL with plasmacytic differentiation such as plasmablastic lymphoma, primary effusion lymphoma (PEL), and HHV8-positive DLBCL.	
<sup>c</sup> Patients should have received at least one anthracycline-based regimen, unless contraindicated.	

<b>NCCN Categories of Evidence and Consensus</b> (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.

<b>NCCN Categories of Preference</b> (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.<sup>10,11</sup> 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.<sup>12</sup>

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 is required, may be approved for up to 4 doses of 800 mg each.

## B-Cell Acute Lymphoblastic Leukemia

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

1. 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. Dose does not exceed (based on member body weight in kilograms [kg]):
  - a. Weight  $\leq 50$  kg:  $5 \times 10^6$  CAR-positive viable T cells per kg; **OR**
  - b. Weight above 50 kg:  $2.5 \times 10^8$  CAR-positive viable T cells.

Requests for continuation of 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. Dose does not exceed  $6 \times 10^8$  CAR-positive viable T cells.

Requests for continuation of therapy will not be authorized, as Kymriah® is indicated to be dosed one time only.

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## Follicular Lymphoma

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

1. 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 central nervous system (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. Dose does not exceed  $6 \times 10^8$  CAR-positive viable T cells.

Requests for continuation of therapy will not be authorized, as Kymriah® is indicated to be dosed one time only.

## Approval Duration and Quantity Limits

	Quantity Limits	Duration
Acute lymphoblastic leukemia (ALL)	<ul style="list-style-type: none"> <li>• <math>\leq 50</math> kg patient weight: limit of <math>5 \times 10^6</math> CAR-positive viable T-cells per kilogram of patient body weight</li> <li>• Patient weight above 50 kg: limit of <math>2.5 \times 10^8</math> CAR-positive viable T-cells</li> </ul>	Limited to one course of treatment per lifetime.
Diffuse large B-cell lymphoma (DLBCL)	Limit of $6 \times 10^8$ CAR-positive viable T cells	
Follicular lymphoma (FL)	Limit of $6 \times 10^8$ 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)
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 (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units/Pkg
00078-0846-19 (Pediatric ALL)	Novartis Pharmaceuticals (00078)	per treatment dose	1	EA	1
00078-0958-19 (DLBCL and FL)	Novartis Pharmaceuticals (00078)	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

- <sup>1</sup> Kymriah® prescribing information (12/2025). Novartis Pharmaceuticals Corporation: East Hanover, NJ. Available online: [www.kymriah-hcp.com](http://www.kymriah-hcp.com). Accessed January 27, 2026.
- <sup>2</sup> 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](http://www.uptodate.com). Accessed February 20, 2026.
- <sup>3</sup> Freedman AS, 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](http://www.uptodate.com). Accessed February 20, 2026.
- <sup>4</sup> Freedman AS, Salles G. Treatment of relapsed or refractory follicular lymphoma. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. [www.uptodate.com](http://www.uptodate.com). Accessed February 20, 2026.
- <sup>5</sup> 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](http://www.uptodate.com). Accessed February 20, 2026.
- <sup>6</sup> Shoushtari AN, Johnson DB. Principles of cancer immunotherapy. Shah SM, ed. UpToDate. Waltham, MA: UpToDate, Inc. [www.uptodate.com](http://www.uptodate.com). Accessed February 23, 2026.
- <sup>7</sup> National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at [www.nccn.org](http://www.nccn.org). Accessed October 20, 2025.

<sup>8</sup> National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at [www.nccn.org](http://www.nccn.org). Accessed October 20, 2025.

<sup>9</sup> NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines<sup>®</sup> 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](http://NCCN.org). NCCN Guidelines<sup>®</sup> referenced (note version number and effective date):

- Acute Lymphoblastic Leukemia (v.2.2025 – June 27, 2025)
- B-Cell Lymphomas (v.1.2026 – December 22, 2025)

<sup>10</sup> 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.

<sup>11</sup> 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.

<sup>12</sup> 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
04/17/2026	CAC	Annual review. Overview section: updated boxed warning to reflect removal of REMS requirement and added post-infusion monitoring requirements in a separate table.	9

Guidelines: reviewed and updated NCCN Guidelines. Updated criteria to remove requirement that Kymriah be administered at a REMS facility.

**Signature**

William (Bill) Jagiello, DO



Change Date	Changed By	Description of Change	Version
04/18/2025	CAC	Annual review. Updated Boxed Warning to include recent warning on T cell malignancies. Reviewed updated NCCN Guidelines.	8

**Signature**

William (Bill) Jagiello, DO



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®).	7

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.

**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



**Criteria Change History (continued)**

<b>Change Date</b>	<b>Changed By</b>	<b>Description of Change</b>	<b>Version</b>
01/21/2022	CAC	Updated descriptions and criteria.	4
<b>Signature</b>			
William (Bill) Jagiello, DO			
<b>Change Date</b>	<b>Changed By</b>	<b>Description of Change</b>	<b>Version</b>
01/15/2021	CAC	Annual review.	3
<b>Signature</b>			
William (Bill) Jagiello, DO			
<b>Change Date</b>	<b>Changed By</b>	<b>Description of Change</b>	<b>Version</b>
10/16/2020	Medical Director	All sections updated.	2
<b>Signature</b>			
William (Bill) Jagiello, DO			
<b>Change Date</b>	<b>Changed By</b>	<b>Description of Change</b>	<b>Version</b>
10/20/2017	Medical Director	Criteria development.	1
<b>Signature</b>			
C. David Smith, MD			

CAC = Medicaid Clinical Advisory Committee