

<b>Title: Kymriah (tisagenlecleucel)</b>	<b>Division: Medical Management</b> <b>Department: Utilization Management</b>
<b>Approval Date: 3/30/2018</b>	<b>LOB: Medicaid, HIV SNP, HARP, CHP, MetroPlus Gold, GoldCare, Marketplace, Essential</b>
<b>Effective Date: 3/30/2018</b>	<b>Policy Number: UM-MP219</b>
<b>Review Date: 4/23/2024</b>	<b>Cross Reference Number:</b>
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**I. POLICY DESCRIPTION:**

Medical Oncology- Anti- CD19 CAR-T Immunotherapy, Kymriah (tisagenlecleucel)

**II. RESPONSIBLE PARTIES:**

Medical Management Administration, Utilization Management, Integrated CareManagement, Pharmacy, Claims Department, Provider Contracting.

**III. DEFINITIONS:**

Kymriah (tisagenlecleucel) is a chimeric antigen receptor T-cell (CAR-T) which reprograms a patient's own T-cells to identify and eliminate CD19 expressing malignant and normal cells. Upon binding to CD-19 expressing cells, the CAR promotes T-cell expansion, activation and target cell elimination.

Kymriah is indicated for the treatment of:

Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.

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.

Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

All other uses for Kymriah are considered experimental and investigational.

**IV. POLICY:**

For the Medicare and UltraCare lines of business, MetroPlusHealth determines medical necessity based on applicable Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD).

<https://www.cms.gov/medicare-coverage-database/search.aspx>

**For all non-Medicare LOBs:**

Kymriah will be considered medically necessary once the following coverage criteria is met.

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Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

**INITIAL REQUEST:**

**1. Pediatric and Young Adult Relapsed or Refractory (r/r) B-cell precursor Acute Lymphoblastic Leukemia (B-ALL)**

**A.** Member is up to 25 years of age;

**AND**

**B.** Member has a diagnosis confirmed by submitted documentation including chart notes of B-cell precursor Acute Lymphoblastic Leukemia (B-ALL) that is refractory or in second or later relapse as defined by one of the following:

**a.** Member has experienced disease relapse after hematopoietic stem cell transplantation (HSCT) and member is  $\geq$  6 months or more from HSCT at the time of Kymriah infusion;

**OR**

**b.** Member has relapse or refractory Philadelphia chromosome-negative B-ALL with ONE of the following:

**i.** Disease progressed after 2 cycles of a standard chemotherapy regimen for initial diagnosis;

**OR**

**ii.** Disease progressed after 1 cycle of standard chemotherapy for relapsed leukemia;

**OR**

**c.** Member has Philadelphia chromosome-positive B-ALL that progressed after trial and failure, intolerance or contraindication to 2 prior regimens, including a tyrosine kinase inhibitor therapy (TKI) containing regimen (Gleevec (imatinib), Bosulif (bosutinib), Sprycel (dasatinib), Tassigna (nilotinib), or Iclusig (ponatinib));

**AND**

**C.** Member has a performance score on Karnofsky or Lansky Scale is  $\geq$  50%;

**AND**

**D.** Member does not have primary central nervous system lymphoma;

**AND**

**E.** Member is screened for HBV, HCV, and HIV in accordance with clinical guidelines prior to collection of cells for manufacturing;

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**AND**

F. Member has not received any live vaccines within the past 6 weeks;

**AND**

G. Member does not have an active systemic infection or inflammatory disorder;

**AND**

H. If member has a history of an allogeneic stem cell transplant, there are no current signs of active graft versus host disease (GVHD);

**AND**

I. Member has not previously been treated with Kymriah or any other CAR-T therapy;

**AND**

J. The requesting provider belongs to a healthcare facility that has enrolled in the Kymriah REMS (Risk Evaluation and Mitigation Strategy) program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities (treatment centers can be found [here](#));

**AND**

K. Authorization is for no more than one dose

## **2. Adult Relapsed or Refractory (r/r) Diffuse Large B-cell Lymphoma (DLBCL)**

A. Member is 18 years of age or older;

**AND**

B. Member has a diagnosis confirmed by submitted documentation including chart notes of relapsed/refractory B-cell lymphoma including any ONE of the following:

a. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified;

**OR**

b. Diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma;

**OR**

c. High grade B-cell lymphoma;

**AND**

C. Member has relapsed or refractory disease after trial and failure or contraindication to at least TWO lines of therapy

*(Examples of systemic therapy include:*

*RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone); DA-EPOCH (dose adjusted etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + Rituximab;*

*RCDOP (rituximab, cyclophosphamide, liposomal doxorubicin, vincristine,*

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*prednisone);*  
*RGCVP (rituximab, gemcitabine, cyclophosphamide, vincristine, prednisone);*  
*RCEPP (rituximab, cyclophosphamide, etoposide, prednisone, procarbazine);*  
*RCEOP (rituximab, cyclophosphamide, etoposide, vincristine, prednisone);*  
*DA-EPOCH ± rituximab;*  
*GDP ± rituximab or (gemcitabine, dexamethasone, carboplatin) ± rituximab;*  
*GemOx ± rituximab; Rituximab)*

**AND**

D. Member does not have primary central nervous system lymphoma;

**AND**

E. Member is screened for HBV, HCV, and HIV in accordance with clinical guidelines prior to collection of cells for manufacturing;

**AND**

F. Member has not received any live vaccines within the past 6 weeks;

**AND**

G. Member does not have an active systemic infection or inflammatory disorder;

**AND**

H. Member has not received prior allogeneic hematopoietic stem cell transplantation (HSCT);

**AND**

I. Member has not previously been treated with Kymriah or any other CAR-T therapy;

**AND**

J. The requesting provider belongs to a healthcare facility that has enrolled in the Kymriah REMS (Risk Evaluation and Mitigation Strategy) program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities (treatment centers can be found [here](#));

**AND**

K. Authorization is for no more than one dose

**3. Adult Relapsed or Refractory (r/r) Follicular lymphoma (FL)**

A. Member is 18 years of age or older;

**AND**

B. Member has a diagnosis confirmed by submitted documentation including chart notes of relapsed or refractory Follicular Lymphoma;

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**AND**

- C. Member has relapsed or refractory disease after trial and failure or contraindication to at least TWO lines of therapy  
*(Examples of system therapy include:*  
*Bendamustine + obinutuzumab or rituximab;*  
*CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + obinutuzumab or rituximab;*  
*CVP (cyclophosphamide, vincristine, prednisone) + binutuzumab or rituximab;*  
*Lenalidomide + rituximab;*  
*Chlorambucil ± rituximab;*  
*Cyclophosphamide ± rituximab)*

**AND**

- D. Member is screened for HBV, HCV, and HIV in accordance with clinical guidelines prior to collection of cells for manufacturing;

**AND**

- E. Member has not received any live vaccines within the past 6 weeks;

**AND**

- F. Member does not have an active systemic infection or inflammatory disorder;

**AND**

- G. Member has not received prior allogeneic hematopoietic stem cell transplantation (HSCT);

**AND**

- H. Member has not previously been treated with Kymriah or any other CAR-T therapy;

**AND**

- I. The requesting provider belongs to a healthcare facility that has enrolled in the Kymriah REMS (Risk Evaluation and Mitigation Strategy) program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities (treatment centers can be found [here](#));

**AND**

- J. Authorization is for no more than one dose

**RENEWAL REQUEST:**

Repeat administration of Kymriah is investigational and will not be covered.

**V. LIMITATIONS/EXCLUSIONS**

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- Repeat administration of Kymriah is considered experimental and investigational because there have been no established studies to demonstrate effectiveness
- Kymriah is not indicated for the treatment of patients with primary central nervous system lymphoma.
- History of prior CAR-T cell therapy or other genetically modified T cell therapy
- Ejection fraction < 50% or evidence of pericardial effusion
- History or presence of CNS disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease with CNS involvement

**VI. APPLICABLE PROCEDURE CODES:**

CPT	Description
<b>Q2042</b>	Tisagenlecleucel, up to 600 millioncar-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

**VII. APPLICABLE DIAGNOSIS CODES:**

Code	Description
<b>C82.00</b>	Follicular lymphoma grade I, unspecified site
<b>C82.01</b>	Follicular lymphoma grade I, lymph nodes of head, face, and neck
<b>C82.02</b>	Follicular lymphoma grade I, intrathoracic lymph nodes
<b>C82.03</b>	Follicular lymphoma grade I, intra-abdominal lymph nodes
<b>C82.04</b>	Follicular lymphoma grade I, lymph nodes of axilla and upper limb
<b>C82.05</b>	Follicular lymphoma grade I, lymph nodes of inguinal region and lower limb
<b>C82.06</b>	Follicular lymphoma grade I, intrapelvic lymph nodes
<b>C82.07</b>	Follicular lymphoma grade I, spleen
<b>C82.08</b>	Follicular lymphoma grade I, lymph nodes of multiple sites
<b>C82.09</b>	Follicular lymphoma grade I, extranodal and solid organ sites
<b>C82.10</b>	Follicular lymphoma grade II, unspecified site
<b>C82.11</b>	Follicular lymphoma grade II, lymph nodes of head, face, and neck
<b>C82.12</b>	Follicular lymphoma grade II, intrathoracic lymph nodes
<b>C82.13</b>	Follicular lymphoma grade II, intra-abdominal lymph nodes
<b>C82.14</b>	Follicular lymphoma grade II, lymph nodes of axilla and upper limb

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<b>C82.15</b>	Follicular lymphoma grade II, lymph nodes of inguinal region and lower limb
<b>C82.16</b>	Follicular lymphoma grade II, intrapelvic lymph nodes
<b>C82.17</b>	Follicular lymphoma grade II, spleen
<b>C82.18</b>	Follicular lymphoma grade II, lymph nodes of multiple sites
<b>C82.19</b>	Follicular lymphoma grade II, extranodal and solid organ sites
<b>C82.20</b>	Follicular lymphoma grade III, unspecified, unspecified site
<b>C82.21</b>	Follicular lymphoma grade III, unspecified, lymph nodes of head, face, and neck
<b>C82.22</b>	Follicular lymphoma grade III, unspecified, intrathoracic lymph nodes
<b>C82.23</b>	Follicular lymphoma grade III, unspecified, intra-abdominal lymph nodes
<b>C82.24</b>	Follicular lymphoma grade III, unspecified, lymph nodes of axilla and upper limb
<b>C82.25</b>	Follicular lymphoma grade III, unspecified, lymph nodes of inguinal region and lower limb
<b>C82.26</b>	Follicular lymphoma grade III, unspecified, intrapelvic lymph nodes
<b>C82.27</b>	Follicular lymphoma grade III, unspecified, spleen
<b>C82.28</b>	Follicular lymphoma grade III, unspecified, lymph nodes of multiple sites
<b>C82.29</b>	Follicular lymphoma grade III, unspecified, extranodal and solid organ sites
<b>C82.30</b>	Follicular lymphoma grade IIIa, unspecified site
<b>C82.31</b>	Follicular lymphoma grade IIIa, lymph nodes of head, face, and neck
<b>C82.32</b>	Follicular lymphoma grade IIIa, intrathoracic lymph nodes
<b>C82.33</b>	Follicular lymphoma grade IIIa, intra-abdominal lymph nodes
<b>C82.34</b>	Follicular lymphoma grade IIIa, lymph nodes of axilla and upper limb
<b>C82.35</b>	Follicular lymphoma grade IIIa, lymph nodes of inguinal region and lower limb
<b>C82.36</b>	Follicular lymphoma grade IIIa, intrapelvic lymph nodes
<b>C82.37</b>	Follicular lymphoma grade IIIa, spleen
<b>C82.38</b>	Follicular lymphoma grade IIIa, lymph nodes of multiple sites
<b>C82.39</b>	Follicular lymphoma grade IIIa, extranodal and solid organ sites
<b>C82.40</b>	Follicular lymphoma grade IIIb, unspecified site
<b>C82.41</b>	Follicular lymphoma grade IIIb, lymph nodes of head, face, and neck
<b>C82.42</b>	Follicular lymphoma grade IIIb, intrathoracic lymph nodes
<b>C82.43</b>	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes
<b>C82.44</b>	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb

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<b>C82.45</b>	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb
<b>C82.46</b>	Follicular lymphoma grade IIIb, intrapelvic lymph nodes
<b>C82.47</b>	Follicular lymphoma grade IIIb, spleen
<b>C82.48</b>	Follicular lymphoma grade IIIb, lymph nodes of multiple sites
<b>C82.49</b>	Follicular lymphoma grade IIIb, extranodal and solid organ sites
<b>C82.50</b>	Diffuse follicle center lymphoma, unspecified site
<b>C82.51</b>	Diffuse follicle center lymphoma, lymph nodes of head, face, and neck
<b>C82.52</b>	Diffuse follicle center lymphoma, intrathoracic lymph nodes
<b>C82.53</b>	Diffuse follicle center lymphoma, intra-abdominal lymph nodes
<b>C82.54</b>	Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb
<b>C82.55</b>	Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb
<b>C82.56</b>	Diffuse follicle center lymphoma, intrapelvic lymph nodes
<b>C82.57</b>	Diffuse follicle center lymphoma, spleen
<b>C82.58</b>	Diffuse follicle center lymphoma, lymph nodes of multiple sites
<b>C82.59</b>	Diffuse follicle center lymphoma, extranodal and solid organ sites
<b>C82.60</b>	Cutaneous follicle center lymphoma, unspecified site
<b>C82.61</b>	Cutaneous follicle center lymphoma, lymph nodes of head, face, and neck
<b>C82.62</b>	Cutaneous follicle center lymphoma, intrathoracic lymph nodes
<b>C82.63</b>	Cutaneous follicle center lymphoma, intra-abdominal lymph nodes
<b>C82.64</b>	Cutaneous follicle center lymphoma, lymph nodes of axilla and upper limb
<b>C82.65</b>	Cutaneous follicle center lymphoma, lymph nodes of inguinal region and lower limb
<b>C82.66</b>	Cutaneous follicle center lymphoma, intrapelvic lymph nodes
<b>C82.67</b>	Cutaneous follicle center lymphoma, spleen
<b>C82.68</b>	Cutaneous follicle center lymphoma, lymph nodes of multiple sites
<b>C82.69</b>	Cutaneous follicle center lymphoma, extranodal and solid organ sites
<b>C82.80</b>	Other types of follicular lymphoma, unspecified site
<b>C82.81</b>	Other types of follicular lymphoma, lymph nodes of head, face, and neck
<b>C82.82</b>	Other types of follicular lymphoma, intrathoracic lymph nodes
<b>C82.83</b>	Other types of follicular lymphoma, intra-abdominal lymph nodes
<b>C82.84</b>	Other types of follicular lymphoma, lymph nodes of axilla and upper limb



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<b>C82.85</b>	Other types of follicular lymphoma, lymph nodes of inguinal region and lower limb
<b>C82.86</b>	Other types of follicular lymphoma, intrapelvic lymph nodes
<b>C82.87</b>	Other types of follicular lymphoma, spleen
<b>C82.88</b>	Other types of follicular lymphoma, lymph nodes of multiple sites
<b>C82.89</b>	Other types of follicular lymphoma, extranodal and solid organ sites
<b>C82.90</b>	Follicular lymphoma, unspecified, unspecified site
<b>C82.91</b>	Follicular lymphoma, unspecified, lymph nodes of head, face, and neck
<b>C82.92</b>	Follicular lymphoma, unspecified, intrathoracic lymph nodes
<b>C82.93</b>	Follicular lymphoma, unspecified, intra-abdominal lymph nodes
<b>C82.94</b>	Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb
<b>C82.95</b>	Follicular lymphoma, unspecified, lymph nodes of inguinal region and lower limb
<b>C82.96</b>	Follicular lymphoma, unspecified, intrapelvic lymph nodes
<b>C82.97</b>	Follicular lymphoma, unspecified, spleen
<b>C82.98</b>	Follicular lymphoma, unspecified, lymph nodes of multiple sites
<b>C82.99</b>	Follicular lymphoma, unspecified, extranodal and solid organ sites
<b>C83.30</b>	Diffuse large B-cell lymphoma, unspecified site
<b>C83.31</b>	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
<b>C83.32</b>	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
<b>C83.33</b>	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
<b>C83.34</b>	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
<b>C83.35</b>	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
<b>C83.36</b>	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
<b>C83.37</b>	Diffuse large B-cell lymphoma, spleen
<b>C83.38</b>	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
<b>C83.39</b>	Diffuse large B-cell lymphoma, extranodal and solid organ sites
<b>C91.00</b>	Acute lymphoblastic leukemia not having achieved remission
<b>C91.02</b>	Acute lymphoblastic leukemia, in relapse
<b>Z51.12</b>	Encounter for antineoplastic immunotherapy

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8. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 4.2023; February 5, 2024). © 2021 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>



Policy and Procedure

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**REVISION LOG:**

<b>REVISIONS</b>	<b>DATE</b>
Creation date	3/30/2018
Annual Review	3/15/2019
CPT Code Change	6/21/2019
Annual Review	6/23/2020
Pharmacy update	10/29/2020
Annual Review	4/30/2021
Annual Review	4/30/2022
Annual Review and Update	4/25/2023
Annual Review	4/23/2024
Update LOBs to remove Medicare and Ultracare	8/9/2024

**Approved:**

**Date:**

**Approved:**

**Date:**

**David Ackman, MD**  
**VP of Medical Directors**

**Sanjiv Shah, MD**  
**Chief Medical Officer**



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**Medical Guideline Disclaimer:**

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