Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Tisagenlecleucel (Kymriah®)	MP-RX-FP-114-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drug

Service Description

This document addresses the use of Tisagenlecleucel (Kymriah®), a CD19-directed genetically modified autologous T-cell immunotherapy approved by the Food and Drug Administration (FDA) for the treatment of certain patients with B-cell precursor acute lymphoblastic leukemia (ALL), large B-cell lymphoma including diffuse large B-cell lymphoma (DLBCL), and Follicular Lymphome.

Background Information

The FDA approved indicotions for Kymriah include individuals up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (also called acute lymphocytic leukemia) that is refractory or in second or later relapse, for adults with relapsed or refractory 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 from follicular lymphoma, and for adults with relapsed or refractory follicular lymphoma after two or more line of systemic therapy.

Kymriah is a CD19-directed genetically-modified autologous T-cell immunotherapy, also known as chimeric antigen receptor (CAR) T- cell therapy. CAR T-cells are made by first collecting T-cells from the patient. The cells are then sent to a laboratory where they are genetically engineered to produce chimeric antigen receptors. The modified T-cells, now known as CAR T-cells, have the ability to better recognize an antigen (the CD19 protein) on targeted tumor cells. After the CAR T-cells have multiplied in the laboratory, they are then infused back into the patient. The modified CAR T-cells help the body's immune system better target and treat the tumor cells.

Kymriah has a black box warning for cytokine release syndrome (CRS), and should not be administered in patients with active infection or inflammatory disorders due to risk of life-threatening reactions and death. Severe or life-threatening CRS should be treated with tocilizumab with or without corticosteroids. Kymriah also has black box warning for causing neurological toxicities, which could also be severe and life-threatening. Monitoring for neurological events after administration is recommended. Due to these black box warnings, Kymriah is only available through a Risk Evaluation and Mitigation Strategy (REMS) program.

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Definitions and Measures

- Allogeneic cells: Harvested from a histocompatible donor. Autologous cells: Harvested from the individual's own cells.
- Bone marrow: A spongy tissue located within flat bones, including the hip and breast bones and the skull. This tissue contains stem cells, the precursors of platelets, red blood cells, and white cells.
- Chemotherapy: The medical treatment of a disease, particularly cancer, with drugs or other chemicals. Chimerism: Cell populations derived from different individuals; may be mixed or complete.
- Complete Response (CR): The disappearance of all signs of cancer as a result of treatment; also called complete remission; does not indicate the cancer has been cured.
- Cytotoxic: Treatment that is destructive to cells, preventing their reproduction or growth.
- ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:
    - 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, for example, light house work, 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
- Hematopoietic stem cells: Primitive cells capable of replication and formation into mature blood cells in order to repopulate the bone marrow.
- Karnofsky Performance Status: A scale and criteria used by doctors and researchers to assess an individual's prognosis, measure changes in their function and abilities, and determine their ability to tolerate therapies. The lower the score (from 0-100), the worse the likelihood of survival.
    - 100 = Normal, no complaints
    - 90 = Able to carry on normal activities
    - 80 = Normal activity with effort
    - 70 = Care for self. Unable to carry on normal activity or to do active work
    - 60 = Requires occasional assistance, but able to care for most of his needs
    - 50 = Requires considerable assistance and frequent medical care
    - 40 = Disabled. Requires special care and assistance
    - 30 = Severely disabled. Hospitalization indicated though death nonimminent
    - 20 = Very sick. Hospitalization necessary. Active supportive treatment necessary
    - 10 = Moribund
    - 0 = Dead

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- Lansky Score: A measure of the individuals overall physical health, judged by their level of activity; the score uses the following scale (generally reserved for individuals less than 16 years of age):
    - 100 Fully active, normal
    - 90 Minor restrictions in physically strenuous activity
    - 80 Active, but tires more quickly
    - 70 Both greater restriction of and less time spent in play activity
    - 60 Up and around, but minimal active play; keeps busy with quieter activities
    - 50 Gets dressed but lies around much of the day, no active play but able to participate in all quiet play and activities
    - 40 Mostly in bed; participates in quiet activities
    - 30 In bed; needs assistance even for quiet play
    - 20 Often sleeping; play entirely limited to very passive activities
    - 10 No play; does not get out of bed
    - 0 Unresponsiv
- 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 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 treatment (second-line therapy) 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.
- Tyrosine kinase inhibitor: Type of drug which works by blocking several enzymes that promote cell growth, which has been found to be an effective approach to treat a variety of cancers. Examples include imatinib (Gleevec), dasatinib (Sprycel), nilotinib (Tasigna), bosutinib (Bosulif), and ponatinib (Iclusig).

Approved Indications

Tisagenlecleucel (Kymriah®) FDA-approved indications include:

- 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.
- Treatment of 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. It is important to note that Kymriah is not indicated for the treatment of patients with primary central nervous system lymphoma.

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- Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This particular 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.

Other Uses

None

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
Q2042	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose [Kymriah]

CPT	Description
0537T	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day [for Kymriah]
0538T	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage) [for Kymriah]
0539T	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration [for Kymriah]
0540T	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous [for Kymriah]

ICD-10 Procedure	Description
XW033C3	Introduction of engineered autologous chimeric antigen receptor T-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3 [when specified as Kymriah]
XW043C3	Introduction of engineered autologous chimeric antigen receptor T-cell immunotherapy into central vein, percutaneous approach, new technology group 3 [when specified as Kymriah]

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ICD-10 Diagnosis	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
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.02	Acute lymphoblastic leukemia, in relapse
Z51.12	Encounter for antineoplastic immunotherapy

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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Tisagenlecleucel (Kymriah®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

Requests for Kymriah (tisagenlecleucel) for B-cell **acute lymphoblastic leukemia** may be approved if the following criteria are met:

i. Individual is 25 years of age or younger; **AND**
ii. Individual has diagnosis of B-cell acute lymphoblastic leukemia; **AND**
iii. Individual has confirmed CD19 tumor expression; **AND**
iv. Individual has relapsed or refractory disease defined by any of the following (NCT02228096):
    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 1 cycle of standard chemotherapy for relapse leukemia; **AND**
v. If individual has Philadelphia chromosome positive (Ph+) ALL, confirmation of trial and inadequate response or intolerance to at least two tyrosine kinase inhibitor (TKI) therapies, or TKI therapy is contraindicated (NCCN 2A, NCT02228096); **AND**
vi. Individual has a Karnofsky or Lansky performance score of greater than or equal to 50%; **AND**
vii. Individual has not received prior treatment with CAR T-cell therapy or other genetically modified T-cell therapy; **AND**
viii. Individual is using as a one-time, single administration treatment.

Requests for Kymriah (tisagenlecleucel) for **large B-cell lymphoma** may be approved if the following criteria are met:

i. Individual is 18 years of age or older; **AND**
ii. Individual has a histologically confirmed diagnosis of one of the following:
    A. Diffuse large B-cell lymphoma (DLBCL), not otherwise specified; **OR**
    B. High-grade B-cell lymphoma; **OR**
    C. DLBCL from follicular lymphoma; **OR**

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D. Monomorphic Post-transplant lymphoproliferative (B-cell type) disorders (NCCN 2A); **OR**
E. AIDS-Related B-cell Lymphomas (NCCN 2A); **OR**
F. Histologic Transformation of Indolent Lymphomas to DLBCL (NCCN 2A); **AND**

iii. Relapsed or refractory disease, defined as progression after two or more lines of systemic therapy (which may or may not include therapy supported by autologous stem cell transplant), including all of the following:
A. An anthracycline-containing chemotherapy regimen; **AND**
B. Rituximab; **AND**

iv. Individual has adequate bone marrow reserve without transfusion defined by *all* of the following:
A. Absolute neutrophil count (ANC) ≥ 1000 cells/uL; **AND**
B. Absolute lymphocyte count (ALC) > 300 cells/uL; **AND**
C. Platelet count ≥ 50,000 cells/uL; **AND**
D. Hemoglobin > 8.0 g/dl; **AND**

v. If individual has a history of an allogeneic stem cell transplant, there are no signs of active graft versus host disease (GVHD);
vi. **AND**
vii. Individual has not received prior treatment with CAR T-cell therapy or other genetically modified T-cell therapy; **AND**
viii. Individual has a current ECOG performance status of 0-1; **AND**
ix. Individual is using as a one-time, single administration treatment.

Requests for Kymriah (tisagenlecleucel) for **Follicular Lymphoma** may be approved if the following criteria are met (NCT03568461):

i. Individual is 18 years of age or older; **AND**
ii. Individual has received ≥ 2 prior lines of systemic therapy or autologous hematopoietic stem cell transplant (HSCT); **AND**
iii. Individual has an ECOG performance status of 0-1; **AND**
iv. Individual has a history of an allogeneic stem cell transplant, there are no signs of active graft versus host disease (GVHD); **AND**
v. Individual has not received prior treatment with CAR T-cell therapy or other genetically modified T-cell therapy; AND
vi. Individual is using as a one-time, single administration treatment

B. Criteria For Continuation of Therapy

i. Further treatment with Kymriah will not be authorized since it is designated for a single-dose administration as per its indication.

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C. Authorization Duration

i. Initial Approval Duration: 3 months (1 dose only, tocilizumab (Actemra) will be approved if requested)
ii. Reauthorization Approval Duration: Not applicable

D. **Conditions Not Covered**

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Kymriah (tisagenlecleucel) for B-cell acute lymphoblastic leukemia may not be approved for the following (Label, NCT02228096):

i. Repeat administration; **OR**
ii. Using in combination with other chemotherapy agents (not including the use of lymphodepleting chemotherapy as labeled prior to Kymriah infusion); **OR**
iii. If prescribed in combination with other CAR T-cell immunotherapy (e.g. Abecma, Breyanzi, Carvykti, Kymriah, Yescarta); **OR**
iv. Active central nervous system (CNS) 3 leukemia (CNS-3) found in cerebral spinal fluid (CSF), defined as white blood cell (WBC) count greater than or equal to 5 WBC/mcL with presence of lymphoblasts (NCCN); **OR**
v. Other forms of active CNS-3 leukemia with CSF involvement, such as CNS parenchymal or ocular disease, cranial nerve involvement, or significant leptomeningeal disease; **OR**
vi. Any acute or ongoing neurologic toxicity greater than Grade 1 as defined by the National Cancer Institute (NCI CTCAE v.5), not including history of controlled seizures or fixed neurologic deficits that have been stable/improving over the past three months; **OR**
vii. Diagnosis of Burkitt's lymphoma/leukemia; **OR**
viii. Active or latent hepatitis B, active hepatitis C, human immunodeficiency virus (HIV) positive, or other active, uncontrolled infection; **OR**
ix. Active neurological autoimmune or inflammatory disorders (for example, Guillain Barre Syndrome, Amyotrophic Lateral Sclerosis) (Label, NCT02445248); **OR**
x. Individual has active GVHD; **OR**
xi. When the above criteria are not met, and for all other indications.

Kymriah (tisagenlecleucel) for large B-cell lymphoma may not be approved for the following (Label, NCT02445248):

i. Repeat administration; **OR**
ii. Diagnosis of primary central nervous system lymphoma; **OR**
iii. Cardiac ejection fraction (EF) less than 40%, or other clinically significant cardiac disease; **OR**

iv. Using in combination with other chemotherapy agents (not including the use of lymphodepleting chemotherapy as labeled prior to Kymriah infusion); **OR**
v. Diagnosis of Burkitt's lymphoma/leukemia (NCT02228096); **OR**
vi. If prescribed in combination with other CAR T-cell immunotherapy (e.g. Abecma, Breyanzi, Carvykti, Tecartus, Yescarta); **OR**
vii. Individual has active GVHD; **OR**
viii. Active or latent hepatitis B, active hepatitis C, human immunodeficiency virus (HIV) positive, or other active, uncontrolled infection; **OR**
ix. Active neurological autoimmune or inflammatory disorders (for example, Guillain Barre Syndrome, Amyotrophic Lateral Sclerosis); **OR**
x. When the above criteria are not met, and for all other indications.

Kymriah (tisagenlecleucel) for Follicular Lymphoma may not be approved for the following criteria (NCT03568461):

xi. Repeat administration; **OR**
xii. Evidence of histologic transformation; **OR**
xiii. Individual has a diagnosis of follicular lymphoma, grade 3B; **OR**
xiv. Individual has active CNS involvement by malignancy; **OR**
xv. Active neurological autoimmune or inflammatory disorders (for example, Guillan – Barre syndrome, amyotrophic lateral sclerosis); **OR**
xvi. Using in combination with other chemotherapy agents (not including the use of lymphodepleting chemotherapy prior to infusion); **OR**
xvii. If prescribed in combination with other CAR T-cell immunotherapy (e.g. Abecma, Breyanzi, Carvykti, Kymriah, Tecartus); OR
xviii. Individual has active GVHD; **OR**
xix. When the above criteria are not met, and for all other indications.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

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B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing Schedule
Pediatric and Young Adult B-cell ALL (up to 25 years of age)	- For patients 50 kg or less, administer 0.2 to 5.0 x 106 CAR-positive viable T cells per kg body weight intravenously. - For patients above 50 kg, administer 0.1 to 2.5 x 108 total CAR- positive viable T cells (non-weight based) intravenously.
Adult Relapsed or Refractory Diffuse Large B-cell Lymphoma and Follicular Lymphoma	Recommended dose is 0.6 to 6.0 x 108 CAR-positive viable T cells intravenously

Additional Dosing Information

- Kymriah is designated for autologous administration via intravenous infusion solely within a certified healthcare setting.
- **Pretreatment**: Kymriah should be initiated 2 days after completing lymphodepleting chemotherapy regimen with cyclophosphamide 250 mg/m^2/day intravenously (IV) and fludarabine 25 mg/m^2/day IV for 3 days. In cases where a patient has previously had Grade 4 hemorrhagic cystitis with cyclophosphamide or has shown resistance to a previous regimen containing cyclophosphamide, an alternative lymphodepleting chemotherapy option is to administer bendamustine at a dose of 90 mg/m2 intravenously daily for 2 days. Lymphodepleting chemotherapy may be omitted if a patient is experiencing significant cytopenia.
- **Premedication** should include acetaminophen and diphenhydramine (or another H1-antihistamine) approximately 30 to 60 minutes before infusion of Kymriah. Prophylactic use of systemic corticosteroids should be avoided, as the use may interfere with the activity of Kymriah.
- **Post-medication**: Tocilizumab plays an important role in the treatment of patients receiving CAR T-cell therapy such as Kymriah. It manages and mitigates cytokine release syndrome (CRS), which can occur after CAR T-cell infusion. Tocilizumab should be available to the patient prior to infusion and during the recovery period.

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Reference Information

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3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 13, 2021.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Fowler NH, Dickinson M, Dreyling M, et al. Tisagenlecleucel in adult relapsed or refractory follicular lymphoma: the phase 2 ELARA trial [published online ahead of print, 2021 Dec 17]. *Nat Med*. 2021;10.1038/s41591-021-01622-0. doi:10.1038/s41591-021-01622- 0
6. Jain T, Bar M, Kansagra AJ, et al., Use of Chimeric Antigen Receptor T Cell Therapy in Clinical Practice for Relapsed/Refractory Aggressive B Cell Non-Hodgkin Lymphoma: An Expert Panel Opinion from the American Society for Transplantation and Cellular Therapy. Biol Blood Marrow Transplant. 2019 Dec;25(12):2305-2321. doi: 10.1016/j.bbmt.2019.08.015. Epub 2019 Aug 22. PMID: 31446199. Accessed October 13, 2021.
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8. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 13, 2021.
    a. Acute Lymphoblastic Leukemia. V2.2021. Revised July 19, 2021.
    b. B-Cell Lymphomas. V5.2021. Revised September 22, 2021.
    c. Pediatric Acute Lymphoblastic Leukemia. V1.2022. Revised October 1, 2021.
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10. NCT02445248. ClinicalTrials.gov. U.S National Library of Medicine, National Institutes of Health website. Available at https://clinicaltrials.gov/ct2/show/NCT02445248?term=nct02445248&rank=1.
11. NCT03568461. ClinicalTrials.gov. U.S National Library of Medicine, National Institutes of Health website. Available at https://clinicaltrials.gov/ct2/show/NCT03568461.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Adopted from Elevance	N/A	12/22/2023
Select Review	Update statement for criteria for initial approval: Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met all approval criteria.	3/25/2024	5/9/2024

Revised: 11/30/2023