Kymriah® (tisagenlecleucel)
(Intravenous)

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Document Number: IC-0452

Last Review Date: 12/07/2023
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I. Length of Authorization

Coverage will be provided for one treatment course (1 dose of Kymriah) and may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 1 dose of up to 600 million CAR-positive viable T-cells *(supplied as 1-3 infusion bags)*

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit (1 infusion of up to 600 million CAR-positive viable T-cells)

III. Initial Approval Criteria [1,4-7]

Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e. genetic and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

- Patient does not have an active infection or inflammatory disorder; **AND**
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during tisagenlecleucel treatment and until immune recovery following treatment; **AND**
- Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection will be followed according to local guidelines; **AND**

- Healthcare facility has enrolled in the Kymriah REMS Program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
- Patient has not received prior CAR-T therapy; **AND**
- Patient has not received other anti-CD19 therapy (e.g., blinatumomab, tafasitamab, loncastuximab tesirine, etc.) OR patient previously received other anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy while awaiting manufacture); **AND**

Adult B-Cell Precursor Acute Lymphoblastic Leukemia (ALL) † Φ [1,8,10-13]

- Patient is 18 to 25 years of age; **AND**
    - Patient has Philadelphia chromosome (Ph)-positive disease; **AND**
        - Patient has refractory disease; **AND**
            - Disease is intolerant or refractory to at least two (2) tyrosine kinase inhibitors (e.g., dasatinib, imatinib, ponatinib, nilotinib, or bosutinib), unless contraindicated; **OR**
        - Disease is in second or greater relapse and previous therapy has included two (2) tyrosine kinase inhibitors (e.g., dasatinib, imatinib, ponatinib, nilotinib, or bosutinib); **OR**
    - Patient has Philadelphia chromosome (Ph)-negative disease; **AND**
        - Disease is refractory or in second or later relapse

Pediatric B-Cell Precursor Acute Lymphoblastic Leukemia (ALL) † Φ [1,8,10-13]

- Patient is 2 to 17 years of age; **AND**
    - Patient has Philadelphia chromosome (Ph)-positive disease; **AND**
        - Disease is intolerant or refractory to at least two (2) tyrosine kinase inhibitors (e.g., dasatinib, imatinib, etc.), unless contraindicated; **OR**
        - Patient has relapsed disease post-hematopoietic stem cell transplant (HSCT); **OR**
    - Patient has Philadelphia chromosome (Ph)-negative disease; **AND**
        - Disease is refractory or in second or later relapse

B-Cell Lymphomas † ‡ Φ [1,3,8,9,14-16]

- Patient is at least 18 years of age; **AND**
- Patient has an ECOG performance status of 0-1; **AND**
- Patient does not have primary central nervous system lymphoma; **AND**
    - Patient has follicular lymphoma (grade 1, 2, or 3A); **AND**

- Patient has received at least two (2) prior lines of systemic therapy which must have included an anti-CD20 antibody and an alkylating agent; **AND**
- Patient has had partial or no response OR has relapsed, refractory, or progressive disease; **OR**

- Patient has histologic transformation of follicular lymphoma or nodal marginal zone lymphoma to diffuse large B-cell lymphoma (DLBCL); **AND**
  - Patient has received at least two (2) prior lines of chemoimmunotherapy for indolent or transformed disease which must have included an anthracycline and rituximab; **OR**
- Patient has DLBCL; **AND**
  - Patient has received at least two (2) prior lines of therapy which must have included an anthracycline and rituximab; **AND**
    - Used as additional therapy for relapsed or refractory disease >12 months after completion of first-line therapy if partial response following second-line therapy; **OR**
    - Used for treatment of disease that is in second or greater relapse in patients with partial response, no response, or progressive disease following therapy for relapsed or refractory disease; **OR**
- Patient has high-grade B-cell lymphoma; **AND**
  - Patient has received at least two (2) prior lines of therapy which must have included an anthracycline and rituximab; **AND**
    - Used as additional therapy for relapsed or refractory disease >12 months after completion of first-line therapy in patients with intention to proceed to transplant who have a partial response following second-line therapy; **OR**
    - Used for treatment of disease that is in second or greater relapse in patients with partial response, no response, or progressive disease following therapy for relapsed or refractory disease

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria

Coverage cannot be renewed.

V. Dosage/Administration [1]

Indication	Dose
B-Cell Precursor ALL	<u>Lymphodepleting chemotherapy:</u> • Administer fludarabine (30 mg/m^2 intravenous daily for 4 days) and cyclophosphamide (500 mg/m^2 intravenous daily for 2 days starting with the first dose of fludarabine). <u>Kymriah infusion:</u> • Infuse 2 to 14 days after completion of lymphodepleting chemotherapy • Kymriah is provided in a single-dose unit containing chimeric antigen receptor (CAR)-positive viable T cells* based on the patient weight reported at the time of leukapheresis: o Patients ≤ 50 kg: administer 0.2 to 5.0 x 10^6 CAR-positive viable T cells per kg body weight o Patients > 50 kg: administer 0.1 to 2.5 x 10^8 CAR-positive viable T cells
B-Cell Lymphomas	<u>Lymphodepleting chemotherapy *(lymphodepleting chemotherapy may be omitted if a patient's white blood cell [WBC] count is less than 1 x 10^9/L within 1 week prior to Kymriah infusion)*:</u> • Administer fludarabine (25 mg/m^2 intravenous daily for 3 days) and cyclophosphamide (250 mg/m^2 intravenous daily for 3 days starting with the first dose of fludarabine); **OR** • Administer bendamustine (90 mg/m^2 intravenous daily for 2 days) if the patient experienced a previous Grade 4 hemorrhagic cystitis with cyclophosphamide or demonstrates resistance to a previous cyclophosphamide containing regimen <u>Kymriah infusion:</u> • Follicular Lymphoma: Infuse 2 to 6 days after completion of lymphodepleting chemotherapy. • All other B-Cell Lymphomas: Infuse 2 to 11 days after completion of lymphodepleting chemotherapy • Kymriah is provided in a single-dose unit containing chimeric antigen receptor (CAR)-positive viable T cells* based on the patient weight reported at the time of leukapheresis: o Administer 0.6 to 6.0 x 10^8 CAR-positive viable T cells
For autologous use only. For intravenous use only. • Kymriah is prepared from the patient's peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure • One treatment course consists of lymphodepleting chemotherapy followed by a single infusion of Kymriah • Confirm Kymriah availability prior to starting the lymphodepleting regimen. • Confirm the patient's identity with the patient identifiers on each KYMRIAH infusion bag(s). • Delay the infusion of Kymriah after lymphodepleting chemotherapy for unresolved serious adverse reactions from preceding chemotherapies (including pulmonary toxicity, cardiac toxicity, or	

hypotension), active uncontrolled infection, active graft versus host disease (GVHD), or worsening of leukemia burden.
Premedication: • Premedicate with acetaminophen and diphenhydramine (or another H1-antihistamine) 30-60 minutes prior to infusion. Avoid prophylactic system corticosteroids which may interfere with Kymriah activity. **Monitoring after infusion:** • Monitor patients 2-3 times during the first week following KYMRIAH infusion at the certified healthcare facility for signs and symptoms of CRS and neurologic toxicities. • Instruct patients to remain within proximity of the certified healthcare facility for at least 4 weeks following infusion. • Instruct patients to refrain from driving or hazardous activities for at least 8 weeks following infusion.
• *See the Certificate of Analysis (CoA) for the actual number of chimeric antigen receptor (CAR)-positive T cells in the product. • Store infusion bag(s) in the vapor phase of liquid nitrogen (less than or equal to minus 120°C) in a temperature-monitored system. Thaw prior to infusion. • In case of manufacturing failure, a second manufacturing may be attempted. • Additional bridging chemotherapy may be necessary between leukapheresis and lymphodepleting chemotherapy. • Tocilizumab must be available on site prior to infusion if needed for the treatment of CRS (2 doses minimum) • Biosafety guidelines must be followed. Product contains human cells genetically modified with a lentivirus. Employ universal precautions when handling.

VI. Billing Code/Availability Information

HCPCS Code:

- Q2042 – Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

NDC(s):

- Kymriah suspension for intravenous infusion (Ped ALL); 1 infusion bag (10 to 50 mL): 00078-0846-xx
- Kymriah suspension for intravenous infusion (DLBCL and FL); 1 infusion bag (10 to 50 mL): 00078-0958-xx

VII. References (STANDARD)

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VIII. References (ENHANCED)

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C82.00	Follicular lymphoma grade I, unspecified site
C82.01	Follicular lymphoma grade I, lymph nodes of head, face and neck
C82.02	Follicular lymphoma, grade I, intrathoracic lymph nodes
C82.03	Follicular lymphoma grade I, intra-abdominal lymph nodes
C82.04	Follicular lymphoma grade I, lymph nodes of axilla and upper limb
C82.05	Follicular lymphoma grade I, lymph nodes of inguinal regional and lower limb
C82.06	Follicular lymphoma grade I, intrapelvic lymph nodes
C82.07	Follicular lymphoma grade I, spleen
C82.08	Follicular lymphoma grade I, lymph nodes of multiple sites
C82.09	Follicular lymphoma grade I, extranodal and solid organ sites
C82.10	Follicular lymphoma grade II, unspecified site
C82.11	Follicular lymphoma grade II, lymph nodes of head, face and neck
C82.12	Follicular lymphoma, grade II, intrathoracic lymph nodes
C82.13	Follicular lymphoma grade II, intra-abdominal lymph nodes
C82.14	Follicular lymphoma grade II, lymph nodes of axilla and upper limb
C82.15	Follicular lymphoma grade II, lymph nodes of inguinal region and lower limb
C82.16	Follicular lymphoma grade II, intrapelvic lymph nodes
C82.17	Follicular lymphoma grade II, spleen
C82.18	Follicular lymphoma grade II, lymph nodes of multiple sites
C82.19	Follicular lymphoma grade II, extranodal and solid organ sites
C82.20	Follicular lymphoma grade III, unspecified, unspecified site
C82.21	Follicular lymphoma grade III, unspecified, lymph nodes of head, face and neck
C82.22	Follicular lymphoma, grade III, unspecified, intrathoracic lymph nodes
C82.23	Follicular lymphoma grade III, unspecified, intra-abdominal lymph nodes
C82.24	Follicular lymphoma grade III, unspecified, lymph nodes of axilla and upper limb
C82.25	Follicular lymphoma grade III, unspecified, lymph nodes of inguinal region and lower limb
C82.26	Follicular lymphoma grade III, unspecified, intrapelvic lymph nodes
C82.27	Follicular lymphoma grade III, unspecified, spleen
C82.28	Follicular lymphoma grade III, unspecified, lymph nodes of multiple sites
C82.29	Follicular lymphoma grade III, unspecified, extranodal and solid organ sites
C82.30	Follicular lymphoma grade IIIa, unspecified site
C82.31	Follicular lymphoma grade IIIa, lymph nodes of head, face and neck
C82.32	Follicular lymphoma, grade IIIa, intrathoracic lymph nodes

C82.33	Follicular lymphoma grade IIIa, intra-abdominal lymph nodes
C82.34	Follicular lymphoma grade IIIa, lymph nodes of axilla and upper limb
C82.35	Follicular lymphoma grade IIIa, lymph nodes of inguinal region and lower limb
C82.36	Follicular lymphoma grade IIIa, intrapelvic lymph nodes
C82.37	Follicular lymphoma grade IIIa, spleen
C82.38	Follicular lymphoma grade IIIa, lymph nodes of multiple sites
C82.39	Follicular lymphoma grade IIIa, extranodal and solid organ sites
C82.40	Follicular lymphoma grade IIIb, unspecified site
C82.41	Follicular lymphoma grade IIIb, lymph nodes of head, face, and neck
C82.42	Follicular lymphoma grade IIIb, intrathoracic lymph nodes
C82.43	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes
C82.44	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb, intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb, spleen
C82.48	Follicular lymphoma grade IIIb, lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb, extranodal and solid organ sites
C82.50	Diffuse follicle center lymphoma, unspecified site
C82.51	Diffuse follicle center lymphoma, lymph nodes of head, face and neck
C82.52	Diffuse follicle center lymphoma, intrathoracic lymph nodes
C82.53	Diffuse follicle center lymphoma, intra-abdominal lymph nodes
C82.54	Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb
C82.55	Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.56	Diffuse follicle center lymphoma, intrapelvic lymph nodes
C82.57	Diffuse follicle center lymphoma, spleen
C82.58	Diffuse follicle center lymphoma, lymph nodes of multiple sites
C82.59	Diffuse follicle center lymphoma, extranodal and solid organ sites
C82.60	Cutaneous follicle center lymphoma, unspecified site
C82.61	Cutaneous follicle center lymphoma, lymph nodes of head, face and neck
C82.62	Cutaneous follicle center lymphoma, intrathoracic lymph nodes
C82.63	Cutaneous follicle center lymphoma, intra-abdominal lymph nodes
C82.64	Cutaneous follicle center lymphoma, lymph nodes of axilla and upper limb
C82.65	Cutaneous follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.66	Cutaneous follicle center lymphoma, intrapelvic lymph nodes
C82.67	Cutaneous follicle center lymphoma, spleen

C82.68	Cutaneous follicle center lymphoma, lymph nodes of multiple sites
C82.69	Cutaneous follicle center lymphoma, extranodal and solid organ sites
C82.80	Other types of follicular lymphoma, unspecified site
C82.81	Other types of follicular lymphoma, lymph nodes of head, face and neck
C82.82	Other types of follicular lymphoma, intrathoracic lymph nodes
C82.83	Other types of follicular lymphoma, intra-abdominal lymph nodes
C82.84	Other types of follicular lymphoma, lymph nodes of axilla and upper limb
C82.85	Other types of follicular lymphoma, lymph nodes of inguinal region and lower limb
C82.86	Other types of follicular lymphoma, intrapelvic lymph nodes
C82.87	Other types of follicular lymphoma, spleen
C82.88	Other types of follicular lymphoma, lymph nodes of multiple sites
C82.89	Other types of follicular lymphoma, extranodal and solid organ sites
C82.90	Follicular lymphoma, unspecified, unspecified site
C82.91	Follicular lymphoma, unspecified, lymph nodes of head, face and neck
C82.92	Follicular lymphoma, unspecified, intrathoracic lymph nodes
C82.93	Follicular lymphoma, unspecified, intra-abdominal lymph nodes
C82.94	Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb
C82.95	Follicular lymphoma, unspecified lymph nodes of inguinal region and lower limb
C82.96	Follicular lymphoma, unspecified, intrapelvic lymph nodes
C82.97	Follicular lymphoma, unspecified, spleen
C82.98	Follicular lymphoma, unspecified, lymph nodes of multiple sites
C82.99	Follicular lymphoma, unspecified, extranodal and solid organ sites
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
C83.50	Lymphoblastic (diffuse) lymphoma, unspecified site
C83.51	Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck
C83.52	Lymphoblastic (diffuse) lymphoma, intrathoracic lymph nodes

C83.53	Lymphoblastic (diffuse) lymphoma, intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma, lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma, lymph nodes of inguinal region and lower limb
C83.56	Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes
C83.57	Lymphoblastic (diffuse) lymphoma, spleen
C83.58	Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites
C83.59	Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites
C85.10	Unspecified B-cell lymphoma, unspecified site
C85.11	Unspecified B-cell lymphoma, lymph nodes of head, face, and neck
C85.12	Unspecified B-cell lymphoma, intrathoracic lymph nodes
C85.13	Unspecified B-cell lymphoma, intra-abdominal lymph nodes
C85.14	Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb
C85.15	Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.16	Unspecified B-cell lymphoma, intrapelvic lymph nodes
C85.17	Unspecified B-cell lymphoma, spleen
C85.18	Unspecified B-cell lymphoma, lymph nodes of multiple sites
C85.19	Unspecified B-cell lymphoma, extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma lymph nodes of head, face, and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma extranodal and solid organ sites
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC