Tisagenlecleucel (Kymriah)	Place of Service **Outpatient Facility Administration** **Hospital Administration** **HCPCS**: **Q2042** per up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Condition listed in policy (*see criteria for details*)

- Acute lymphoblastic leukemia (B-cell precursor)
- B-cell lymphomas *(see criteria for subtypes covered)*
- Follicular lymphoma

AHFS therapeutic class: Antineoplastic-CD19 directed CAR-T cell immunotherapy

Mechanism of action: CD19-directed genetically modified autologous T cell immunotherapy

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Kymriah (tisagenlecleucel) must be sent for clinical review and receive authorization for both tisagenlecleucel and for hospital admission prior to drug administration or claim payment.

Acute lymphoblastic leukemia (B-cell precursor)

1. Diagnosis of B-cell precursor acute lymphoblastic leukemia, **AND**
2. Patient is ≤ 25 years old, **AND**
3. Being used as a single-agent, **AND**
4. Patient has refractory or relapsed disease and meets one of the following:
    a. Primary refractory: Patient did not achieve remission following initial chemotherapy treatment, OR
    b. Chemo-refractory: Patient did not achieve remission following chemotherapy treatment for relapsed disease, OR
    c. Second or greater bone marrow (BM) relapse: Patient experienced relapse following at least a second (or later) remission post-chemotherapy, OR
    d. Patient experienced relapse following hematopoietic stem cell transplant (HSCT), OR
    e. For Philadelphia chromosome-positive (Ph +), treatment failure or intolerance to a tyrosin kinase inhibitor (TKI) drug

Covered Doses
≤50 kg or less: 0.2 to 5.0 x 10^6 CAR-positive viable T cells per kg IV x1
>50 kg: 0.1 to 2.5 x 10^8 total CAR-positive viable T cells (non-weight based) IV x1

Coverage Period
Single infusion per lifetime

ICD-10:
C83.50-C83.59, C91.00, C91.02

B-cell lymphomas

1. Diagnosis of B-cell lymphoma defined as one of the following: diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma or from nodal marginal zone lymphoma, B-cell monomorphic post-transplant lymphoproliferative disorders (PTLD), AIDS-related B-cell lymphomas (DLBCL, primary effusion lymphoma, and HHV8-positive diffuse DLBCL not otherwise specific [NOS], **AND**
2. Patient does not have primary central nervous system lymphoma, **AND**
3. Patient is ≥ 18 years old, **AND**
4. Patient has not received prior treatment with CAR-T therapy, **AND**
5. Being used as single-agent therapy, **AND**
6. Patient has not achieved complete response or has experienced loss of response after receiving at least two prior lines of systemic therapy (with or without prior hematopoietic stem cell transplantation)

Covered Dose
0.6 to 6.0 x 10^8 CAR-positive viable T cells as a single IV infusion

Coverage Period
Once per lifetime

ICD-10:

B20, C83.30-C83.39, C83.80-C83.89, C83.90-C83.99, C85.20-C85.29, C85.80-C85.89, D47.Z1

Follicular lymphoma

1. Patient has received two or more lines of systemic therapy, **AND**
2. Patient has not received prior treatment with CAR-T therapy, including Kymriah, **AND**
3. Being used as a single agent

Covered Doses
0.6 to 6.0 x 10^8 CAR-positive viable T cells as a single IV infusion

Coverage Period
Single infusion per lifetime

ICD-10:
C82.00-C82.09, C82.10-C82.19, C82.20-C82.29, C82.30-C82.39, C82.40-C82.49, C82.50-C82.59, C82.60-C82.69, C82.80-C82.89, C82.90-C82.99, C83.30-C83.39, C85.20-C85.29

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Kymriah (tisagenlecleucel) must be sent for clinical review and receive authorization for both tisagenlecleucel and for hospital admission prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

Per prescribing information
Ped ALL:

- Patients 50 kg or less: 0.2 to 5.0 x 10^6 CAR-positive viable T cells per kg body weight (single dose)
- Patients more than 50 kg: 0.1 to 2.5 x 10^8 CAR-positive viable T cells (single dose)

DLBCL and Follicular lymphoma: 0.6 to 6.0 x 10^8 CAR-postive viable T cells (single-dose)

A Kymriah dose may be contained in up to 3 cryopreserved patient specific infusion bags. Verify the number of bags for the dose with the Certificate of Conformance (CoC) and Certificate of Analysis (CoA).

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Kymriah® (tisagenlecleucel) [Prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 5/2022.
- National Comprehensive Cancer Network. Acute lymphoblastic leukemia (Version 2.2023). Available at: www.nccn.org
- National Comprehensive Cancer Network. B-cell lymphomas (Version 5.2023). Available at: www.nccn.org

- National Comprehensive Cancer Network. Pediatric acute lymphoblastic leukemia (Version 1.2024). Available at: www.nccn.org.

(7) Policy Update

Date of last review: 4Q2023
Date of next review: 4Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee