

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Kymriah (tisagenlecleucel)
BILLING CODE	Q2042
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Inpatient/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see Dosage allowed below
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Kymriah (tisagenlecleucel) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)

For **initial** authorization:

1. Member is 1 to 25 years of age; AND
2. Member has a diagnosis of relapsed or refractory B-cell ALL defined by **one** of the following:
 - a) Second or greater relapse;
 - b) Relapse after allogeneic stem cell transplantation (SCT);
 - c) Primary refractory as defined by not achieving a complete remission (CR) after 2 cycles of a standard chemotherapy regimen or chemorefractory as defined by not achieving a CR after 1 cycle of standard chemotherapy for relapsed leukemia;
 - d) Philadelphia chromosome positive (Ph+) ALL and intolerant to or have failed 2 lines of tyrosine kinase inhibitor (TKI) therapy [e.g. imatinib mesylate (Gleevec), dasatinib (Sprycel)];
 - e) Ineligible for allogeneic SCT; AND
3. Documentation of CD19 tumor expression; AND
4. Bone marrow with $\geq 5\%$ lymphoblasts by morphologic assessment; AND
5. Member has been pre-screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (negative results must be submitted); AND
6. Healthcare facility/provider has enrolled in the Kymriah REMS program; AND
7. Member does **not** have ANY of the following:
 - a) Prior gene or CAR-T cell therapy;
 - b) Life expectancy less than 12 weeks.
8. **Dosage allowed:** Weight 50 kg or less: administer 0.2 to 5.0×10^6 CAR-positive viable T cells per kg body weight intravenously. Weight above 50 kg: administer 0.1 to 2.5×10^8 total CAR-positive viable T cells (non-weight based) intravenously.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Kymriah will not be reauthorized for continued therapy.

LARGE B-CELL LYMPHOMA

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member has a diagnosis of relapsed or refractory large B-cell lymphoma including **one** of the following:
 - a) Diffuse large B-cell lymphoma (DLBCL) not otherwise specified;
 - b) High grade B-cell lymphoma;
 - c) DLBCL arising from follicular lymphoma; AND
3. Member has received 2 or more lines of chemotherapy, including rituximab and anthracycline, and relapsed following autologous hematopoietic stem cell transplantation (SCT) or is not eligible for SCT; AND
4. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
5. Member does **not** have ANY of the following:
 - a) Active central nervous system malignancy involvement;
 - b) Prior allogenic HSCT;
 - c) Prior CAR-T therapy (e.g. Yescarta); AND
6. Member has been pre-screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (negative results must be submitted); AND
7. Healthcare facility/provider has enrolled in the Kymriah REMS program.
8. **Dosage allowed:** Administer 0.6 to 6.0 x 10⁸ CAR-positive viable T cells.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Kymriah will not be reauthorized for continued therapy.

CareSource considers Kymriah (tisagenlecleucel) not medically necessary for the treatment of disease states not included in this document.

DATE	ACTION/DESCRIPTION
10/24/2017	New policy for Kymriah created.
08/27/2018	New indication of Large B-cell lymphoma was added. Criteria expanded for ALL diagnosis for member's disease history requirement.
08/18/2020	Updated billing code. Amended criteria for both diagnoses. ALL: changed lower age limit from 3 years to 1 year. Added #3, 4. Removed TKI's that were listed but not relevant in this context. B cell lymphoma: minor changes. Removed criterion for premedication. Removed some of the exclusion cut offs that appeared to be arbitrary to the controlled trial environment but not necessary to mandate from a utilization management perspective for the clinical setting.
05/27/2021	B cell lymphoma: Removed life expectancy restriction. Added ECOG score.

References:

1. Kymriah [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corp., May 2018.
2. The Leukemia & Lymphoma Society (LLS). Ph-Positive ALL Therapy. Available at <https://www.lls.org/leukemia/acute-lymphoblastic-leukemia/treatment/ph-positive-all-therapy>.
3. ClinicalTrials.gov. Identifier NCT02228096. Study of Efficacy and Safety of CTL019 in Pediatric ALL Patients. Available at <https://clinicaltrials.gov/ct2/show/NCT02228096?term=tisagenlecleucel&rank=1>. Accessed in October, 2017.
4. Schuster SJ, et al. Primary analysis of Juliet: a global, pivotal, phase 2 trial of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma. Blood. 2017;130(s1):577 [Abstract 577 from 2017 ASH annual meeting].

5. Maude SL, et al. Tisagenlecleucel in Children and Young Adults with B-Cell Lymphoblastic Leukemia. *N Engl J Med*. 2018;378(5):439-448. [PubMed 29385370]
6. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia. (Version 2.2020). https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed August 3, 2020.
7. National Comprehensive Cancer Network. B-Cell Lymphomas. (Version 4.2020). https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed August 18, 2020.
8. Schuster SJ, Bishop MR, Tam CS, et al. Tisagenlecleucel in Adult Relapsed or Refractory Diffuse Large B-Cell Lymphoma. *N Engl J Med*. 2019;380(1):45-56. doi:10.1056/NEJMoa1804980
9. Tilly H, Gomes da Silva M, Vitolo U, et al. Diffuse large B-cell lymphoma (DLBCL): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol*. 2015;26 Suppl 5:v116-v125. doi:10.1093/annonc/mdv304
10. Chaganti S, Illidge T, Barrington S, et al. Guidelines for the management of diffuse large B-cell lymphoma. *British Journal of Haematology*. 2016;174:43-56. doi:10.1111/bjh.14136
11. Halford Z, Anderson MK, Bennett LL, Moody J. Tisagenlecleucel in Acute Lymphoblastic Leukemia: A Review of the Literature and Practical Considerations [published online ahead of print, 2020 Aug 7]. *Ann Pharmacother*. 2020;1060028020948165. doi:10.1177/1060028020948165

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