CareSource

PHARMACY POLICY STATEMENT **Georgia 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 ≥ 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 x 10^6CAR-positive viable T cells per kg body weight intravenously. Weight above 50 kg: administer 0.1 to 2.5 x 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 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);
   d) Life expectancy less than 12 weeks; 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.
7. **Dosage allowed:** Administer 0.6 to 6.0 x 10^8 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.

References:

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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]

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