CareSource

PHARMACY POLICY STATEMENT **Georgia Medicaid**	
DRUG NAME	Kymriah (tisagenlecleucel)
BILLING CODE	Q2040 (1 unit = 250 million T cells)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Office
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.

CAR-T CELL IMMUNOTHERAPY (autologous use only)

For **initial** authorization:

1. Member is 25 years of age or younger and has documentation of CD19 tumor expression; AND
2. Member has B-cell acute lymphoblastic leukemia that is refractory or in second or later relapse as defined by **one** of the following:
   a) 2nd or greater Bone Marrow (BM) relapse;
   b) Any BM relapse after allogeneic stem cell transplantation (SCT) and must be >6 months from SCT at the time of CAR-T cell immunotherapy infusion;
   c) Refractory as defined by not achieving a complete remission (CR) after 2 cycles of a standard chemotherapy regimen chemotherapy regimen or chemorefractory as defined by not achieving a CR after 1 cycle of standard chemotherapy for relapse leukemia;
   d) Member with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia that is intolerant to or have failed 2 lines of tyrosine kinase inhibitor (TKI) therapy (e.g. imatinib mesylate (Gleevec), dasatinib (Sprycel), nilotinib (Tasigna) or ponatinib (Iclusig)), or if TKI therapy is contraindicated;
   e) Member is not eligible for allogeneic SCT; AND
3. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (leukapheresis); AND
4. Healthcare facility/provider has enrolled in the Kymriah REMS and has training on the management of cytokine release syndrome (CRS) and neurological toxicities; AND
5. Member must be premedicated with acetaminophen and an H1-antihistamine, and tocilizumab (Actemra) must be available in healthcare facility prior to infusion; AND
6. Member has a life expectancy >12 weeks; AND
7. Member has not received prior CAR-T therapy.
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.

CareSource considers Kymriah (tisagenlecleucel) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
10/24/2017	New policy for Kymriah created.
12/21/2017	Member's age requirement adjusted to 25 years of age or younger.

References:

1. Kymriah [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corp., August 2017. Accessed October 2017.
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.

Effective date: 01/31/2018
Revised date: 12/21/2017