MEDICAL POLICY STATEMENT
INDIANA MARKETPLACE

Policy Name	Policy Number	Date Effective
CAR-T medications – Kymriah (tisagenlecleucel)	MM-1122	07/01/2021-05/31/2022

Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

Table of Contents

A. Subject

CAR-T medications – Kymriah (tisagenlecleucel)

B. Background

Chimeric antigen receptor T cell therapy (CAR-T) is an autologous T-cell immunotherapy. The member's own T lymphocytes are genetically modified with a gene that encodes a CAR-T to the T cells which can then target the lymphoma cells. Once the member's T cells are modifier, the T cells are infused back into the member.

CAR-T is associated with severe complications and may be life-threatening. These complications include cytokine release syndrome and neurological toxicities. Therefore, CAR-T therapy administration should be based on clinical benefits, potential long-term disease control, and toxicity.

This policy is to define medically necessary criteria for Kymriah.

C. Definitions

- **Risk Evaluation and Mitigation Strategy (REMS)** - A drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication.

D. Policy

I. Kymriah
   A. Kymriah may be approved for 3 months.
   B. Kymriah will not be reauthorized for continued therapy.
   C. Kymriah is limited to one infusion per lifetime.

II. Kymriah is a non-preferred product and will only be considered for coverage under the medical benefit when either of the following medically necessary criteria are met:
   A. Diagnosis of Acute lymphoblastic Leukemia and all of the following criteria:
      1. Member is 1 to 25 years of age;
      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)];or
         e. Ineligible for allogeneic SCT;

3.
4. Documentation of CD19 tumor expression;
5. Bone marrow with ≥ 5% lymphoblasts by morphologic assessment;
   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);
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; or
   b. Life expectancy less than 12 weeks.

OR

B. Diagnosis of Large B-cell lymphoma and all of the following criteria:
   1. Member is 18 years of age or older;
   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; or
      c. DLBCL arising from follicular lymphoma;
   3. Member has received 2 or more lines of chemotherapy, including rituximab and anthracycline, and relapsed following autologous hematopoietic stem cell transplantation (HSCT) or is not eligible for HSCT;
   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);or
      d. Life expectancy less than 12 weeks;
   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.

III. CareSource considers Kymriah not medically necessary for the treatment of disease states not in this document.

E. Conditions of Coverage

NA

F. Related Policies/Rules

Evidence of Coverage and Health Insurance Contract Indiana
Pharmacy Policy Statement: CAR-T medications
CAR-T medications – Yescarta
CAR-T medications – Tecartus
Pharmacy Policy Statement: Kymriah (tisagenlecleucel)

G. Review/Revision History

	DATE	ACTION
Date Issued	04/14/2021	
Date Revised		
Date Effective	07/01/2021	
Date Archived	05/31/2022	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

1. Kymriah [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corp., May 2018.
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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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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

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – 08/2020