

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Kymriah (tisagenlecleucel)
BILLING CODE	TBD
BENEFIT TYPE	Carved out to FFS (fee-for-service) benefit
SITE OF SERVICE ALLOWED	N/A
COVERAGE REQUIREMENTS	Prior Authorization is required and reviews will be performed by CareSource and forward to IN Medicaid for a final decision and payment

Kymriah (tisagenlecleucel) is a product that is carved out from managed care benefits and is included in the Indiana Medicaid Fee-For-Service (FFS) program. Requests for authorization of this product will be reviewed by CareSource using the criteria below and forwarded to Indiana Medicaid FFS for a final decision.

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 3-25 years of age 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 10⁶CAR-positive viable T cells per kg body weight intravenously. Weight above 50 kg: administer 0.1 to 2.5 x 10⁸ 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.
05/01/2018	Carve out information added—No longer paid for by CareSource. CareSource will review authorization requests and final decision on coverage and payment with be made by IN Medicaid.

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.

Effective date: 05/01/2018

Revised date: 05/01/2018