



MEDICAL POLICY STATEMENT

Indiana Medicaid

Policy Name & Number	Date Effective
CAR-T Medications - Kymriah - IN MCD- MM-1167	08/01/2022-09/30/2022
Policy Type	
MEDICAL	

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.

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A. Subject

CAR-T Medications – Kymriah (tisagenlecleucel)

B. Background

Chimeric antigen receptor T-cell therapy (CAR-T) is an autologous T-cell immunotherapy. The patient's own T lymphocytes are genetically modified with a gene to produce chimeric antigen receptors (CARs) on the cell surface, making the lymphocytes a CAR-T cell, allowing recognition of an antigen on targeted tumor cells. Once the T-cells are modified and multiplied, they are infused back into the patient to attack cells with the targeted antigen on the surface, eradicating cancer cells, and possibly, resulting in long-term remission for patients.

CAR-T is associated with severe complications and may be life-threatening. These complications include, but are not limited to, cytokine release syndrome, macrophage activation syndrome, anaphylaxis, neurological toxicities, other toxicities, and other medical conditions. Therefore, CAR-T therapy administration should be based on clinical benefits, potential long-term disease control, and toxicity.

C. Definitions

- **Antigen** – A toxin or other foreign substance that induces an immune response in the body, especially the production of antibodies.
- **Chimeric Antigen Receptors** – Proteins that allow T-cells to recognize an antigen on a targeted tumor cell.
- **T Lymphocyte (T-cell)** – A subtype of white blood cells comprising a major portion of the immune system and functioning to make antibodies that fight infection by directly killing infected cells in the body.

D. Policy

This product is carved out from managed care benefits and is included in the Indiana Medicaid Fee-For-Service (FFS) program. Requests for coverage of this product must be submitted directly to Gainwell Technology, the fee-for-service vendor, for review.

E. Conditions of Coverage

NA

F. Related Policies/Rules

Pharmacy Policy Statement: Kymriah (tisagenlecleucel)

G. Review/Revision History

DATE		ACTION
Date Issued	04/14/2021	
Date Revised	02/08/2022	Added definitions, Added references
Date Effective	08/01/2022	
Date Archived	09/30/2022	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.

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

H. References

1. Indiana Health Coverage Programs. Oncology Services (April 20, 2021). Retrieved February 08, 2022 from www.in.gov.
2. Indiana Health Coverage Programs. Pharmacy Services (August 24, 2021). Retrieved February 08, 2022 from www.in.gov.

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