



& Number	Date Effective
CAR-T Medications - Kymriah - OH MP - MM-1115	07/01/2022-11/30/2022
Policy Type	
MEDICAL	

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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 therapy 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 and 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

- x **Antigen** – A toxin or other foreign substance that induces an immune response in the body, especially the production of antibodies.
- x **Chimeric Antigen Receptors** – Proteins that allow T-cells to recognize an antigen on a targeted tumor cell.
- x **Immunotherapy** – A type of treatment that utilizes the body's own immune system to fight cancer, improves the body's ability to detect and kill cancer cells, and is based on the concept that immune cells or antibodies can recognize and kill cancer cells.
- x **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.
- x **T Lymphocyte (T-cell)** – A subtype of white blood cells comprising a major portion of the immune system and functioning to make antibodies.

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 two cycles of a standard chemotherapy regimen, or chemorefractory, as defined by not achieving a CR after one cycle of standard chemotherapy for relapsed leukemia
 - d. Philadelphia chromosome positive (Ph+) ALL and intolerant to or have

Archived



Medications - Kymriah

CAR-T