

**SOUTH DAKOTA MEDICAID  
PRIOR AUTHORIZATION CRITERIA**

*Physician Administered Drugs, Vaccines, and Immunizations*

**Tisagenlecleucel (Kymriah) – PA Criteria**

HCPC: Q2042

Tisagenlecleucel (Kymriah) is a Chimeric Antigen Receptor T-Cell (CAR-T) immunotherapy indicated for the treatment of relapsed or refractory acute lymphoblastic leukemia, relapsed or refractory diffuse large B-cell lymphoma and relapsed or refractory follicular lymphoma. It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

**\*\* All requests under this policy require SD medical director review in addition to meeting specified criteria below \*\***

• **Initial Therapy (must meet all):**

- Therapy is prescribed by a hematologist or oncologist
- Individual has a diagnosis of **one** of the following:
  - B cell precursor, acute lymphoblastic leukemia
  - Diffuse large B-cell lymphoma
  - Follicular lymphoma
- Individual meets **one** of the following regarding disease severity/previous therapy failures:
  - B cell precursor, acute lymphoblastic leukemia (must meet **one**):
    - Disease is classified as refractory, defined as failure to achieve complete response after ≥ 2 cycles of chemotherapy (primary refractory) or after 1 cycle of chemotherapy for relapsed leukemia (chemorefractory)
    - Member has had ≥2 relapses
    - Disease is relapsed or refractory, Philadelphia chromosome positive (Ph+): member has failed ≥2 lines of chemotherapy that included 2 tyrosine kinase inhibitors
    - Member has relapsed following allogeneic stem cell transplantation (SCT) and must be ≥6 months out from SCT at the time of Kymriah infusion
  - Diffuse large B-cell lymphoma (including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high-grade B-cell lymphoma and DLBCL arising from follicular lymphoma): disease is relapsed or refractory and documentation is provided indicating failure of 2 or more lines of systemic therapy
  - Follicular lymphoma: disease is relapsed or refractory and documentation is provided indicating failure of ≥2 lines of systemic therapy or autologous hematopoietic stem cell transplant
- Member has not received Car-T therapy in the past and therapy will not be utilized in conjunction with other Car-T therapies
- Individual is ≥18 years of age if therapy is requested for diffuse large B-cell lymphoma or follicular lymphoma and ≤25 years of age for acute lymphoblastic leukemia
- Approval duration: one dose

• **Continuation of Therapy:** not authorized