



Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	December 1, 2017 July 27, 2018, July 16, 2020

## **KYMRIAH™ (tisagenlecleuce)\***

LENGTH OF AUTHORIZATION: Date of service

ADMINISTRATION: Hospital inpatient or outpatient setting

REVIEW CRITERIA:

### **Pediatric and Young Adult Relapsed or Refractory (r/r) B-cell Acute Lymphoblastic Leukemia**

- Patient is 25 years of age or younger
- Must have diagnosis of B-cell precursor acute lymphoblastic leukemia
- Patient is refractory or in second or later relapse

### **Adult Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)**

- Patient must be 18 years of age or older
- Patient has relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

DOSING:

### **Pediatric and Young Adult Relapsed or Refractory (r/r) B-cell Acute Lymphoblastic Leukemia:**

50kg and less: A single dose of KYMRIAH™ contains 0.2 to 5.0 x 10<sup>6</sup> CAR-positive viable T cells per kg of body weight.

Above 50kg: A single dose of KYMRIAH™ contains 0.1 to 2.5 x 10<sup>8</sup> CAR-positive viable T cells per kg of body weight.

### **Adult Relapsed or Refractory Diffuse Large B-Cell Lymphoma:**

A single dose of KYMRIAH™ 0.6 to 6.0 x 10<sup>8</sup> CAR-positive viable T cells.

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\* Because of the risk of Cytokine Release Syndrome and neurological toxicities, KYMRIAH™ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIAH REMS. Further information is available at [www.kymriah-rems.com](http://www.kymriah-rems.com) or at 1-844-4KYMRIAH.