



MONTANA HEALTHCARE PROGRAMS

March 12, 2019

Physician Administered Drug Prior Authorization Criteria for KYMRIAH®

Version 2, 03-12-19

KYMRIAH (tisagenlecleucel) is a CD19 directed genetically modified autologous T cell immunotherapy

Indications: KYMRIAH is used for:

- Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.
- Adult patients with 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.

Criteria for Approval:

B-Cell Lymphoma:

- Must be 18 years of age or older **AND**
- Must be prescribed by a hematologist/oncologist **AND**
- The administering facility has been certified to dispense KYMRIAH and is enrolled in the KYMRIAH REMS program **AND**
- Diagnosis of approved indication including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. **AND**
- Relapsed or refractory disease after two or more lines of systemic therapy detailed in NCCN clinical practice guidelines. For DLBCL arising from follicular lymphoma, prior regimens must include at least one anthracycline or anthracenedione-based regimen unless contraindicated **AND**
- No prior allogeneic hematopoietic stem cell transplantation **AND**
- Complete documentation is provided of disease history and previous therapies.

Acute Lymphoblastic Leukemia:

- Must be 25 years of age or younger **AND**
- Must be prescribed by a hematologist/oncologist **AND**

- The administering facility has been certified to dispense KYMRIAHA and is enrolled in the KYMRIAHA REMS program **AND**
- Complete documentation is provided containing **ALL** of the following information:
 1. Diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in a second or later relapse as defined by any one of the following items:
 - Second or greater bone marrow relapse **OR**
 - Any bone marrow relapse after allogenic stem cell transplantation **OR**
 - Primary refractory (not achieving a complete response after 2 cycles of standard chemotherapy) or chemorefractory (not achieving a complete response after 1 cycle of standard chemotherapy for relapsed disease) **OR**
 - Patients with Philadelphia chromosome (Ph) positive disease have a contraindication, intolerance, or have failed two prior lines of tyrosine kinase inhibitor therapy
 2. Confirmed CD19 tumor expression and Confirmed Philadelphia chromosome (Ph) status
 3. All previous therapies with response(s) documented

Exclusion Criteria:

- History of primary central nervous system lymphoma
- Previous CAR-T therapy
- Current serious infection

References:

1. Kymriah [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2017, Accessed March 9, 2019.
2. Porter DL, Hwang WT, Frey NV, et al. Chimeric antigen receptor T cells persist and induce sustained remissions in relapsed refractory chronic lymphocytic leukemia. *Sci Transl Med*. 2015 Sep 2;7(303):303ra139. doi: 10.1126/scitranslmed.aac5415.
3. "Determine Efficacy and Safety of CTL019 in Pediatric Patients With Relapsed and Refractory B-Cell ALL (ELIANA)." Determine Efficacy and Safety of CTL019 in Pediatric Patients With Relapsed and Refractory B-Cell ALL - Full Text View - ClinicalTrials.gov, clinicaltrials.gov/ct2/show/NCT02435849.
4. NCCN Drugs & Biologics Compendium®: tisagenlecleucel. Accessed online 01/2018
5. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Acute Lymphoblastic Leukemia. Version 5.2017. Accessed online 01/2018
6. NCCN Guidelines for B-cell Lymphomas Version 2.2019. March 6, 2019. Accessed March 9, 2019 https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf