STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

KYMRIAH (*tisagenlecleucel*)

Billed under Q2040

KYMRIAH is a CD19-directed modified autologous T-cell immunotherapy indicated for the treatment of:

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

2) Treatment of adult patients with relapsed* or refractory** diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy

KYMRIAH may be considered medically necessary only when being used for one of the approved indications and if ALL the following criteria are met:

- All previous therapies and responses must be documented; **and**
- Documentation of CD19 tumor expression demonstration in bone marrow or peripheral blood; **and**
- No active or latent hepatitis B or active hepatitis C, human immunodeficiency virus (HIV) positive or any uncontrolled infection; **and**
- No presence of grade 2-4 acute or extensive chronic graft-versus-host disease (GVHD); **and**
- No active central nervous system involvement by malignancy; **and**
- No prior anti-CD19/anti-CD3 therapy, or any other anti-CD19 therapy, or gene therapy; **and**
- Karnofsky/Lansky score must be greater than or equal to 50; **and**
- No live vaccination within two (2) weeks prior to initiation of lymphodepleting chemotherapy**; and**
- Apheresis product received and accepted by manufacturing site; **AND**
- **For Philadelphia chromosome-positive ALL patients**, patient must have failed at least 2 lines of tyrosine kinase inhibitor (TKI) therapy.

Approval duration: One month to allow for a one-time infusion of therapy

Additional Information:

Tisagenlecleucel (Kymriah) is considered experimental/investigational and therefore non-covered for any other indications than those listed above. There is insufficient evidence regarding its effectiveness and safety for any other indications.

***** Refractory is defined by not achieving an initial complete remission after two cycles of a standard chemotherapy regimen (primary refractory). Subjects who were refractory to subsequent chemotherapy regimens after an initial remission are considered chemorefractory.

******Relapse is defined by greater than 5% lymphoblasts and second or subsequent bone marrow (BM) relapse, or any BM relapse after allogeneic (stem cell transplant) SCT and must be greater than or equal to (six) 6 months from SCT at the time of tisagenlecleucel infusion.

Because of the risk of cytokine release syndrome (CRS) and neurological toxicities, Kymriah is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIAH REMS. The required components of the KYMRIAH REMS are:

- Healthcare facilities that dispense and administer Kymriah must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available for each patient for administration within two hours after Kymriah infusion, if needed for treatment of CRS.

Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense or administer Kymriah are trained about the management of CRS and neurological toxicities.

Place of Service: Inpatient/Outpatient:

Treatment with tisagenlecleucel (Kymriah) and Axicabtagene ciloleucel (Yescarta) are typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of CRS and neurologic toxicities. The product labeling gives specific treatment recommendations for the different grades of CRS and neurologic toxicity. Instruct patients to remain within proximity of the certified healthcare facility for at least 4 weeks following infusion.

References:

1.) LexiComp Clinical Reference (last updated 7/31/2018)

2.) Kymriah package insert – Novartis (last updated 5/2018)

3.) https://www.fda.gov/downloads/biologicsbloodvaccines/cellulargenetherapyproducts/approvedproducts/ucm581259.pdf (Accessed 04/27/2018)

4.) www.fda.gov/biologicsbloodvaccines/cellulargenetherapyproducts/approvedproducts/ucm573706.htm (Accessed 04/27/2018)

5.) ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier CCTL019B2202, Determine Efficacy and Safety of CTL019 in Pediatric Patients With Relapsed and Refractory B-cell ALL (ELIANA); 20017 July 28 [cited 2017 Sept 15].

6.) https://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM573941.pdf Package insert KYMRIAH (Accessed 04/27/2018)

7.) https://www.fda.gov/downloads/biologicsbloodvaccines/cellulargenetherapyproducts/approvedproducts/ucm581226.pdf Package insert Yescarta (Accessed 04/27/2018)

8.) NCCN Drugs & Biologics Compendium™. Tisagenlecleucel. 2017. National Comprehensive Cancer Network (NCCN)

9.) **REMS:** https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm (Accessed 04/30/2018)