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

Office of Pharmacy Service
Prior Authorization Criteria

YESCARTA (*axicabtagene ciloleucel*)
Billed under Q2041

YESCARTA (axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of 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, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

YESCARTA may be considered medically necessary for individuals 18 years of age or older when ALL the following criteria are met:

- Individual has a diagnosis of **ANY ONE** of the following aggressive forms of NHL:
    - Diffuse large B-cell lymphoma (DLBCL), not otherwise specified; **or**
    - High-grade B-cell lymphoma; **or**
    - Double hit lymphoma; **or**
    - Primary mediastinal large B-cell lymphoma (PMBCL); **or**
    - Transformed follicular lymphoma (TFL); **and**
- For the treatment of DLCBL, High-grade B-cell lymphoma, double hit lymphoma, or PMBCL individual meets EITHER of the following criteria:
    - Axicabtagene ciloleucel (Yescarta) is additional therapy for individuals with intention to proceed to high-dose therapy who have partial response, no response, or progressive disease following second-line therapy for relapsed or refractory disease; **or**
    - Treatment of disease in second relapse or greater (if not previously given); **or**
- For the treatment of TFL individual meets **EITHER** of the following criteria:
    - For individuals who have received minimal or no prior chemotherapy prior to histologic transformation to DLBCL and have partial response, no

response, relapsed, or progressive disease (only after treatment with greater than or equal to two (2) chemoimmunotherapy regimens which included at least one anthracycline or anthracenedione-based regimen, unless contraindicated); **or**

- For individuals who have received multiple therapies (not including axicabtagene ciloleucel) prior to histologic transformation to DLBCL (only after treatment with greater than or equal to two (2) chemoimmunotherapy regimens which included **AT LEAST** one anthracycline or anthracenedione-based regimen, unless contraindicated); **and**

- No active or latent hepatitis B or active hepatitis C, HIV positive or any uncontrolled infection; **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**
- An Eastern Cooperative Oncology Group (ECOG) scale of performance status less than or equal to one (1); **and**
- No live vaccination within two weeks prior to initiation of lymphodepleting chemotherapy; **and**
- Apheresis product received and accepted by manufacturing site.

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

Because of the risk of CRS and neurological toxicities, Yescarta is available only through a restricted program under a REMS called the YESCARTA REMS. The required components of the YESCARTA REMS are:

- Healthcare facilities that dispense and administer Yescarta 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 Yescarta infusion, if needed for treatment of CRS.

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

Approval duration: 60 days to allow for a one-time infusion of therapy

Place of Service: Inpatient/Outpatient:

Treatment with axicabtagene ciloleucel (Yescarta) is 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.

Resources:

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

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].

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

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