Title: Yescarta	Division: Medical Management Department: Utilization Management
Approval Date: 3/30/18	LOB: Medicaid, FHP, HIV SNP, CHP, MetroPlus Gold, Market Plus, Essential, HARP
Effective Date: 3/30/18	Policy Number: UM-MP230
Review Date: 3/30/19	Cross Reference Number:
Retired Date:	Page 1 of 4

1. POLICY DESCRIPTION:

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.

Repeat administration of Yescarta is considered experimental and investigational because there have been no established studies to demonstrate effectiveness. Yescarta is also considered experimental or investigational for the following indications due to no established studies of clinical efficacy:

- Acute lymphoblastic leukemia (ALL)
- Follicular lymphoma
- Indolent non-Hodgkin lymphoma (NHL)
- Mantle cell lymphoma
- Marginal zone lymphoma
- Primary central nervous system (CNS) lymphoma

2. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claims Department, Provider Contracting.

3. POLICY:

Yescarta will be considered medically necessary when the following conditions of coverage have been met:

a. Member is 18 years of age or older
b. Member is diagnosed with large B-cell lymphoma (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)
    i. The disease is relapsed or refractory to treatment after two or more lines of systemic therapy.
        1. An anthracycline-containing chemotherapy regimen; **and**
        2. For CD20+ disease, anti-CD20 monoclonal antibody; **and**

3. For subjects with transformed follicular lymphoma, prior chemotherapy for follicular lymphoma with chemotherapy refractory disease after transformation to DLBCL

ii. Documentation of all of the following:
   1. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **and**
   2. Absolute neutrophil count (ANC) ≥ 1000/uL; **and**
   3. Absolute lymphocyte count (ALC) > 100/uL; **and**
   4. Platelet count ≥ 75,000/uL; **and**

iii. This member has not previously been treated with Yescarta

iv. The member has documentation of CD19 positive protein on the surface of the B-Cell.

Exclusions:

- History of malignancy other than non-melanoma skin cancer or carcinoma in situ (e.g., bladder, breast, cervix) or follicular lymphoma unless disease free for at least 3 years
- History of allogeneic stem cell transplantation or prior CAR T cell therapy or other genetically modified T cell therapy
- Active, uncontrolled infection
- Known history of infection with HIV or hepatitis B (HBsAG positive) or hepatitis C virus (anti-HCV positive). A history of hepatitis B or hepatitis C is permitted if the viral load is undetectable per quantitative PCR and/or nucleic acid testing
- Subjects with detectable cerebrospinal fluid (CSF) malignant cells, or brain metastases, or with a history of CNS lymphoma, CSF malignant cells or brain metastases
- History or presence of CNS disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease with CNS involvement

4. APPLICABLE PROCEDURE CODES

CPT Code	Description
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR T cells, including leukopheresis and dose preparation procedures, per infusion

References

1. Food and Drug Administration. FDA approves CAR-T cell therapy to treat adults with certain types of large B-cell lymphoma. FDA: Silver Spring, MD. October 18, 2017. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm581216.htm.
2. Highlights of Prescribing Information. Yescarta (axicabtagene ciloleucel) suspension for intravenous infusion. Initial U.S. Approval: October 2017. Kite Pharma, Inc. Santa Monica, CA. Available at: https://www.yescarta.com/wp-content/uploads/yescarta-pi.pdf.
3. Kite Pharma, Inc. A Phase 1-2 multi-center study evaluating KTE-C19 in subjects with refractory aggressive non-hodgkin lymphoma (ZUMA-1). NCT 02348216. Updated December 14, 2017. Available at: https://clinicaltrials.gov/ct2/show/NCT02348216?term=zuma+kte&rank=2.

REVISION LOG:

REVISIONS	DATE
Creation date	

Approved:	Date:	Approved:	Date:
Bruce Sosler, MD Clinical Medical Director		Talya Schwartz, MD Chief Medical Officer	

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Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication.