MetroPlusHealth

Policy and Procedure

Title: Yescarta (axicabtagene ciloleucel)	Division: Medical Management Department: Utilization Management
Approval Date: 3/30/18	LOB: Medicaid, FHP, HIV SNP, CHP, MetroPlus Gold, Goldcare I&II Market Plus, Essential, HARP
Effective Date: 3/30/18	Policy Number: UM-MP230
Review Date: 8/29/23	Cross Reference Number:
Retired Date:	Page 1 of 5

1. POLICY DESCRIPTION

Immunological Agent, Yescarta (Rx)

2. RESPONSIBLE PARTIES

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

3. DEFINITIONS

Yescarta (Axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy. It is also indicated for 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.

4. POLICY

Yescarta used for the treatment of B-cell lymphoma will be covered with prior authorization when the following criteria are met:

a. Patient is 18 years of age or older **AND**
b. Patient has a confirmed diagnosis consistent 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, or DLBCL arising from follicular lymphoma)* **AND**
c. The disease is relapsed or refractory to treatment after at least **two** of the following lines of systemic therapy:
    i. An anthracycline-containing chemotherapy regimen (ex: Doxorubicin, Daunorubicin, Epirubicin, or Mitoxantrone)
    ii. For CD20+ disease, anti-CD20 monoclonal antibody (ex: Rituximab, Gazyva, Ocrevus, Kesimpta, Zevalin, Arzerra, Bexxar)
    iii. For subjects with transformed follicular lymphoma, prior chemotherapy for follicular lymphoma with chemotherapy refractory disease after transformation to DLBCL
    OR
    iv. Relapsed or refractory disease (≤ 12 months) after first-line rituximab and anthracycline-based chemotherapy
    AND

d. Documentation of **ALL** of the following has been submitted for approval*:
    i. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
    ii. Absolute neutrophil count (ANC) ≥ 1000/uL
    iii. Absolute lymphocyte count (ALC) ≥ 100/uL
    iv. Platelet count ≥ 75,000/uL **AND**
e. Patient has not received any live vaccines within the past 6 weeks (42 days) **AND**
f. This member has not previously been treated with Yescarta **AND**
g. The member has documentation of CD19 positive protein on the surface of the B-cell* **AND**
h. The healthcare facility is enrolled and complies with standards of the Yescarta REMS program **AND**
i. Dose is within approved FDA dosing:
    i. Administer a lymphodepleting regimen of cyclophosphamide and fludarabine before infusion
    ii. Premedicate with acetaminophen and an H1-antihistamine
    iii. Dosing of YESCARTA is based on the number of chimeric antigen receptor (CAR)-positive viable T cells. The target YESCARTA dose is 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.

Yescarta used for the treatment follicular lymphoma will be covered with prior authorization when the following criteria are met:

a. Patient is 18 years of age or older **AND**
b. Patient has a confirmed diagnosis of one relapsed or refractory indolent follicular lymphoma (grades 1-3a) **AND**
c. Disease progression after two or more lines of systemic therapy with combination chemoimmunotherapy including anti-CD20 monoclonal antibody, such as rituximab, combined with an alkylating agent **AND**
d. Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 **AND**
e. Patient has not received any live vaccines within the past 6 weeks (42 days) **AND**
f. This member has not previously been treated with Yescarta **AND**
g. The healthcare facility is enrolled and complies with standards of the Yescarta REMS program **AND**
h. Dose is within approved FDA dosing:

a. Administer a lymphodepleting regimen of cyclophosphamide and fludarabine before infusion
b. Premedicate with acetaminophen and an H1-antihistamine
c. Dosing of YESCARTA is based on the number of chimeric antigen receptor (CAR)-positive viable T cells. The target YESCARTA dose is 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.

***Documentation, including chart notes and lab results, MUST be submitted for approval**

5. LIMITATIONS/EXCLUSIONS:

a. Repeat administration of Yescarta is considered experimental and investigational because there have been no established studies to demonstrate effectiveness.
b. Yescarta is also considered experimental or investigational for the following indications due to no established studies of clinical efficacy:
    1. Acute lymphoblastic leukemia (ALL)
    2. Indolent non-Hodgkin lymphoma (NHL)
    3. Mantle cell lymphoma
    4. Marginal zone lymphoma
    5. Primary central nervous system (CNS) lymphoma
c. 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
d. History of allogeneic stem cell transplantation or prior CAR T cell therapy or other genetically modified T cell therapy
e. Active, uncontrolled infection
f. 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
g. Ejection fraction < 50% or evidence of pericardial effusion
h. Subjects with detectable cerebrospinal fluid (CSF) malignant cells, or brain metastases, or with a history of CNS lymphoma, CSF malignant cells or brain metastases
i. History or presence of CNS disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease with CNS involvement

6. 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

7. 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. IBM Micromedex. Available at: micromedexsolutions.com
4. 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	3/30/18
Review	3/15/19
Annual Review	6/8/2020
Annual Review	9/1/2021
Annual Review	8/29/2022

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Approved: **Date:**	**Approved:** **Date:**
Glendon Henry Digitally signed by Glendon Henry Date: 2022.08.30 14:34:13 -04'00'	Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2022.08.30 15:03:14 -04'00'
Glendon Henry **Senior Medical Director**	**Sanjiv Shah, MD** **Chief Medical Officer**

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.