

Title: Yescarta (axicabtagene ciloleucel)	Division: Medical Management
	Department: Utilization Management
Approval Date: 3/30/2018	LOB: Medicaid, HIV SNP, HARP, CHP,
	MetroPlus Gold, GoldCare, Marketplace,
	Essential, Medicare, Ultracare
Effective Date: 3/30/2018	Policy Number: UM-MP230
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I. POLICY DESCRIPTION

Immunological Agent, Yescarta (Rx)

II. RESPONSIBLE PARTIES

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

III. DEFINITIONS

Yescarta (Axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T-cell immunotherapy which binds to CD19-expressing cancer cells and normal B cells. As studies have shown, following anti-CD19 CAR-T cell engagement with CD19-expressing target cells, the CD28 and CD3-zeta co-stimulatory domains activate downstream signaling cascades that lead to T-cell activation, proliferation, acquisition of effector functions. This results in secretion of inflammatory cytokines and chemokines which relays messages that coordinate the immune system to fend off attackers. As a result, this sequence of events leads to killing of CD19-expressing cells.

Yescarta is 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.

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.

Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate.

IV. POLICY

For Medicare and Ultracare Only: Per CMS regulation, Metroplus Health Plan follows the following National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy

1. NCD 110.24



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For all non-Medicare LOBs:

Yescarta will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

INITIAL REQUEST:

- 1. Adult Large B-cell lymphoma
 - A. Member is 18 years of age or older;

AND

- **B.** Member has a diagnosis confirmed by submitted documentation including chart notes consistent with ONE of the following:
 - a. Large B-cell lymphoma;

OR

b. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified;

OR

c. Primary mediastinal large B-cell lymphoma;

OR

d. High grade B-cell lymphoma;

OR

e. DLBCL arising from follicular lymphoma;

AND

- **C.** ONE of the following:
 - a. Member has disease refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy (Examples of chemoimmunotherapy include: RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone); Pola-R-CHP (polatuzumab vedotin-piiq, rituximab, cyclophosphamide, doxorubicin, prednisone));

OR

b. Member has relapsed or refractory disease after two or more lines of systemic therapy

(Examples of systemic therapy include:

CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + Gazyva (obinutuzumab intravenous infusion) or rituximab products;



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CVP (cyclophosphamide, vincristine, prednisone) + rituximab products; lenalidomide + rituximab products));

AND

D. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1;

AND

E. Member has not received any live vaccines within the past 6 weeks;

AND

F. Member does not have an active systemic infection or inflammatory disorder;

AND

- **G.** Member has not previously been treated with Yescarta or any other CAR-T therapy; **AND**
- **H.** The requesting provider belongs to a healthcare facility that has enrolled in the Yescarta REMS (Risk Evaluation and Mitigation Strategy) program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities (treatment centers can be found here);

AND

I. Authorization is for no more than one dose

2. Adult Follicular lymphoma

A. Member is 18 years of age or older;

AND

B. Member has a diagnosis of Follicular lymphoma confirmed by submitted documentation including chart notes;

AND

C. Member has relapsed or refractory disease after trial and failure or contraindication to at least TWO lines of therapy that includes a combination of an anti-CD 20 monoclonal antibody (e.g., Rituxan (rituximab), Gazyva (Obinutuzumab)) and an alkylating agent (e.g., bendamustine, cyclophosphamide, chlorambucil); (Examples of systemic therapy include:

Bendamustine + obinutuzumab or rituximab;

CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + binutuzumab or rituximab:

CVP (cyclophosphamide, vincristine, prednisone) + obinutuzumab or rituximab; Lenalidomide + rituximab;

Chlorambucil ± rituximab;

Cyclophosphamide ± rituximab))



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D. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1;

AND

E. Member has not received any live vaccines within the past 6 weeks;

AND

F. Member does not have an active systemic infection or inflammatory disorder;

AND

G. Member has not previously been treated with Yescarta or any other CAR-T therapy; **AND**

H. The requesting provider belongs to a healthcare facility that has enrolled in the Yescarta REMS (Risk Evaluation and Mitigation Strategy) program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities (treatment centers can be found here);

AND

I. Authorization is for no more than one dose

RENEWAL REQUEST:

Repeat administration of Yescarta is investigational and will not be covered.

V. LIMITATIONS/EXCLUSIONS:

- 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)
 - Indolent non-Hodgkin lymphoma (NHL)
 - Mantle cell lymphoma
 - Marginal zone lymphoma
 - Primary central nervous system (CNS) lymphoma
- History of allogeneic stem cell transplantation or prior CAR-T cell therapy or other genetically modified T cell therapy
- Ejection fraction < 50% or evidence of pericardial effusion
- History or presence of CNS disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease with CNS involvement



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VI. 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	

VII. APPLICABLE DIAGNOSIS CODES:

	AFFEICABLE DIAGROSIS CODES.		
CODE	Description		
C82.00	Follicular lymphoma grade I, unspecified site		
C82.01	Follicular lymphoma grade I, lymph nodes of head, face, and neck		
C82.02	Follicular lymphoma grade I, intrathoracic lymph nodes		
C82.03	Follicular lymphoma grade I, intra-abdominal lymph nodes		
C82.04	Follicular lymphoma grade I, lymph nodes of axilla and upper limb		
C82.05	Follicular lymphoma grade I, lymph nodes of inguinal region and lower limb		
C82.06	Follicular lymphoma grade I, intrapelvic lymph nodes		
C82.07	Follicular lymphoma grade I, spleen		
C82.08	Follicular lymphoma grade I, lymph nodes of multiple sites		
C82.09	Follicular lymphoma grade I, extranodal and solid organ sites		
C82.10	Follicular lymphoma grade II, unspecified site		
C82.11	Follicular lymphoma grade II, lymph nodes of head, face, and neck		
C82.12	Follicular lymphoma grade II, intrathoracic lymph nodes		
C82.13	Follicular lymphoma grade II, intra-abdominal lymph nodes		
C82.14	Follicular lymphoma grade II, lymph nodes of axilla and upper limb		
C82.15	Follicular lymphoma grade II, lymph nodes of inguinal region and lower limb		
C82.16	Follicular lymphoma grade II, intrapelvic lymph nodes		
C82.17	Follicular lymphoma grade II, spleen		
C82.18	Follicular lymphoma grade II, lymph nodes of multiple sites		
C82.19	Follicular lymphoma grade II, extranodal and solid organ sites		
C82.20	Follicular lymphoma grade III, unspecified, unspecified site		
C82.21	Follicular lymphoma grade III, unspecified, lymph nodes of head, face, and neck		
C82.22	Follicular lymphoma grade III, unspecified, intrathoracic lymph nodes		
C82.23	Follicular lymphoma grade III, unspecified, intra-abdominal lymph nodes		
C82.24	Follicular lymphoma grade III, unspecified, lymph nodes of axilla and upper limb		
C82.25	Follicular lymphoma grade III, unspecified, lymph nodes of inguinal region and		
602.26	lower limb		
C82.26	Follicular lymphoma grade III, unspecified, intrapelvic lymph nodes		



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C82.27	Follicular lymphoma grade III, unspecified, spleen
C82.28	Follicular lymphoma grade III, unspecified, lymph nodes of multiple sites
C82.29	Follicular lymphoma grade III, unspecified, extranodal and solid organ sites
C82.30	Follicular lymphoma grade IIIa, unspecified site
C82.31	Follicular lymphoma grade IIIa, lymph nodes of head, face, and neck
C82.32	Follicular lymphoma grade IIIa, intrathoracic lymph nodes
C82.33	Follicular lymphoma grade IIIa, intra-abdominal lymph nodes
C82.34	Follicular lymphoma grade IIIa, lymph nodes of axilla and upper limb
C82.35	Follicular lymphoma grade IIIa, lymph nodes of inguinal region and lower limb
C82.36	Follicular lymphoma grade IIIa, intrapelvic lymph nodes
C82.37	Follicular lymphoma grade IIIa, spleen
C82.38	Follicular lymphoma grade IIIa, lymph nodes of multiple sites
C82.39	Follicular lymphoma grade IIIa, extranodal and solid organ sites
C82.40	Follicular lymphoma grade IIIb, unspecified site
C82.41	Follicular lymphoma grade IIIb, lymph nodes of head, face, and neck
C82.42	Follicular lymphoma grade IIIb, intrathoracic lymph nodes
C82.43	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes
C82.44	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb, intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb, spleen
C82.48	Follicular lymphoma grade IIIb, lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb, extranodal and solid organ sites
C82.50	Diffuse follicle center lymphoma, unspecified site
C82.51	Diffuse follicle center lymphoma, lymph nodes of head, face, and neck
C82.52	Diffuse follicle center lymphoma, intrathoracic lymph nodes
C82.53	Diffuse follicle center lymphoma, intra-abdominal lymph nodes
C82.54	Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb
C82.55	Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.56	Diffuse follicle center lymphoma, intrapelvic lymph nodes
C82.57	Diffuse follicle center lymphoma, spleen
C82.58	Diffuse follicle center lymphoma, lymph nodes of multiple sites
C82.59	Diffuse follicle center lymphoma, extranodal and solid organ sites
C82.60	Cutaneous follicle center lymphoma, unspecified site
C82.61	Cutaneous follicle center lymphoma, lymph nodes of head, face, and neck
C82.62	Cutaneous follicle center lymphoma, intrathoracic lymph nodes



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C82.83 Other types of follicular lymphoma, intra-abdominal lymph nodes C82.84 Other types of follicular lymphoma, lymph nodes of axilla and upper limb C82.85 Other types of follicular lymphoma, lymph nodes of inguinal region and lower limb C82.86 Other types of follicular lymphoma, intrapelvic lymph nodes C82.87 Other types of follicular lymphoma, spleen C82.88 Other types of follicular lymphoma, lymph nodes of multiple sites C82.89 Other types of follicular lymphoma, extranodal and solid organ sites C82.90 Follicular lymphoma, unspecified, unspecified site C82.91 Follicular lymphoma, unspecified, lymph nodes of head, face, and neck C82.92 Follicular lymphoma, unspecified, intra-abdominal lymph nodes C82.93 Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb C82.95 Follicular lymphoma, unspecified, lymph nodes of inguinal region and lower limb C82.96 Follicular lymphoma, unspecified, intrapelvic lymph nodes C82.97 Follicular lymphoma, unspecified, spleen C82.98 Follicular lymphoma, unspecified, spleen C82.99 Follicular lymphoma, unspecified, lymph nodes of multiple sites C83.30 Diffuse large B-cell lymphoma, unspecified site C83.31 Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck C83.32 Diffuse large B-cell lymphoma, intrathoracic lymph nodes C83.34 Diffuse large B-cell lymphoma, intra-abdominal lymph nodes C83.35 Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb C83.35 Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb	C82.81	Other types of follicular lymphoma, lymph nodes of head, face, and neck	
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C82.87 Other types of follicular lymphoma, spleen C82.88 Other types of follicular lymphoma, lymph nodes of multiple sites C82.89 Other types of follicular lymphoma, extranodal and solid organ sites C82.90 Follicular lymphoma, unspecified, unspecified site C82.91 Follicular lymphoma, unspecified, lymph nodes of head, face, and neck C82.92 Follicular lymphoma, unspecified, intrathoracic lymph nodes C82.93 Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb C82.94 Follicular lymphoma, unspecified, lymph nodes of inguinal region and lower limb C82.95 Follicular lymphoma, unspecified, lymph nodes of inguinal region and lower limb C82.96 Follicular lymphoma, unspecified, spleen C82.97 Follicular lymphoma, unspecified, lymph nodes of multiple sites C82.99 Follicular lymphoma, unspecified, extranodal and solid organ sites C83.30 Diffuse large B-cell lymphoma, unspecified site C83.31 Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck C83.32 Diffuse large B-cell lymphoma, intrathoracic lymph nodes C83.33 Diffuse large B-cell lymphoma, intra-abdominal lymph nodes C83.34 Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb C83.35 Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb	C82.85	,, , , , , , , , , , , , , , , , , , , ,	
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C82.92 Follicular lymphoma, unspecified, intrathoracic lymph nodes C82.93 Follicular lymphoma, unspecified, intra-abdominal lymph nodes C82.94 Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb C82.95 Follicular lymphoma, unspecified, lymph nodes of inguinal region and lower limb C82.96 Follicular lymphoma, unspecified, intrapelvic lymph nodes C82.97 Follicular lymphoma, unspecified, spleen C82.98 Follicular lymphoma, unspecified, lymph nodes of multiple sites C82.99 Follicular lymphoma, unspecified, extranodal and solid organ sites C83.30 Diffuse large B-cell lymphoma, unspecified site C83.31 Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck C83.32 Diffuse large B-cell lymphoma, intrathoracic lymph nodes C83.33 Diffuse large B-cell lymphoma, intra-abdominal lymph nodes C83.34 Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb C83.35 Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb	C82.90	Follicular lymphoma, unspecified, unspecified site	
C82.93 Follicular lymphoma, unspecified, intra-abdominal lymph nodes C82.94 Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb C82.95 Follicular lymphoma, unspecified, lymph nodes of inguinal region and lower limb C82.96 Follicular lymphoma, unspecified, intrapelvic lymph nodes C82.97 Follicular lymphoma, unspecified, spleen C82.98 Follicular lymphoma, unspecified, lymph nodes of multiple sites C82.99 Follicular lymphoma, unspecified, extranodal and solid organ sites C83.30 Diffuse large B-cell lymphoma, unspecified site C83.31 Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck C83.32 Diffuse large B-cell lymphoma, intrathoracic lymph nodes C83.33 Diffuse large B-cell lymphoma, intra-abdominal lymph nodes C83.34 Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb C83.35 Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb	C82.91	Follicular lymphoma, unspecified, lymph nodes of head, face, and neck	
C82.94 Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb C82.95 Follicular lymphoma, unspecified, lymph nodes of inguinal region and lower limb C82.96 Follicular lymphoma, unspecified, intrapelvic lymph nodes C82.97 Follicular lymphoma, unspecified, spleen C82.98 Follicular lymphoma, unspecified, lymph nodes of multiple sites C82.99 Follicular lymphoma, unspecified, extranodal and solid organ sites C83.30 Diffuse large B-cell lymphoma, unspecified site C83.31 Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck C83.32 Diffuse large B-cell lymphoma, intrathoracic lymph nodes C83.33 Diffuse large B-cell lymphoma, intra-abdominal lymph nodes C83.34 Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb C83.35 Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb	C82.92	Follicular lymphoma, unspecified, intrathoracic lymph nodes	
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C83.31 Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck C83.32 Diffuse large B-cell lymphoma, intrathoracic lymph nodes C83.33 Diffuse large B-cell lymphoma, intra-abdominal lymph nodes C83.34 Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb C83.35 Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb	C82.99	Follicular lymphoma, unspecified, extranodal and solid organ sites	
C83.32 Diffuse large B-cell lymphoma, intrathoracic lymph nodes C83.33 Diffuse large B-cell lymphoma, intra-abdominal lymph nodes C83.34 Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb C83.35 Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb	C83.30	Diffuse large B-cell lymphoma, unspecified site	
C83.33 Diffuse large B-cell lymphoma, intra-abdominal lymph nodes C83.34 Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb	C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck	
C83.34 Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb C83.35 Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb	C83.32	, , , , , , , , , , , , , , , , , , , ,	
C83.35 Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb	C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes	
	C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb	
C83.36 Diffuse large B-cell lymphoma, intrapelvic lymph nodes	C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb	
	C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes	



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C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C85.10	Unspecified B-cell lymphoma, unspecified site
C85.11	Unspecified B-cell lymphoma, lymph nodes of head, face, and neck
C85.12	Unspecified B-cell lymphoma, intrathoracic lymph nodes
C85.13	Unspecified B-cell lymphoma, intra-abdominal lymph nodes
C85.14	Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb
C85.15	Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.16	Unspecified B-cell lymphoma, intrapelvic lymph nodes
C85.17	Unspecified B-cell lymphoma, spleen
C85.18	Unspecified B-cell lymphoma, lymph nodes of multiple sites
C85.19	Unspecified B-cell lymphoma, extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face, and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites



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Sanjiv Shah, MD Chief Medical Officer			



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