



# Yescarta® (axicabtagene ciloleucel) (Intravenous)

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## I. Length of Authorization

Coverage will be provided for one treatment course (1 dose of Yescarta) and may not be renewed.

# **II.** Dosing Limits

#### Max Units (per dose and over time) [HCPCS Unit]:

• 1 billable unit (1 infusion up to 200 million autologous anti-CD19 CAR-positive viable T-cells)

# III. Initial Approval Criteria <sup>1</sup>

Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e. genetic and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); AND
- Patient does not have a clinically significant active systemic infection or inflammatory disorder;
  AND
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during axicabtagene ciloleucel treatment, and until immune recovery following treatment; AND
- Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); AND
- Prophylaxis for infection will be followed according to local guidelines; AND
- Healthcare facility must be enrolled in and comply with the requirements of the YESCARTA & TECARTUS REMS Program; AND
- Patient has not received prior CAR-T therapy; AND

- Patient has not received other anti-CD19 therapy (e.g., blinatumomab, tafasitamab, loncastuximab tesirine, etc.) OR patient previously received other anti-CD19 therapy and rebiopsy indicates CD-19 positive disease; AND
- Used as a single agent (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); AND
- Patient has an ECOG performance status of 0-1; AND
- Patient does not have primary central nervous system lymphoma; AND

## B-Cell Lymphomas $\dagger \ddagger \Phi^{1,7,12,13}$

- Patient has histologic transformation of follicular lymphoma (indolent lymphoma) to diffuse large b-cell lymphoma (DLBCL); AND
  - Prior therapy included an anthracycline and an anti-CD20 monoclonal antibody, unless contraindicated or tumor is CD20-negative; AND
    - Disease is refractory to first-line chemoimmunotherapy; OR
    - Used for treatment of disease that has relapsed within 12 months of first-line chemoimmunotherapy; OR
    - Patient has relapsed or refractory disease after two (2) or more prior lines of chemoimmunotherapy for indolent or transformed disease; OR
- Patient has histologic transformation of marginal zone lymphoma (indolent lymphoma) to DLBCL Ω OR Richter's transformation of CLL to DLBCL Ω; AND
  - Patient has received two (2) or more prior lines of chemoimmunotherapy for indolent or transformed disease which must have included an anthracycline and an anti-CD20 monoclonal antibody, unless contraindicated or tumor is CD20-negative; OR
- Patient has HIV-related large B-cell lymphoma (i.e., HIV-related DLBCL, primary effusion lymphoma, or HHV8-positive DLBCL, not otherwise specified) Ω, DLBCL, primary mediastinal large B-cell lymphoma (PMBCL), high grade B-cell lymphoma, or monomorphic post-transplant lymphoproliferative disorder (B-cell type) Ω; AND
  - Prior therapy included an anthracycline and an anti-CD20 monoclonal antibody, unless contraindicated or tumor is CD20-negative; AND
    - Used as additional therapy for relapsed disease >12 months after completion of first-line therapy and partial response following second-line therapy; OR
    - Used as additional therapy for patients with primary refractory disease (partial response, no response, or progression) or relapsed disease <12 months after completion of first-line therapy; OR
    - Used for treatment of disease that is in second or greater relapse in patients with partial response, relapse, or progressive disease following therapy for relapsed or refractory disease; OR
- Patient has nodal marginal zone lymphoma (MZL) or follicular lymphoma (grade 1, 2 or 3A);
  AND



- Used as third-line and subsequent therapy for partial response, no response, relapsed, or progressive disease after prior therapy including an anti-CD20 monoclonal antibody and an alkylating agent (e.g., R-bendamustine, R-CHOP, etc.), unless contraindicated;
   OR
- Patient has extranodal marginal zone lymphoma (EMZL) of the stomach or of nongastric sites (noncutaneous); AND
  - Used as third-line and subsequent therapy for relapsed, refractory, or progressive disease after prior therapy including an anti-CD20 monoclonal antibody and an alkylating agent (e.g., R-bendamustine, R-CHOP, etc.), unless contraindicated; OR
- Patient has splenic marginal zone lymphoma (MZL); AND
  - Used as third-line and subsequent therapy for recurrent disease after prior therapy including an anti-CD20 monoclonal antibody and an alkylating agent (e.g., Rbendamustine, R-CHOP, etc.), unless contraindicated

#### Pediatric Aggressive Mature B-Cell Lymphomas $\ddagger \Omega^{2,7,11,15}$

- Patient is ≤ 18 years of age; AND
- Patient has primary mediastinal large B-Cell lymphoma; AND
- Used as consolidation or additional therapy in patients with a partial response after therapy for relapsed or refractory disease; AND
- Patient previously received ≥ 2 prior chemoimmunotherapy regimens which included an anthracycline and an anti-CD20 monoclonal antibody, unless contraindicated or tumor is CD20negative

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

**Ω** Please note that the supporting data for this indication has been assessed and deemed to be of insufficient quality based on the review conducted for the Enhanced Oncology Value (EOV) program. However, due to the absence of viable alternative treatment options, this indication will be retained in our policy and evaluated on a case-by-case basis.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); ◆ Orphan Drug

#### IV. Renewal Criteria 1

Coverage cannot be renewed.

# V. Dosage/Administration <sup>1</sup>

Indication Dose



#### B-Cell

Lymphomas •

#### Lymphodepleting chemotherapy:

Administer cyclophosphamide 500 mg/m² and fludarabine 30 mg/m² intravenously on the fifth, fourth, and third day before infusion of Yescarta

#### Yescarta infusion:

 Each single infusion bag of Yescarta contains a suspension of chimeric antigen receptor (CAR)-positive T cells in approximately 68 mL. The target dose is 2 x 10<sup>6</sup> CAR-positive viable T cells per kg body weight, with a maximum of 2 x 10<sup>8</sup> CAR-positive viable T cells (for patients 100 kg and above).

#### For autologous use only. For intravenous use only.

- Yescarta is prepared from the patient's peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure
- One treatment course consists of lymphodepleting chemotherapy followed by a single infusion of Yescarta.
- Confirm Yescarta availability prior to starting the lymphodepleting regimen.
- Confirm the patient's identity matches the patient identifiers on the Yescarta cassette.

#### Premedication:

Premedicate with 650 mg acetaminophen and 12.5 mg diphenhydramine 1 hour prior to infusion.
 Only consider the use of prophylactic systemic corticosteroids in patients after weighing the potential benefits and risks.

#### Monitoring after infusion:

- Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of CRS and neurologic toxicities.
- Instruct patients to remain within proximity of the certified healthcare facility for at least 4 weeks following infusion.
- Instruct patients to refrain from driving or hazardous activities for at least 8 weeks following infusion.
- Store infusion bag in the vapor phase of liquid nitrogen (less than or equal to minus 150°C). Thaw prior to infusion.
- In case of manufacturing failure, a second manufacturing may be attempted.
- Additional chemotherapy (not the lymphodepletion) may be necessary while the patient awaits the product.
- Ensure that 2 doses of tocilizumab and emergency equipment are available prior to infusion and during the recovery period.
- Yescarta contains human blood cells that are genetically modified with replication incompetent retroviral vector. Follow universal precautions and local biosafety guidelines for handling and disposal.

# VI. Billing Code/Availability Information

#### **HCPCS Code:**

 Q2041 – Axicabtagene Ciloleucel, up to 200 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

#### NDC:

Yescarta suspension for intravenous infusion; 1 infusion bag (68 mL): 71287-0119-xx

# VII. References (STANDARD)

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## VIII. References (ENHANCED)

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# **Appendix 1 – Covered Diagnosis Codes**

ICD-10	ICD-10 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 regional 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 lower limb	
C82.26	Follicular lymphoma grade III, unspecified, intrapelvic lymph nodes	
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	
C82.63	Cutaneous follicle center lymphoma, intra-abdominal lymph nodes	
C82.64	Cutaneous follicle center lymphoma, lymph nodes of axilla and upper limb	
C82.65	Cutaneous follicle center lymphoma, lymph nodes of inguinal region and lower limb	
C82.66	Cutaneous follicle center lymphoma, intrapelvic lymph nodes	
C82.67	Cutaneous follicle center lymphoma, spleen	
C82.68	Cutaneous follicle center lymphoma, lymph nodes of multiple sites	
C82.69	Cutaneous follicle center lymphoma, extranodal and solid organ sites	
C82.80	Other types of follicular lymphoma, unspecified site	
C82.81	Other types of follicular lymphoma, lymph nodes of head, face and neck	
C82.82	Other types of follicular lymphoma, intrathoracic lymph nodes	
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, 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	
C83.00	Small cell B-cell lymphoma, unspecified site	
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face and neck	
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes	
C83.03	small cell B-cell lymphoma, intra-abdominal lymph nodes	
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb	
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb	
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes	
C83.07	Small cell B-cell lymphoma, spleen	
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites	
C83.09	Small cell B-cell lymphoma, 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	
C83.36	Diffuse large B-cell lymphoma intrapelvic lymph nodes	
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	
C83.90	Non-follicular (diffuse) lymphoma, unspecified site	
C83.91	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of head, face, and neck	
C83.92	Non-follicular (diffuse) lymphoma, unspecified intrathoracic lymph nodes	
C83.93	Non-follicular (diffuse) lymphoma, unspecified intra-abdominal lymph nodes	
C83.94	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of axilla and upper limb	
C83.95	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of inguinal region and lower limb	
C83.96	Non-follicular (diffuse) lymphoma, unspecified intrapelvic lymph nodes	
C83.97	Non-follicular (diffuse) lymphoma, unspecified spleen	
C83.98	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of multiple sites	
C83.99	Non-follicular (diffuse) lymphoma, unspecified 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	
C85.80	Other specified types of non-Hodgkin lymphoma, unspecified site	
C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face and neck	
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes	
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes	
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb	
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region of lower limb	
C85.86	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes	
C85.87	Other specified types of non-Hodgkin lymphoma, spleen	
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites	
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites	
C85.87	Other specified types of non-Hodgkin lymphoma, spleen	
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma]	
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission	
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse	
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)	



# **Appendix 2 – Centers for Medicare and Medicaid Services (CMS)**

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <a href="https://www.cms.gov/medicare-coverage-database/search.aspx">https://www.cms.gov/medicare-coverage-database/search.aspx</a>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

#### Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions				
Jurisdiction	Applicable State/US Territory	Contractor		
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC		
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC		
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)		
6	MN, WI, IL	National Government Services, Inc. (NGS)		
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.		
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)		
N (9)	FL, PR, VI	First Coast Service Options, Inc.		
J (10)	TN, GA, AL	Palmetto GBA		
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA		
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.		
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)		
15	KY, OH	CGS Administrators, LLC		

