Axicabtagene ciloleucel (Yescarta®)	Place of Service Outpatient Facility Administration Hospital Administration HCPCS: **Q2041** per infusion

Condition listed in policy (*see criteria for details*)

- Follicular lymphoma
- Large B-cell lymphoma
- Marginal zone lymphomas

AHFS therapeutic class: Antineoplastic-CD19 directed CAR-T cell immunotherapy

Mechanism of action: CD19-directed genetically modified autologous T cell immunotherapy

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Yescarta® (axicabtagene ciloleucel) must be sent for clinical review and receive authorization for both axicabtagene ciloleucel and for hospital admission prior to drug administration or claim payment.

Follicular lymphoma

1. Patient has received two or more lines of systemic therapy, **AND**
2. Patient has not received prior treatment with CAR-T therapy, including Yescarta, **AND**
3. Being used as single-agent therapy

Covered Dose
One-time IV infusion. 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.

Coverage Period
Single infusion per lifetime

ICD-10:
C82.00-C82.09, C82.10-C82.19, C82.20-C82.29, C82.30-C82.39, C82.40-C82.49, C82.50-C82.59, C82.60-C82.69, C82.80-C82.89, C82.90-C82.99, C83.30-C83.39, C85.20-C85.29

Large B-cell lymphoma

1. Diagnosis of large B-cell lymphoma defined as one of the following: Diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, DLBCL arising from follicular lymphoma (also known as transformation FL) or from nodal marginal zone lymphoma, B-cell monomorphic post-transplant lymphoproliferative disorders (PTLD), and the following AIDS-related B-cell lymphoma: DLBCL, primary effusion lymphoma, and HHV8-positive DLBCL not otherwise specific (NOS), **AND**
2. Patient does not have primary central nervous system lymphoma, **AND**
3. Patient has not received prior treatment with CAR-T therapy, including Yescarta, **AND**
4. Being used as a single agent therapy, **AND**
5. Patient has not achieved complete response or has experienced loss of response after receiving at least one prior line of systemic therapy (with or without prior hematopoietic stem cell transplantation)

Covered Dose
One-time IV infusion. 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.

Coverage Period
Single infusion per lifetime

ICD-10:
B20, C82.0-C82.99, C83.30- C83.39, C85.1-C85.19, C85.20-C85.29, C85.80-C85.89

Marginal zone lymphomas

1. Diagnosis of one of the following: nodal marginal zone lymphoma, extranodal marginal zone lymphoma of nongastric sites (non-cutaneous), splenic marginal zone lymphoma, extranodal marginal zone lymphoma (EMZL) of the stomach, **AND**
2. Patient has received two or more lines of systemic therapy, **AND**
3. Patient has not received prior treatment with CAR-T therapy, including Yescarta, **AND**

4. Being used as single-agent therapy

Covered Dose
One-time IV infusion. 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.

Coverage Period
Single infusion per lifetime

ICD-10:
C83.00, C83.07, C83.08, C83.80-C83.89, C85.87, C88.4

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Yescarta® (axicabtagene ciloleucel) must be sent for clinical review and receive authorization for both axicabtagene ciloleucel and for hospital admission prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- Yescarta is supplied in an infusion bag containing genetically modified autologous T cells [2×10^6 CAR-positive viable T cells per kg of body weight, with a maximum of 2×10^8 CAR-positive viable T cells] in approximately 68 mL of frozen suspension in 5% DMSO and 2.5% albumin (human).

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network Drugs & Biologics Compendium. Yescarta® (2021). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. B-Cell lymphomas (Version 5.2021). Available at: www.nccn.org
- Yescarta® (axicabtagene ciloleucel) [Prescribing information]. Santa Monica, CA: Kite Pharma, Inc.; 2021.

(7) Policy Update

Date of last review: 2Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee