Policy:	**Oncology (Injectable – CAR-T) – Yescarta Utilization Management Medical Policy** • Yescarta® (axicabtagene ciloleucel intravenous infusion – Kite Pharma)
Date:	04/20/2026
Applicable Lines of Business:	Medicare Advantage - Medical
Applicable States:	All States
Applicable NCDs, LCDs, and/or LCAs	NCD 110.24

SUMMARY OF EVIDENCE

Yescarta, a CD19-directed genetically modified autologous T-cell immunotherapy, is indicated for the treatment of adults with:[1]

- **Follicular lymphoma** that has relapsed or is refractory after two or more lines of systemic therapy. This indication was approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials(s).
- **Large B-cell lymphoma** in the following situations:
  - Disease that is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy.
  - Relapsed or refractory disease after two or more lines of systemic therapy, including diffuse B-cell lymphoma (DLBCL) not otherwise specified, primarily mediastinal large B-cell lymphoma, high-grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Yescarta, a chimeric antigen receptor T-cell (CAR-T) therapy, is supplied as an infusion bag containing approximately 68 mL of frozen suspension of genetically modified autologous T cells.[1] The target dose is 2 x 10^6 CAR-positive T cell per kg body weight with a maximum of 2 x 10^8 viable T cells. Yescarta is stored in the vapor phase of liquid nitrogen (less than or equal to minus 150°C) and supplied in a liquid nitrogen dry shipper.

Guidelines

The National Comprehensive Cancer Network (NCCN) has addressed Yescarta in the following guidelines:

- **B-cell lymphomas:** Guidelines (version 3.2026 – March 12, 2026) recommend Yescarta for the treatment of a variety of B-cell lymphomas in patients with relapsed or refractory disease and after at least two chemotherapy regimens.[2,3] Recommended indications include follicular lymphoma, extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites (noncutaneous), nodal marginal zone lymphoma, splenic marginal zone lymphoma, DLBCL, DLBCL which transformed from indolent lymphoma, high-grade B-cell lymphoma, human immunodeficiency virus (HIV)-related B-cell lymphoma, primary effusion lymphoma, human herpes virus 8 (HHV8)-positive DLBCL, and post-transplant lymphoproliferative disorders (category 2A). In addition, Yescarta is recommended for DLBCL, high-grade B-cell lymphoma, HIV-related B-cell lymphoma, primary effusion lymphoma, HHV8-positive DLBCL, and post-transplant lymphoproliferative disorders as additional therapy for relapsed or refractory disease > 12 months after completion of first-line therapy and partial response following second-line therapy (category 2A) and for patients with

primary refractory or relapsed disease < 12 months after first-line therapy (category 1 for DLBCL, category 2A for all others).

- **Pediatric aggressive mature B-cell lymphoma:** Guidelines (version 1.2026 – March 20, 2026) recommend Yescarta for relapsed or refractory primary mediastinal large B-cell lymphoma after at least two chemoimmunotherapy regimens, as consolidation/additional therapy if partial response following therapy for refractory or relapsed disease (category 2A).[3,4]
- **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma:** Guidelines (version 2.2026 – December 22, 2025) recommend Yescarta for Richter transformation in patients with CLL (category 2A).[5] It can be used after at least one prior systemic therapy regimen.

Safety

Yescarta has a Boxed Warning regarding cytokine release syndrome, neurological toxicities, and secondary hematological malignancies.[1]

ANALYSIS OF EVIDENCE

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Yescarta. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the Sources of Information section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Sources of Information section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

Indications with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.

Indications with a @ below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.

Indications with a # below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Yescarta is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. B-Cell Lymphoma. ^

Criteria. Approve a single dose if the patient meets ALL of the following (A, B, C, and D):

A) Patient meets ONE of the following (i or ii):

- **i.** Patient meets BOTH of the following (a and b):
  - **a)** Patient has ONE of the following diagnoses [(1), (2), (3), (4), (5), or (6)]:
    - **1)** Follicular lymphoma; IC-COMP OR
    - **2)** Extranodal marginal zone lymphoma of the stomach; IC-COMP OR
    - **3)** Extranodal marginal zone lymphoma of nongastric sites (noncutaneous); IC-COMP OR
    - **4)** Nodal marginal zone lymphoma; IC-COMP OR
    - **5)** Splenic marginal zone lymphoma; IC-COMP OR
    - **6)** Diffuse large B-cell lymphoma arising from indolent lymphoma; IC-COMP OR
  - **b)** Yescarta is used for disease that is relapsed or refractory after two or more lines of systemic therapy; IC-COMP OR

    Note: Examples of systemic therapy include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + Gazyva (obinutuzumab intravenous infusion) or rituximab products, CVP (cyclophosphamide, vincristine, prednisone) + rituximab products, lenalidimide + rituximab products.
- **ii.** Patient meets BOTH of the following (a and b):

a) Patient has ONE of the following diagnoses [(1), (2), (3), (4), (5), (6), (7) or (8)]:
- **1)** Human immunodeficiency virus (HIV)-related B-cell lymphoma; IC-COMP OR
- **2)** HIV-related plasmablastic lymphoma; IC-COMP OR
- **3)** Human herpes virus 8-positive diffuse large B-cell lymphoma; IC-COMP OR
- **4)** Primary effusion lymphoma; IC-COMP OR
- **5)** Post-transplant lymphoproliferative disorders; IC-COMP OR
- **6)** Diffuse large B-cell lymphoma; IC-COMP OR
- **7)** Primary mediastinal large B-cell lymphoma; IC-COMP OR
- **8)** High-grade B-cell lymphoma; IC-COMP OR
- **9)** Large B-cell lymphoma; IC-COMP AND

b) Yescarta is used in ONE of the following situations [(1), (2), (3), or (4)]:
- **1)** For disease that is relapsed or refractory after two or more lines of systemic therapy; IC-COMP OR
  Note: Examples of systemic therapy include RCHOP (rituximab product, cyclophosphamide, doxorubicin, vincristine, prednisone), dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab product, DHA (dexamethasone, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin) ± rituximab product.
- **2)** For primary refractory disease; IC-COMP OR
- **3)** For relapsed disease < 12 months after completion of first-line therapy; IC-COMP OR
  Note: Examples of first-line therapy include RCHOP (rituximab product, cyclophosphamide, doxorubicin, vincristine, prednisone), dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab product, RCDOP (rituximab product, cyclophosphamide, liposomal doxorubicin, vincristine, prednisone).
- **4)** For disease relapse > 12 months after first-line therapy and partial response to second-line therapy; IC-COMP AND
  Note: Examples of systemic therapy include RCHOP (rituximab product, cyclophosphamide, doxorubicin, vincristine, prednisone), dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab product, RCDOP (rituximab product, cyclophosphamide, liposomal doxorubicin, vincristine, prednisone).

B) The patient is ≥ 18 years of age; IC-COMP AND

C) The patient received or plans to receive lymphodepleting chemotherapy prior to Yescarta infusion; IC-COMP AND

D) The patient has not been previously treated with chimeric antigen receptor T-cell (CAR-T) therapy. IC-COMP
Note: Examples of CAR-T therapy includes Yescarta, Breyanzi (lisocabtagene maraleucel intravenous infusion), Kymriah (tisagenlecleucel intravenous infusion), Tecartus (brexucabtagene autoleucel intravenous infusion) Abecma (idecabtagene vicleucel intravenous infusion) and Carvykti (ciltacabtagene autoleucel intravenous infusion).

Dosing. The dose is up to a maximum of 2 x 10^8 CAR-positive viable T-cells administered intravenously.[1]

Other Uses with Supportive Evidence

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2. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. ^

Criteria. Approve a single dose if the patient meets ALL of the following (A, B, C, D, and E):

A) Patient is ≥ 18 years of age; [IC-COMP] AND

B) Patient has histologic transformation to diffuse large B-cell lymphoma; [IC-COMP] AND

C) Patient has received at least one prior systemic therapy; [IC-COMP] AND

Note: Examples of systemic therapy include dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin, rituximab), RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone), hyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone, rituximab), Venclexta (venetoclax tablets) + Tecentriq (atezolizumab intravenous infusion) + Gazyva (obinutuzumab intravenous infusion), Opdivo (nivolumab intravenous infusion) or Keytruda (pembrolizumab intravenous infusion) ± ibrutinib, Jaypirca (pirtobrutinib tablets), Epkinly (epcoritamab-bysp subcutaneous injection), Columvi (glofitamab-gxbm intravenous infusion), Brukinsa (zanubrutinib capsule) + Tevimbra (tislelizumab-jsgr intravenous infusion).

D) Patient received or plans to receive lymphodepleting chemotherapy prior to Yescarta infusion; [IC-COMP] AND

E) Patient has not been previously treated with chimeric antigen receptor T-cell (CAR-T) therapy. [IC-COMP]

Note: Examples of CAR-T therapy includes Yescarta, Breyanzi (lisocabtagene maraleucel intravenous infusion), Kymriah (tisagenlecleucel intravenous infusion), Tecartus (brexucabtagene autoleucel intravenous infusion) Abecma (idecabtagene vicleucel intravenous infusion) and Carvykti (ciltacabtagene autoleucel intravenous infusion).

Dosing. The dose is up to a maximum of 2 x 10^8 CAR-positive viable T-cells administered intravenously.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Yescarta is not recommended in the following situations.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

SOURCES OF INFORMATION

1. Yescarta® intravenous infusion [prescribing information]. Santa Monica, CA: Kite Pharma; February 2026.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 3.2026 – March `12, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed March 23, 2026.
3. The NCCN Drugs and Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 23, 2026. Search term: axicabtagene.
4. The NCCN Pediatric Aggressive Mature B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 1.2026 – March 20, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed March 23, 2026.
5. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 2.2026 – December 22, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 16, 2026.
6. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). Original effective date 8/7/2019. Implementation date 2/16/2021. Revision date: 07/2025. Accessed April 20, 2026.

HISTORY

Type of Revision	Summary of Changes*	Date
New Policy	New Medicare Advantage Medical Policy	10/09/2019
Select revision	Non-clinical update to policy to add the statement "This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage."	1/30/2020
Select revision	Added the following to the Policy Statement "Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles."	04/03/2020
Policy revision	**B-cell lymphoma:** Added approval criteria for diffuse large B-cell lymphoma arising from nodal marginal zone lymphoma. Revised criteria to not allow previous treatment with Kymriah.	05/04/2020
Policy revision	**B-cell lymphoma:** Added follicular lymphoma to the list of approvable diagnoses. Revised criterion: Patient has not been previously treated with Yescarta or Kymriah, to: Patient has not been previously treated with chimeric antigen receptor (CAR)-T therapy. Added Note listing all CAR-T therapies Revised dose to specify maximum dose is 2 x 10^8 CAR-positive T-cells and removed "per kg of body weight." **Conditions Not Recommended for Approval:** Removed Retreatment with Yescarta criteria (not needed since addressed in criteria section).	04/14/2021
Policy revision	**B-Cell Lymphoma:** Added "or plan to receive" to the requirement that the patient receive lymphodepleting chemotherapy prior to Yescarta infusion. Also, for the criterion "The patient has not been previously treated with CAR-T therapy" – added Abecma to the list of examples of CAR-T therapy.	01/14/2022
Policy revision	**B-Cell Lymphoma:** Added gastric MALT lymphoma, nongastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma as additional options of approval.	04/08/2022
Policy revision	**B-Cell Lymphoma:** Added other options for approval for diffuse large B-cell lymphoma (DLBCL), acquired immune deficiency syndrome-related B-cell lymphoma, human herpes virus 8-positive DLBCL, post-transplant lymphoproliferative disorders, DLBCL, primary mediastinal large B-cell lymphoma, high-grade B-cell lymphoma, and large B-cell lymphoma. Approval options include primary refractory disease, disease relapse < 12 months after completion of first-line therapy, and disease relapse > 12 months after first-line therapy in a patient with intent to proceed to transplantation who has a partial response to second-line therapy.	06/28/2022
Policy revision	**B-Cell Lymphoma:** Gastric MALT lymphoma was changed to	05/01/2023

	extranodal marginal zone lymphoma of the stomach. Nongastric MALT lymphoma (noncutaneous) was changed to extranodal marginal zone lymphoma of nongastric sites (noncutaneous). Acquired immune deficiency syndrome (AIDS) was changed to human immunodeficiency virus (HIV). Primary effusion lymphoma was added as an option for approval.	
Policy revision	Added: "The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy." to the Policy Statement.	07/26/2023
Policy revision	**B-Cell Lymphoma:** Follicular was changed to indolent in the option for approval "diffuse large B-cell lymphoma arising from indolent lymphoma." Removed diffuse large B-cell lymphoma arising from nodal marginal zone lymphoma. Removed "in a patient with intent to proceed to transplantation who has" from option for approval "disease relapse > 12 months after first-line therapy and partial response to second-line therapy." Based on review of commercial policy revision	04/22/2024
Policy review	No criteria changes. Review based on NCD surveillance review.	01/06/2025
Policy revision	No criteria changes. Formatting and notation updates.	03/11/2025
Policy revision	**B-Cell Lymphoma:** Added HIV-related plasmablastic lymphoma as a new option for approval.	03/25/2025
Policy review	No criteria changes. Review based on NCD surveillance review.	06/03/2025
Policy review	No criteria changes. Review based on NCD surveillance review.	09/05/2025
Policy revision	**Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma:** This new condition of approval was added to the policy.	04/20/2026