Yescarta (axicabtagene ciloleucel)
PAM – 031

Iowa Medicaid Program	Prior Authorization	**Effective Date**	07/01/2021
Revision Number	6	**Last Reviewed**	10/17/2025
Reviewed By	Medicaid Medical Director	**Next Review**	10/16/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	01/15/2021

Overview

Medication: [1]	axicabtagene ciloleucel
Brand Name:	Yescarta®
Pharmacologic Category:	Antineoplastic; CD19-directed genetically modified autologous T cell immunotherapy
FDA-Approved Indication(s):	1. Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy. 2. 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. ▶ Limitations of Use: Yescarta® is not indicated for the treatment of patients with primary central nervous system lymphoma. 3. Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. ▶ Accelerated Approval: This indication is 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 trial(s).
How Supplied:	Infusion bag containing approximately 68 mL of frozen suspension of genetically modified autologous T cells in 5% DMSO and 2.5% albumin (human)
Dosage and Administration:	• Target dose: 2 x 10^6 CAR-positive viable T cells per kilogram (kg) body weight • Maximum dose: 2 x 10^8 CAR-positive viable T cells
Benefit Category:	Medical

BOXED WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, AND SECONDARY HEMATOLOGICAL MALIGNANCIES

- Cytokine release syndrome (CRS), including life-threatening reactions, occurred in patients receiving Yescarta®. Do not administer to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.

BOXED WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, AND SECONDARY HEMATOLOGICAL MALIGNANCIES
• Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving Yescarta®, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment. Provide supportive care and/or corticosteroids, as needed. • T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including Yescarta®.

POST-INFUSION MONITORING
• Monitor patients at least daily for seven days following YESCARTA infusion for signs and symptoms of CRS and neurologic toxicities. • Instruct patients to remain within proximity of a healthcare facility for at least two weeks following infusion. • Advise patients to avoid driving for at least 2 weeks following infusion.

Descriptive Narrative

Diffuse Large B-Cell Lymphoma (DLBCL)

Diffuse large B-cell lymphoma (DLBCL) is the most common histologic subtype of non-Hodgkin lymphoma (NHL) accounting for approximately 25 percent of NHL cases in the developed world. In the United States, the incidence of DLBCL is approximately 7 cases per 100,000 persons per year. Incidence varies by ethnicity, with White Americans having higher rates than Black, Asian, and American Indian or Alaska Native individuals, in order of decreasing incidence. Like most other NHLs, there is a male predominance with approximately 55 percent of cases occurring in men. Incidence increases with age; the median age at presentation is 64 years for patients as a whole but appears to be younger for Black compared with White Americans.[2]

Follicular Lymphoma (FL)

Follicular lymphoma (FL) is the second most common subtype of NHL and is the most common of the clinically indolent NHLs (defined as those lymphomas in which survival of the untreated patient is measured in years). The vast majority of patients treated for FL will have an initial response to therapy, with 40 to 80 percent demonstrating a complete response, depending on the initial regimen used. However, conventional therapy for FL is not curative and most of these patients will ultimately develop progressive disease. In addition, less than 10 percent of patients treated with initial chemoimmunotherapy will not respond to treatment (i.e., refractory disease).[3]

In the United States as a whole, the estimated incidence of FL is 3.18 cases per 100,000 people. The incidence is stable over time, but varies, with the incidence in White populations being more than twice that in African and Asian

populations. The incidence increases with age; FL most frequently presents in middle-aged individuals and the elderly; the median age at diagnosis is 65 years. Rarely, FL arises in children or adolescents.[4]

Definitions

CAR T-cell therapy: A type of treatment in which a patient's T cells taken from a patient's blood are changed in the laboratory so they will attack cancer cells. Then the gene for a special receptor that binds to a certain protein on the patient's cancer cells is added to the T cells in the laboratory. The special receptor is called a chimeric antigen receptor (CAR). Large numbers of the CAR T cells are grown in the laboratory and given to the patient by infusion. Also called chimeric antigen receptor T-cell therapy.

Refractory disease: illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Guidelines

The National Comprehensive Cancer Network (NCCN) publishes guidelines for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines® are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. The guidelines are developed and updated by 61 individual panels, comprising over 1,700 clinicians and oncology researchers from the 33 NCCN Member Institutions.

Guidelines are reviewed and updated on a continual basis to ensure that the recommendations take into account the most current evidence. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.[5,6]

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):[7]

- B-Cell Lymphomas (v.3.2024 – August 26, 2024)

NCCN Guidelines® Recommendation(s) for axicabtagene ciloleucel in B-cell lymphomas
(1) Diffuse large B-cell lymphoma (DLBCL) a. Category 1, second-line option for relapsed disease < 12 months or primary refractory disease b. Category 2A, third-line and subsequent treatment option for DLBCL (2) Follicular lymphoma (FL) a. Category 2A, third-line and subsequent treatment option for FL (grade 1-2) (3) Marginal zone lymphomas (MZL) a. Category 2A, third-line and subsequent treatment option for MZL (if not previously given) (4) Histologic transformation of indolent lymphomas (FL or nodal MZL) to DLBCL a. Category 2A treatment option (T-cell engager therapy) ** patients should have received at least one anthracycline or anthracenedione-based regimen, unless contraindicated*

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale [8]

Developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group, and published in 1982, the ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). It is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient, and to determine appropriate treatment and prognosis.

Grade	ECOG Performance Status [Synonyms: WHO/Zubrod score]
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair.
5	Dead.

Criteria

Tocilizumab (Actemra®) may be required to manage cytokine release syndrome or neurologic toxicities. If tocilizumab therapy is required, may be approved for up to 4 doses of 800 mg each. HCPCS code J3262 suspends for claims review.

Prior authorization is required.

Large B-Cell Lymphoma (LBCL)

Yescarta® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of large B-cell lymphoma [including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high-grade B-cell lymphoma (HGBL), primary mediastinal large B-cell lymphoma (PMBCL), DLBCL from follicular lymphoma (FL), monomorphic post-transplant lympho-proliferative disorders (B-cell type), HIV-related DLBCL, primary effusion lymphoma, and human herpesvirus-8 (HHV8)-positive DLBCL not otherwise specified]; **AND**
2. Disease meets one of the following (a or b):
    a. Disease is refractory or member has relapsed after receiving two or more lines of systemic therapy, which includes an anthracycline-containing chemotherapy regimen (e.g., doxorubicin) and rituximab; **OR**
    b. Disease is refractory to first-line chemoimmunotherapy or has relapsed within twelve (12) months of first-line chemoimmunotherapy; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
5. Prescribed by, or in consultation with, an oncologist; **AND**
6. Member does not have primary central nervous system lymphoma; **AND**
7. Member has not received any previous treatment with chimeric antigen receptor (CAR) T-cell immunotherapy or other genetically modified T-cell therapy (e.g., Abecma®, Carvykti®, Breyanzi®, Kymriah®, or Tecartus®), nor will CAR T therapy or other genetically modified T-cell therapy be prescribed concurrently with Yescarta®; **AND**
8. Yescarta® is given as a one-time, single administration treatment; **AND**
9. Dose does not exceed 2 x 10^8 CAR-positive viable T-cells.

Continued therapy will not be authorized, as Yescarta® is indicated to be dosed one time only.

Relapsed or Refractory Follicular Lymphoma (r/r FL)

Yescarta® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of follicular lymphoma (FL) (grade 1, 2, or 3a); **AND**
2. Disease is relapsed or refractory after receiving two or more lines of systemic therapy that includes a combination of an anti-CD20 monoclonal antibody (e.g., rituximab or obinutuzumab) and an alkylating agent (e.g., bendamustine, cyclophosphamide, chlorambucil); **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
5. Prescribed by, or in consultation with, an oncologist; **AND**
6. Member does not have transformed lymphoma or other aggressive lymphoma; **AND**
7. Member has not had a prior autologous hematopoietic stem cell transplantation; **AND**
8. Member has not received any previous treatment with chimeric antigen receptor (CAR) T-cell immunotherapy or other genetically modified T-cell therapy (e.g., Abecma®, Carvykti®, Breyanzi®, Kymriah®, or Tecartus®), nor will CAR T therapy or other genetically modified T-cell therapy be prescribed concurrently with Yescarta®; **AND**
9. Yescarta® is given as a one-time, single administration treatment; **AND**
10. Dose does not exceed 2 x 10^8 CAR-positive viable T-cells.

Continued therapy will not be authorized, as Yescarta® is indicated to be dosed one time only.

Approval Duration and Quantity Limits

	Initial Authorization	**Subsequent Authorization(s)**
Approval Duration	One course of treatment per lifetime	Not applicable
Quantity Limits	Not to exceed 2 x 10^8 CAR-positive viable T-cells	

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J3262	Injection, tocilizumab, 1 mg (Actemra: may be required to manage cytokine release syndrome or neurologic toxicities)
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

ICD-10	Description
C82.00-C82.99	Follicular lymphoma
C83.30-C83.39	Diffuse large B-cell lymphoma
C85.20-C85.29	Mediastinal (thymic) large B-cell lymphoma

NDC	Labeler	Dosage	Pkg Size	Pkg Qty	Units /Pkg
71287-0119-01	Kite Pharma, Inc. (71287)	per therapeutic dose	1	EA	1

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Yescarta® prescribing information (06/2025). Kite Pharma, Inc.: Santa Monica, CA. Available online: www.yescartahcp.com. Accessed August 25, 2025.

[2] Aster JC, Herrera AF. Diffuse large B cell lymphoma and other large B cell lymphomas: Presentation, diagnosis, and classification. Rosmarin AG, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed June 9, 2025.

[3] Freedman AS, Friedberg JW. Treatment of relapsed or refractory follicular lymphoma. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed September 11, 2024.

[4] Freedman AS, Aster JC. Clinical manifestations, pathologic features, diagnosis, and prognosis of follicular lymphoma. Rosmarin AG, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed September 11, 2024.

[5] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[6] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[7] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

- B-Cell Lymphomas (v.3.2024 – August 26, 2024)

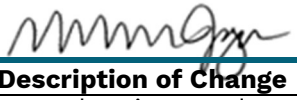
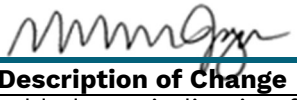
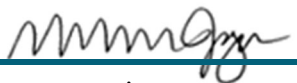
[8] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
10/17/2025	CAC	Annual review. Updated boxed warning to reflect removal of REMS requirement and added post-infusion monitoring requirements in a separate table (Overview section). Updated criteria to remove requirement that Yescarta® be administered at a REMS facility.	6
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
10/18/2024	CAC	Annual review. Updated boxed warning to include new warning for possible occurrence of T cell malignancies following treatment with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies. Updated statistics in Descriptive Narrative. Reviewed NCCN recommendations; no changes.	5
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
07/21/2023	CAC	Annual review. Updated Overview table (new indication from April 2022 wasn't added to this section in previous update). Updated NCCN recommendations. Added standard CAR T language to criteria (e.g., administered at REMS facility, max dosing, etc.)	4
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
07/15/2022	CAC	Added new indication for large B-cell lymphoma refractory to first-line therapy or that relapses within 12 months of first-line therapy.	3
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
07/16/2021	CAC	Added new indication for Relapsed or Refractory Follicular Lymphoma. Updated references. Updated criteria format.	2
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
01/15/2021	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee