

Yescarta™ (axicabtagene ciloleucel)



Pharmacy Coverage Policy

Effective Date: January 01, 2023

Revision Date: January 01, 2023

Page: 1 of 6

Review Date: September 22, 2022

Line of Business: Medicaid - Louisiana

Policy Type: Prior Authorization

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to date version. Refer to http://apps.humana.com/tad/tad_new/home.aspx to verify that this is the current version before utilizing.

**Disclaimer
Description
Coverage Determination**

**Background
Medical Terms
References**

Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at <http://www.cms.hhs.gov/>. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise without permission from Humana.

Description

Yescarta (axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T cell immunotherapy, which involves reprogramming a patient's own T cells with a retroviral transduction to express a chimeric antigen receptor (CAR) to identify and eliminate CD19-expressing malignant and normal cells.

Yescarta (axicabtagene ciloleucel) is indicated for the treatment of 1) adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy or 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; and 2) adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.

Axicabtagene ciloleucel is available as Yescarta as a frozen suspension of genetically modified autologous T cells in one infusion bag labeled for the specific recipient.

Coverage

Please note the following regarding medically accepted indications:

Page: 2 of 6

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to http://apps.humana.com/tad/tad_new/home.aspx to verify that this is the current version before utilizing.

Determination

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- **American Hospital Formulary Service-Drug Information (AHFS-DI)**
- **National Comprehensive Cancer Network (NCCN) Drugs and Biologics**
- **Compendium**
- **Truven Health Analytics Micromedex DrugDEX**

See the **[DISCLAIMER](#)**. All Humana member health plan contracts are NOT the same. All legislation/regulations on this subject

Elsevier/Gold Standard Clinical Pharmacology

Wolters Kluwer Lexi-Drugs

Yescarta (axicabtagene ciloleucel) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Large B-cell Lymphoma (3L)

- **The member has a diagnosis of large B-cell lymphoma [i.e. 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] AND**
- **The member has had two or more lines of previous systemic therapy AND For**
 - **DLBCL arising from follicular lymphoma, must have received prior chemotherapy for follicular lymphoma and subsequently have chemorefractory disease after transformation to DLBCL**
- **The member has relapsed or refractory disease, defined as one of the**
 - **following: Best response to most recent regimen was progressive disease or stable disease and relapse is occurring within 6 months from last dose OR**
 - **Disease progression or recurrence less than or equal to 12 months after**
prior

Page: 3 of 6

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to http://apps.humana.com/tad/tad_new/home.aspx to verify that this is the current version before utilizing.

autologous stem cell transplant (ASCT) AND

- **The member is greater than or equal to 18 years of age AND**
- **The member will be using Yescarta in conjunction with lymphodepleting chemotherapy (fludarabine 30 mg/m2 daily for 3 days and cyclophosphamide 500 mg/m2 daily for 3 days) AND**
- **The member will be using Yescarta (axicabtagene ciloleucel) at a treatment center that is certified to administer Yescarta (axicabtagene ciloleucel)**

Large B-Cell Lymphoma (2L)

- The member has a diagnosis of large B-cell lymphoma AND
- The member is refractory to first-line chemoimmunotherapy* OR
- The member has relapsed or refractory disease within 12 months of first-line chemoimmunotherapy

AND

- The member is greater than or equal to 18 years of age AND
- The member will be using Yescarta in conjunction with lymphodepleting chemotherapy (fludarabine 30 mg/m2 daily for 3 days and cyclophosphamide 500 mg/m2 daily for 3 days) AND
- The member will be using Yescarta (axicabtagene ciloleucel) at a treatment center that is certified to administer Yescarta (axicabtagene ciloleucel)

*Refractory to first-line chemoimmunotherapy is defined as partial response, no response, or progression while on therapy

Follicular Lymphoma

- The member has a diagnosis of follicular lymphoma AND
- The member has had two or more lines of previous systemic therapy AND
- The member has relapsed or refractory disease, defined as one of the following:
Best response to most recent regimen was progressive disease or stable disease

Page: 4 of 6

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to date version. Refer to http://apps.humana.com/tad/tad_new/home.aspx to verify that this is the current version before utilizing.

- and relapse is occurring within 6 months from last dose OR
 - Disease progression or recurrence less than or equal to 12 months after prior autologous stem cell transplant (ASCT) AND
- The member is greater than or equal to 18 years of age AND
- The member will be using Yescarta in conjunction with lymphodepleting chemotherapy (fludarabine 30 mg/m2 daily for 3 days and cyclophosphamide 500 mg/m2 daily for 3 days) AND

See the [DISCLAIMER](#). All Humana member health plan contracts are NOT the same. All legislation/regulations on this subject

- The member will be using Yescarta (axicabtagene ciloleucel) at a treatment center that is certified to administer Yescarta (axicabtagene ciloleucel)

Yescarta (axicabtagene ciloleucel) will be approved for 60 days duration or as determined through clinical review. A maximum of one dose per lifetime will apply.

Coverage
Limitations

Yescarta (axicabtagene ciloleucel) therapy is not considered medically necessary for members with the following concomitant conditions:

- The member has received prior CD-19 targeted therapy
- The member has received prior CD-19 targeted CAR-T cell therapy (e.g. tisagenlecleucel)
- The member has active hepatitis B (HBs AG-positive) or hepatitis C infection
- The member has HIV/AIDs
- The member has a diagnosis of primary central nervous system lymphoma
- The member has received prior allogeneic transplant

• Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature. Background This is a prior authorization policy about Yescarta (axicabtagene ciloleucel).

Refer all requests or questions regarding Yescarta (axicabtagene ciloleucel) to the

Page: 5 of 6

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to date version. Refer to http://apps.humana.com/tad/tad_new/home.aspx to verify that this is the current version before utilizing.

Corporate Transplant Department at 1-866-421-5663.



Fax: 502-508-9300



Email: transplant@humana.com

Yescarta (axicabtagene ciloleucel) is only available at certain centers. For more information, please visit: <https://www.yescarta.com/authorized-treatment-centers/>.

See the [DISCLAIMER](#). All Humana member health plan contracts are NOT the same. All legislation/regulations on this subject

Black Box Warnings

- **Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving Yescarta. Do not administer Yescarta to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab.**
- **Neurological toxicities, which may be severe or life-threatening, can occur following treatment with Yescarta, including concurrently with CRS. Monitor for neurological events after treatment with Yescarta. Provide supportive care as needed.**
- **Yescarta is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA REMS.**

Warnings and Precautions

- **Serious infections**
- **Prolonged cytopenias**
- **Hypogammaglobulinemia**
- **Secondary malignancies**

The American Society of Clinical Oncology HBV screening and management provisional clinical opinion (ASCO [Hwang 2020]) recommends HBV screening with hepatitis B surface antigen, hepatitis B core antibody, total Ig or IgG, and antibody to hepatitis B surface antigen prior to beginning (or at the beginning of) systemic anticancer therapy; do not delay treatment for screening/results. Detection of chronic or past HBV infection

Page: 6 of 6

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to date version. Refer to http://apps.humana.com/tad/tad_new/home.aspx to verify that this is the current version before utilizing.

requires a risk assessment to determine antiviral prophylaxis requirements, monitoring, and follow-up.

Hwang JP, Feld JJ, Hammond SP, et al. Hepatitis B virus screening and management for patients with cancer prior to therapy: ASCO provisional clinical opinion update. *J Clin Oncol*. 2020;38(31):3698-3715. doi:10.1200/JCO.20.01757[PubMed 32716741]

See the [DISCLAIMER](#). All Humana member health plan contracts are NOT the same. All legislation/regulations on this subject

Yescarta™ (axicabtagene ciloleucel)

Effective Date: 1/1/2023

Revision Date: 1/1/2023

Review Date: 9/22/2022

Line of Business: Medicaid - Louisiana

Policy Type: Prior Authorization

<u>Provider</u>	<u>For medically billed requests, please visit www.humana.com/PAL. Select applicable</u>
<u>Claims Codes</u>	<u>Preauthorization and Notification List(s) for medical and procedural coding</u>
	<u>information.</u>
<u>Medical Terms</u>	<u>Yescarta ; axicabtagene ciloleucel; large B-cell lymphoma; DLBCL; follicular</u>
	<u>lymphoma; FL; CAR-T; pharmacy</u>
<u>References</u>	<u>Yescarta (axicabtagene ciloleucel) [prescribing information]. Kite Pharma. Santa</u>
	<u>Monica, CA. April 2022.</u>
	<u>Clinical Pharmacology [online database]. Tampa, FL: Gold Standard, Inc. URL:</u>
	<u>http://www.clinicalpharmacology.com. Updated periodically.</u>
	<u>Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated</u>
	<u>periodically.</u>
	<u>Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo:</u>
	<u>Thomson Healthcare. Updated periodically.</u>
	<u>NCCN Drug and Biologics Compendium. Fort Washington, PA: National</u>
	<u>Comprehensive Cancer Network (NCCN); Updated periodically.</u>

See the [DISCLAIMER](#). All Humana member health plan contracts are NOT the same. All legislation/regulations on this subject

may not be included. This document is for informational purposes only.