CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Yescarta (axicabtagene ciloleucel)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Yescarta, approved by the FDA in 2017, is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adults with: 1) Large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy, 2) 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; and 3) Relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy (accelerated approval). NCCN supports off label use of Yescarta for marginal zone lymphoma as a third or subsequent line of therapy per the ZUMA-5 study.

Yescarta (axicabtagene ciloleucel) will be considered for coverage when the following criteria are met:

Large B-Cell Lymphoma (LBCL)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Member has a documented diagnosis of large B-cell lymphoma including any of the following:
   a) Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS)
   b) Primary mediastinal large B-cell lymphoma (PMBCL)
   c) High grade B-cell lymphoma (HGBCL)
   d) DLBCL arising from follicular lymphoma (transformation FL; TFL)
   e) Intravascular LBCL
   f) DLBCL associated with chronic inflammation
   g) Fibrin-associated DLBCL
   h) EBV-positive DLBCL, NOS
   i) T-cell/histiocyte-rich LBCL; AND
3. Member's condition meets one of the following:
   a) Refractory to first-line chemoimmunotherapy (primary refractory)
   b) Relapsed within 12 months of first-line chemoimmunotherapy
   c) Relapsed or refractory after 2 or more lines of systemic therapy; AND
4. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
5. Member does NOT have any of the following:
   a) Prior allogeneic HSCT
   b) History or presence of primary central nervous system (CNS) lymphoma
   c) Prior CAR-T therapy; AND
6. Member has been or will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells; AND
7. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program; AND
8. Member's weight is documented for dose calculation.
9. **Dosage allowed/Quantity limit:** 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Yescarta will not be reauthorized for continued therapy.

Follicular Lymphoma (FL)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Member has a documented diagnosis of relapsed or refractory follicular lymphoma; AND
3. Member's disease has progressed after 2 or more lines of systemic therapy; AND
4. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
5. Member does NOT have any of the following:
   a) Prior allogeneic HSCT
   b) History or presence of primary central nervous system (CNS) lymphoma
   c) Prior CAR-T therapy; AND
6. Member has been or will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells; AND
7. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program; AND
8. Member's weight is documented for dose calculation.
9. **Dosage allowed/Quantity limit:** 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Yescarta will not be reauthorized for continued therapy.

Marginal Zone Lymphoma (MZL) [off-label]

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Member has a diagnosis of marginal zone lymphoma; AND
3. Member's disease has progressed after 2 or more lines of systemic therapy; AND
4. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
5. Member does NOT have any of the following:
   a) Prior allogeneic HSCT
   b) History or presence of primary central nervous system (CNS) lymphoma
   c) Prior CAR-T therapy; AND
6. Member has been or will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells; AND
7. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program; AND
8. Member's weight is documented for dose calculation.
9. **Dosage allowed/Quantity limit:** Off-label; consider FL dosing or consult literature.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Yescarta will not be reauthorized for continued therapy.

CareSource considers Yescarta (axicabtagene ciloleucel) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/24/2017	New policy for Yescarta created.
08/27/2018	Criteria expanded for member's disease history requirement.
08/04/2020	Defined age 18 or older for adults. Specified trial requirement for 2 or more lines of chemo or relapsed after autologous stem cell transplant. Removed pre-treatment regimens because they are already addressed in REMS. Required screening results for active infections. Removed hypersensitivity to aminoglycoside requirement, CNS disorders, and other forms of malignancy from exclusion list. Added prior CAR-T treatment, life expectancy to exclusion list. Updated the name of REMS program.
05/19/2021	Added criteria for new indication of follicular lymphoma. Large B-Cell Lymphoma: Removed life expectancy restriction. Added ECOG score. Added "partial response" to 3a per NCCN slide BCEL-7.
05/05/2022	Transferred to new template. Updated references. Added documentation of weight. Modified large B cell criteria to accommodate label expansion to include 2nd line use. Removed list of large B cell lymphoma subtypes.
12/09/2024	Updated refs. Changed "has been screened" to "has been or will be screened." Added off-label section for MZL; NCCN supported. FL: Removed specific agents required as previous therapy. Changed measurable disease to has progressed. LBCL: Removed auto-HSCT prior therapy option. Added types of LBCL, simplified prior therapy requirements (label, NCCN).

References:

1. Yescarta [package insert]. Santa Monica, CA; Kite Pharma, Inc., 2024.
2. National Comprehensive Cancer Network. B-Cell Lymphomas (Version 3.2024). https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed December 9, 2024.
3. Neelapu SS, et al. Axicabtagene ciloleucel CAR T-cell therapy in refractory large B-cell lymphoma. *N Engl J Med*. 2017;377(26):2531-2544.
4. Locke FL, Miklos DB, Jacobson CA, et al. Axicabtagene Ciloleucel as Second-Line Therapy for Large B-Cell Lymphoma. *N Engl J Med*. 2022;386(7):640-654. doi:10.1056/NEJMoa2116133
5. Jacobson C, Chavez JC, Sehgal AR, et al. Primary analysis of zuma-5: a phase 2 study of axicabtagene ciloleucel (Axi-Cel) in patients with relapsed/refractory (R/R) indolent non-hodgkin lymphoma (iNHL). *Blood*. 2020;136(suppl 1):40-41. [Abstract 623 from ASH 2020 annual meeting].

Effective date: 07/01/2025
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