

## SPECIALTY GUIDELINE MANAGEMENT

### YESCARTA (axicabtagene ciloleucel)

#### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### A. FDA-Approved Indications

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 (NOS), primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.
3. Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Limitations of use: Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.

##### B. Compendial Uses

1. Histologic transformation of indolent lymphomas to DLBCL
2. Human immunodeficiency virus (HIV)-related B-cell lymphomas (including HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specific)
3. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
4. Marginal zone lymphomas (MZL):
  - a. Extranodal MZL of the stomach (gastric mucosa associated lymphoid tissue (MALT) lymphoma)
  - b. Extranodal MZL of nongastric sites (nongastric MALT lymphoma)
  - c. Nodal MZL
  - d. Splenic MZL
5. Pediatric primary mediastinal large B-cell lymphoma

All other indications are considered experimental/investigational and not medically necessary.

#### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:  
Chart notes, medical record documentation or claims history supporting previous lines of therapy.

#### III. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:

- A. Primary central nervous system lymphoma
- B. Previous treatment course with the requested medication or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.
- C. ECOG performance status greater than or equal to 3 (member is not ambulatory and not capable of all self-care, confined to bed or chair more than 50% of waking hours)
- D. Inadequate and unstable kidney, liver, pulmonary or cardiac function
- E. Active hepatitis B, active hepatitis C or a clinically significant active systemic infection
- F. Active inflammatory disorder

#### IV. CRITERIA FOR INITIAL APPROVAL

##### A. Adult Large B-cell Lymphomas

Authorization of 3 months may be granted as treatment of B-cell lymphomas in members 18 years of age or older when either of the following criteria are met:

1. The member has received prior treatment with two or more lines of systemic therapy and has any of the following B-cell lymphoma subtypes:
  - i. Diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma
  - ii. Histologic transformation of indolent lymphomas to DLBCL
  - iii. Diffuse large B-cell lymphoma (DLBCL)
  - iv. Primary mediastinal large B-cell lymphoma
  - v. High-grade B-cell lymphomas (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
  - vi. Human immunodeficiency virus (HIV)-related B-cell lymphomas (including HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specific)
  - vii. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
  - viii. Follicular lymphoma
  - ix. Extranodal marginal zone lymphoma of the stomach (gastric MALT)
  - x. Extranodal marginal zone lymphoma of nongastric sites (nongastric MALT)
  - xi. Nodal marginal zone lymphoma
  - xii. Splenic marginal zone lymphoma
2. The member has received prior treatment with first-line chemoimmunotherapy and has any of the following B-cell lymphoma subtypes:
  - i. Diffuse large B-cell lymphoma (DLBCL)
  - ii. Primary mediastinal large B-cell lymphoma
  - iii. High-grade B-cell lymphomas (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
  - iv. Human immunodeficiency virus (HIV)-related B-cell lymphomas (including HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specific)
  - v. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)

##### B. Pediatric Primary Mediastinal Large B-cell Lymphoma

Authorization of 3 months may be granted for treatment of primary mediastinal large B-cell lymphoma in members less than 18 years of age when the member has received prior therapy with at least two prior chemoimmunotherapy regimens and achieved partial response.

#### V. REFERENCES

1. Yescarta [package insert]. Santa Monica, CA: Kite Pharma; April 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 15, 2024.
3. NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas (Version 1.2024). © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 8, 2024.
4. Neelapu SS, Locke FL, Bartlett NL, et al. Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma. N Engl J Med. 2017;377(26):2531-2544.