# 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 Indication

- 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.
- 2. Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

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

# B. Compendial Uses

- 1. Histologic transformation of nodal marginal zone lymphoma to DLBCL
- 2. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (including AIDS-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)

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. CRITERIA FOR INITIAL APPROVAL

# **Adult 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 all of the following criteria are met:

- A. Member has any of the following B-cell lymphoma subtypes:
  - i. Diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma (also known as histologic transformation of follicular lymphoma to DLBCL)
  - ii. Histologic transformation of nodal marginal zone lymphoma to DLBCL
  - iii. Diffuse large B-cell lymphoma (DLBCL)
  - iv. Primary mediastinal large B-cell lymphoma

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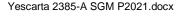


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- v. High-grade B-cell lymphomas (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
- vi. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (including AIDS-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
- B. The member has received prior treatment with two or more lines of systemic therapy.
- C. The member does not have primary central nervous system lymphoma.
- D. The member has not received a previous treatment course of the requested medication or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.
- E. Member has an ECOG performance status 0 to 2 (member is ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours).
- F. The member has adequate and stable kidney, liver, pulmonary and cardiac function.
- G. The member does not have active hepatitis B or hepatitis C or a clinically significant active systemic infection.
- H. The member does not an active inflammatory disorder.

### IV. REFERENCES

- 1. Yescarta [package insert]. Santa Monica, CA: Kite Pharma; March 2021.
- 2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 5, 2021.
- 3. The NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas (Version 3.2021).© 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 05, 2021.
- 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.



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