Reference number(s)
2385-A

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
   1. 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.

   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 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

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.