Reference number(s)
2386-A

STANDARD MEDICARE PART B 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 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.
   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. Diffuse large B-cell lymphoma
   2. Histologic transformation of nodal marginal zone lymphoma to DLBCL
   3. 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)
   4. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. EXCLUSIONS

Coverage will not be provided for members less than 18 years of age.

III. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Testing or analysis confirming CD19 protein on the surface of the B-cell.

IV. CRITERIA FOR INITIAL APPROVAL

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

A. Member meets one of the following (1, 2 or 3)
   1. Member has any of the following B-cell lymphoma subtypes, and has received prior treatment with two or more chemoimmunotherapy regimens (including at least one anthracycline or anthracenedione-based regimen, unless contraindicated):
      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
   2. Member 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 lymphoma (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. 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)
      v. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
   3. Member has relapsed or refractory follicular lymphoma (FL) and has received at least two or more lines of systemic therapy
B. The member does not have primary central nervous system lymphoma.
C. The member has not received a previous treatment course of the requested medication or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.
D. The B-cells must be CD19-positive as confirmed by testing or analysis.

V. REFERENCES

1. Yescarta [package insert]. Santa Monica, CA: Kite Pharma; March 2021.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 13, 2020.
3. The NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas (Version 1.2020).© 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 06, 2020.
4. National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24-Version 1). http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=344&ncdver=1&DocID=110.22&from2=search.asp&bc=gAAAAAgAAAAA& Accessed December 2, 2020.