Reference number(s)
2384-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]
Yescarta is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of 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.

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

B. Compendial Uses[2]
1. AIDS-related B-cell lymphoma (including HHV8-positive diffuse large B-cell lymphoma)
2. Post-transplant lymphoproliferative disorders

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED Documentation

Testing or analysis confirming CD19 protein on the surface of the B-cell.

III. CRITERIA FOR INITIAL APPROVAL

A. Large B-cell lymphoma[1]
Authorization of 3 months may be granted to members 18 years of age or older for treatment of large B-cell lymphoma (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) when documentation confirms all of the following criteria are met:
1. The disease is relapsed or refractory to treatment after two or more lines of therapy.
2. The member has not received a previous treatment course of Yescarta.
3. The member does not have primary central nervous system lymphoma.
4. The B-cells must be CD19-positive as confirmed by testing or analysis.

B. AIDS-related B-cell lymphoma[2]

Authorization of 3 months may be granted to members 18 years of age or older for treatment of AIDS-related B-cell lymphoma (including HHV8-positive diffuse large B-cell lymphoma) when documentation confirms all of the following criteria are met:

1. The member has not received a previous treatment course of Yescarta.
2. The B-cells must be CD19-positive as confirmed by testing or analysis.
3. The member has had partial response, no response, or progressed disease following second-line therapy for relapsed or refractory disease or treatment of disease that is in second relapse or greater.

C. Post-transplant Lymphoproliferative disorders[2]

Authorization of 3 months may be granted to members 18 years of age or older for treatment of post-transplant lymphoproliferative disorders when documentation confirms all of the following criteria are met:

1. The member has not received a previous treatment course of Yescarta.
2. The B-cells must be CD19-positive as confirmed by testing or analysis.
3. The member has had partial response, no response, or progressed disease following second-line chemoimmunotherapy for relapsed or refractory disease or treatment of disease that is in second relapse or greater.

IV. REFERENCES

1. Yescarta [package insert]. Santa Monica, CA: Kite Pharma; October 2017.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 30, 2018.