



## Yescarta (axicabtagene ciloleucel) Coverage Criteria

### **Description:**

Yescarta (axicabtagene ciloleucel) is a CD19-directed genetically-modified autologous T cell immunotherapy indicated for the treatment of the following:

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

Note: Axicabtagene ciloleucel is not indicated for the treatment of patients with primary central nervous system lymphoma.

Yescarta is a type of treatment called chimeric antigen receptor T cell (CAR-T) therapy, which uses the patient's own genetically altered T cells to attack cancer cells. It is the second FDA-approved CAR-T cell therapy.

Yescarta has black boxed warnings for cytokine release syndrome (CRS) and neurological toxicities. Because of the risk of CRS and neurological toxicities, Yescarta is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called Yescarta REMS. Healthcare facilities that dispense and administer Yescarta must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available for each patient for administration within 2 hours after Yescarta infusion, if needed for treatment of CRS. Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense or administer Yescarta are trained about the management of CRS and neurological toxicities.

### **Policy:**

The intent of this policy is to define clinical characteristics to identify patients who qualify for Yescarta (axicabtagene ciloleucel). Yescarta requires a prior authorization and will be covered when the criteria have been met.

**Prior Authorization Criteria:**

Axicabtagene ciloleucel (Yescarta) is considered medically necessary when the following are met:

1. Initial Therapy: Approve for once per lifetime if the member meets ALL of the following:
  - a. Member is at least 18 years of age;
  - b. Member is prescribed by or in consultation with an oncologist or hematologist;
  - c. Member has been diagnosed with ONE of the following B-cell lymphoma:
    - i. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified; or
    - ii. Primary mediastinal large B-cell lymphoma; or
    - iii. High-grade B-cell lymphomas; or
    - iv. DLBCL arising from follicular lymphoma; or
    - v. Relapsed or refractor follicular lymphoma;
  - d. Member has received at least two or more lines of systemic therapy
  - e. Member has not been previously treated with CAR-T therapy.  
Note: CAR-T therapy includes Kymriah (tisagenlecleucel), Breyanzi (lisocabtagene maraleucel), Tecartus (brexucabtagene autoleucel), Yescarta (axicabtagene ciloleucel), and Abecma (idecabtagene vicleucel).
  - f. Member does not have primary central nervous system lymphoma;
  - g. Member does not have a clinically significant active systemic infection or inflammatory disorder;
  - h. Healthcare facility has enrolled in the Yescarta REMS Program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities;
2. Renewal Therapy: Coverage cannot be renewed. Initial therapy and approval is for a single dose per lifetime.

**Approved Dosing Guidelines:**

1. Yescarta (axicabtagene ciloleucel) is available as a cell suspension for infusion for autologous and intravenous use only administered in a certified healthcare facility.
2. Yescarta comprises a suspension of  $2 \times 10^6$  CAR-positive viable T cells per kg of body weight, with a maximum of  $2 \times 10^8$  CAR-positive viable T cells in approximately 68 ml.

**References:**

1. Yescarta™ suspension for intravenous infusion [prescribing information]. Santa Monica, CA: Kite Pharma; January 2022.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology. 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed January 28, 2022.
3. The NCCN Drugs and Biologics Compendium. 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed January 28, 2022.