PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Yescarta (axicabtagene ciloleucel)
BILLING CODE	Q2041
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Inpatient Hospital
STATUS	Prior Authorization Required

Yescarta is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of: 1) Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy; and 2) 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; and 3) Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy (accelerated approval).

Yescarta (axicabtagene ciloleucel) will be considered for coverage when the following criteria are met:

Large B-Cell Lymphoma

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member has a diagnosis of large B-cell lymphoma; AND
3. Member's disease is refractory or relapsed, defined as one of the following:
   a) No response, partial response, disease progression, or relapse after two or more lines of systemic therapy, including both:
      i) an anti-CD20 monoclonal antibody (e.g., rituximab) unless tumor is CD20-negative and
      ii) a chemotherapy regimen that contains an anthracycline
   b) Relapsed after autologous hematopoietic stem cell transplantation (HSCT)
   c) Primary refractory disease (incomplete response to first line chemoimmunotherapy, including at least an anti-CD20 monoclonal antibody unless tumor is CD20-negative and a chemotherapy regimen that contains an anthracycline)
   d) Relapsed within 12 months (complete remission following first line chemoimmunotherapy that includes at least an anti-CD20 monoclonal antibody unless tumor is CD20-negative and a chemotherapy regimen that contains an anthracycline, followed by relapse); AND
4. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
5. Member does NOT have any of the following:
   a) Prior allogeneic HSCT
   b) History or presence of primary central nervous system (CNS) lymphoma
   c) Prior CAR-T therapy; AND
6. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (negative results must be submitted); AND
7. Healthcare facility/provider has enrolled in the Yescarta and Tecartus REMS program; AND
8. Member's weight is documented for dose calculation.

9. **Dosage allowed/Quantity limit:** 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.

If all the above requirements are met, the medication will be approved for 3 months.

05/05/2022	Transferred to new template. Updated references. Added documentation of weight. Modified large B cell criteria to accommodate label expansion to include 2nd line use. Removed list of large B cell lymphoma subtypes.

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