Humana.

CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Yescarta (axicabtagene ciloleucel)
BILLING CODE	TBD
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Yescarta (axicabtagene ciloleucel) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

LARGE B-CELL LYMPHOMA – for autologous use only

For **initial** authorization:

1. Medication is being use for adult member with relapsed or refractory large B-cell lymphoma (diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma); AND
2. Member has relapsed/refractory transplant ineligible disease, documented in chart notes and defined as **one** or more of the following:
   a) No response to first (primary refractory disease), second or greater lines of therapy;
   b) Relapsed after autologous hematopoietic stem cell transplantation (HSCT);
   c) Relapsed transplant ineligible disease; AND
3. Member must have received adequate prior therapy including at a minimum **both** of the following:
   a) Anti-CD20 monoclonal antibody (unless tumor is CD20 negative);
   b) An anthracycline containing chemotherapy regimen; AND
4. Member received the lymphodepleting regimen (cyclophosphamide 500 mg/m^2 intravenously and fludarabine 30 mg/m^2 intravenously, both given on the fifth, fourth, and third day before Yescarta); AND
5. Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) prior to collection of cells (leukapheresis); AND
6. Healthcare facility/provider has enrolled in the Yescarta REMS and has training on the management of cytokine release syndrome (CRS) and neurological toxicities; AND
7. Member must be premedicated with acetaminophen and an H1-antihistamine, and tocilizumab (Actemra) must be available in healthcare facility prior to infusion; AND
8. Member does **not** have history of ANY of the following:
   a) Severe, immediate hypersensitivity reaction attributed to aminoglycosides;
   b) Prior allogeneic HSCT;
   c) History or presence of primary CNS lymphoma and/or CNS disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease with CNS involvement;

d) HIV infection or acute or chronic active hepatitis B or hepatitis C infection;
e) Malignancy other than nonmelanoma skin cancer or carcinoma in situ (e.g., cervix, bladder, breast) or follicular lymphoma unless disease free for at least 3 years.

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

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

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Yescarta will not be reauthorized for continued therapy.

CareSource considers Yescarta (axicabtagene ciloleucel) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Primary central nervous system lymphoma

DATE	ACTION/DESCRIPTION
10/24/2017	New policy for Yescarta created.
08/27/2018	Criteria expanded for member's disease history requirement.

References:

1. Yescarta [package insert]. Santa Monica, CA; Kite Pharma, Inc., October 2017. Accessed October 2017.
2. The Leukemia & Lymphoma Society (LLS). Ph-Positive ALL Therapy. Available at https://www.lls.org/leukemia/acute-lymphoblastic-leukemia/treatment/ph-positive-all-therapy.
3. ClinicalTrials.gov. Identifier NCT03153462. Axicabtagene Ciloleucel Expanded Access Study (ZUMA-9). Available at https://clinicaltrials.gov/ct2/show/NCT03153462?term=axicabtagene&rank=1. Accessed in October, 2017.
4. NCCN Guidelines. Non-Hodgkins Lymphoma. V.4.2018.
5. Neelapu SS, et al. Axicabtagene ciloleucel CAR T-cell therapy in refractory large B-cell lymphoma. N Engl J Med. 2017;377(26):2531-2544.

Effective date: 09/07/2018
Revised date: 08/27/2018