CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Yescarta (axicabtagene ciloleucel)
BILLING CODE	TBD
BENEFIT TYPE	Carved out to FFS (fee-for-service) benefit
SITE OF SERVICE ALLOWED	N/A
COVERAGE REQUIREMENTS	Prior Authorization is required and reviews will be performed by CareSource and forward to IN Medicaid for a final decision and payment

Yescarta (axicabtagene ciloleucel) is a product that is carved out from managed care benefits and is included in the Indiana Medicaid Fee-For-Service (FFS) program. Requests for authorization of this product will be reviewed by CareSource using the criteria below and forwarded to Indiana Medicaid FFS for a final decision.

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

CAR-T CELL IMMUNOTHERAPY (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 CNS disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease with CNS involvement.

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 diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
10/24/2017	New policy for Yescarta created.
05/01/2018	Carve out information added—No longer paid for by CareSource. CareSource will review authorization requests and final decision on coverage and payment with be made by IN Medicaid.

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.

Effective date: 05/01/2018
Revised date: 05/01/2018