Policy Title:	Yescarta (axicabtagene ciloleucel) (Intravenous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	4/10/2019, 12/13/2019		
Revision Date:	4/10/2019, 12/13/2019		

Purpose: To support safe, effective and appropriate use of Yescarta (axicabtagene ciloleucel).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Yescarta (axicabtagene ciloleucel) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Yescarta (axicabtagene ciloleucel) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Patient must have documentation of testing or analysis confirming CD19 protein on the surface of the B-cell; AND
- Authorizations will only be granted if Yescarta is provided at a Neighborhood Health Plan of Rhode Island authorized and approved facility for Yescarta administration; AND

Large B-cell lymphoma

- Authorization 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 all of the following criteria are met:
    - The disease is relapsed or refractory to treatment after two or more lines of therapy; AND
    - The member has not received a previous treatment course of Yescarta; AND
    - The member does not have primary central nervous system lymphoma; AND
    - The B-cells must be CD19-positive as confirmed by testing or analysis; OR

AIDS-related B-cell lymphoma

- Authorization 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 all of the following criteria are met:
    - The member has not received a previous treatment course of Yescarta; AND
    - The B-cells must be CD19-positive as confirmed by testing or analysis; AND
    - 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; OR

Post-transplant Lymphoproliferative disorders

- Authorization may be granted to members 18 years of age or older for treatment of post-transplant lymphoproliferative disorders when all of the following criteria are met:
    - The member has not received a previous treatment course of Yescarta; AND
    - The B-cells must be CD19-positive as confirmed by testing or analysis; AND
    - 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

Coverage durations:

- Initial coverage: 3 months for one infusion
- Continuation of therapy coverage: cannot be renewed

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = one infusion)**
Diffuse Large B-cell Lymphoma	For autologous use only. For intravenous use only. • Yescarta is prepared from the patient's peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure • One treatment course consists of lymphodepleting chemotherapy followed by a single infusion of Yescarta <u>Lymphodepleting chemotherapy:</u> • Confirm Yescarta availability prior to starting the lymphodepleting regimen • Administer cyclophosphamide 500 mg/m2 and fludarabine 30 mg/m2 intravenously on the fifth, fourth, and third day before infusion of Yescarta	1 BU per lifetime

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

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.