POLICY AND PROCEDURE

POLICY NAME: Axicabtagene Ciloleucel (Yescarta®)	**POLICY ID:** TX.PHAR.48
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 4/2018	**PRODUCT(S):** CHIP, STAR, STAR PLUS, STAR HEALTH, STAR KIDS
REVIEWED/REVISED DATE: 2/13/2019, 10/1/2019, 9/14/2020, 5/4/2021, 10/2021, 07/1/2022, 9/1/2022	
REGULATOR MOST RECENT APPROVAL DATE(S):	

POLICY STATEMENT:
It is the policy of Superior HealthPlan (SHP) to follow state guidance for medical necessity review of Yescarta® (axicabtagene ciloleucel).

PURPOSE:
This medication is a pass through drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Superior Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

Additionally, this medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage Precision Drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All Precision Drug requests or potential requests must be reported to the PDAC for tracking, regardless of whether agents are carved out, passed through, etc. All Precision Drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

In addition, the procedure code Q2041 (used for Yescarta®) will be limited to once per lifetime, by any provider. If the code is updated in the future it will still be limited to once per lifetime.

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

- Treatment of 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
- Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy
- Treatment of adult patients who have large B-cell lymphoma that is refractory to first line chemoimmunotherapy or that relapses within 12 months of first line chemoimmunotherapy

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

SCOPE:
This policy applies to Superior HealthPlan Pharmacy Department, Medical Directors, Claims.

DEFINITIONS:
PDAC = Precision Drug Action Committee
UM = Utilization Management

POLICY:
It is the policy of Superior HealthPlan (SHP) to follow state guidance for medical necessity review of Yescarta® (axicabtagene ciloleucel). This medication is a pass through drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Superior Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

There are only seven centers in Texas authorized to provide this drug due to REMS (Risk Evaluation and Mitigation Strategy) requirements for the drug. Medical Directors should attempt to direct to a participating (PAR) provider. On a

case-by-case basis, said Medical Director may make an exception outside of a PAR provider but will require a single case agreement (SCA). The approved centers are:

- St. David's Healthcare (Austin)
- Baylor Charles A. Sammons Cancer Center (Dallas)
- UT Southwestern Simmons Comprehensive Cancer Center (Dallas)
- Medical City (Dallas)
- Texas Transplant Institute (San Antonio)
- The University of Texas MD Anderson Cancer Center (Houston)
- Houston Methodist (Houston)

PROCEDURE:

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

1. A Medical Director is required to review and approve or deny all requests. A pharmacist will make a recommendation on the prior authorization, but ultimate determination will be made by the medical director only.

2. Medical necessity determinations will be supported by PDAC UM recommendation. The SHP pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the SHP Medical Director but will not make the ultimate determination on any case.

3. Age ≥ 18 years

4. For the treatment large B-cell lymphoma, patient has histologically confirmed diagnosis and meets one of the following (a or b):
    a. Patient has relapsed or refractory disease, defined as progression after two or more lines of systemic therapy (which may or may not include therapy supported by autologous stem cell transplant)
    b. Disease is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.

Applicable Diagnosis Codes							
C8330	C8331	C8332	C8333	C8334	C8335	C8336	C8337
C8338	C8339	C8510	C8520				

5. For the treatment of follicular lymphoma, patient has histologically confirmed diagnosis and has relapsed or refractory disease defined as progression after two or more lines of systemic therapy (which may or may not include therapy supported by autologous stem cell transplant).

Applicable Diagnosis Codes							
C8200	C8201	C8202	C8203	C8204	C8205	C8206	C8207
C8208	C8209	C8210	C8211	C8212	C8213	C8214	C8215
C8216	C8217	C8218	C8219	C8220	C8221	C8222	C8223
C8224	C8225	C8226	C8227	C8228	C8229	C8230	C8231
C8232	C8233	C8234	C8235	C8236	C8237	C8238	C8239
C8240	C8241	C8242	C8243	C8244	C8245	C8246	C8247
C8248	C8249	C8250	C8251	C8252	C8253	C8254	C8255
C8256	C8257	C8258	C8259	C8260	C8261	C8262	C8263
C8264	C8265	C8266	C8267	C8268	C8269	C8280	C8281
C8282	C8283	C8284	C8285	C8286	C8287	C8288	C8289
C8290	C8291	C8292	C8293	C8294	C8295	C8296	C8297
C8298	C8299						

6. The health-care facility has enrolled in the Yescarta® Risk Evaluation and Mitigation Strategies and training has been given to the provider on the management of cytokine release syndrome and neurological toxicities. Currently there are only 7 facilities which may provide this drug under these parameters and these are:

    - St. David's Healthcare (Austin)
    - Baylor Charles A. Sammons Cancer Center (Dallas)
    - UT Southwestern Simmons Comprehensive Cancer Center (Dallas)
    - Medical City (Dallas)
    - Texas Transplant Institute (San Antonio)
    - The University of Texas MD Anderson Cancer Center (Houston)
    - Houston Methodist (Houston)

7. Patient does not have primary central nervous system lymphoma/disease.

8. Patient does not have an active infection or inflammatory disorder.

9. Patient has not received prior CD-19 directed CAR-T therapy.

10. If the facility is non-PAR the medical director will redirect to a PAR provider. On a case-by-case basis, said Medical Director may make an exception outside of a PAR provider but will require a single case agreement (SCA). Once the case is determined, the pharmacy team via pharmacy management will work with the SCA team to assist on the SCA. This should be the exception and not the rule as a PAR facility/provider is preferable. The pharmacist supporting the medical director will contact pharmacy management to start the SCA process.

Approval duration: Only 1 dose per lifetime will be provided on this drug regardless of Provider. Dose does not exceed 2 x 10^8 CAR-positive viable T cells (as absolute maximum).

II. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Large B-Cell Lymphoma	Target dose: 2 × 10^6 CAR-positive viable T cells per kg body weight	2 × 10^8 CAR-positive viable T cells
Follicular Lymphoma	Target dose: 2 × 10^6 CAR-positive viable T cells per kg body weight	2 × 10^8 CAR-positive viable T cells

REFERENCES: Yescarta® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Yescarta® REMS. https://www.yescarta.com/find-a-treatment-center/

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook. September 2022

ATTACHMENTS:

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad Hoc Review	Changed "Justin M.Weiss, Sr. V.P., Pharmacy Operations" to "Karen Tadlock, V.P., Pharmacy Operations" Formatting	2/13/2019
Ad Hoc Review	Added information and criteria step regarding Centene's Precision Drug Action Committee (PDAC)	10/1/2019

	Added exclusion criteria of primary CNS lymphoma, active infection, and inflammatory disorder	
Ad Hoc Review	Updated list of authorized treatment centers in Texas per https://www.yescarta.com/find-a-treatment-center/	9/14/2020
Ad Hoc Review	Removed neutrophil, lymphocyte, and platelet count requirements Added statement that patient has not received prior CD-19 directed CAR-T therapy Updated CNS lymphoma to CNS lymphoma/disease	5/4/2021
Ad Hoc Review	Added new indication: Follicular Lymphoma Added diagnosis codes Removed criteria for oncologist requirement, prior therapy specifications, Eastern Cooperative Oncology Group performance requirements, and exclusion of active infection or inflammatory disorder	10/2021
Ad Hoc Review	Added new indication: large B-cell lymphoma that is refractory to first line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy Added diagnosis codes Added exclusion criteria of active infection and inflammatory disorder Formatting Updated references	7/1/2022
Ad Hoc Review	Added diagnosis codes for Follicular Lymphoma indication Put applicable ICD-10 codes in table format	9/1/2022

POLICY AND PROCEDURE APPROVAL

Karen Tadlock, V.P., Pharmacy Operations	Approval on file
Dr. David Harmon, Sr. V.P., Chief Medical Officer	Approval on file
Pharmacy & Therapeutics Committee	Approval on file

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.