TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Axicabtagene ciloleucel (Yescarta®)	**CRITERIA ID:** TX.CC.PHAR.03
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 4/2018	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 2/13/2019, 10/1/2019, 9/14/2020, 5/4/2021, 10/2021, 07/1/2022, 9/1/2022, 8/14/2023, 11/3/2023, 2/27/2024, 11/21/2024	
REGULATOR MOST RECENT APPROVAL DATE(S):	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for axicabtagene ciloleucel (Yescarta®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment 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 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.

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

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
NRB = Non-risk based
PDAC = Precision Drug Action Committee
UM = Utilization Management

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of axicabtagene ciloleucel (Yescarta®); procedure code: Q2041.

Description/Mechanism of Action:
Axicabtagene ciloleucel (Yescarta®) is a CD19-directed genetically modified autologous T-cell immunotherapy.

F*DA Approved Indications:*
Axicabtagene ciloleucel (Yescarta®) is indicated to treat the following:

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

Certified healthcare facilities must enroll and comply with the Risk Evaluation and Mitigation Strategies (REMS) requirements for this drug. There are only eight 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)
- Methodist Hospital (San Antonio)
- The University of Texas MD Anderson Cancer Center (Houston)
- Houston Methodist (Houston)
- Baylor Scott & White Medical Center (Temple)

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:

A. Large B-Cell Lymphoma (relapsed or refractory):

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician 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 pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the Medical Director but will not make the ultimate determination on any case.
3. The client is 18 years of age or older.
4. The client has histologically confirmed diagnosis and meets one of the following (a or b):
    a. Client 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. Client has disease that 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	C83398	C833A	C8510	C851A	C8520	C852A	

5. The client does not have primary central nervous system lymphoma/disease.
6. The client does not have active infection or inflammatory disorder.
7. The client has not received prior CD-19 directed CAR-T therapy.
8. 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 8 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)
- Methodist Hospital (San Antonio)
- The University of Texas MD Anderson Cancer Center (Houston)
- Houston Methodist (Houston)
- Baylor Scott & White Medical Center (Temple)

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

B. Follicular Lymphoma (relapsed or refractory):

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 CPS or 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. The client is 18 years of age or older.
4. The client 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).
5. The client has a histologically confirmed diagnosis of one of the following types of follicular lymphoma:

Applicable Diagnosis Codes							
C8200	C8201	C8202	C8203	C8204	C8205	C8206	C8207
C8208	C8209	C820A	C8210	C8211	C8212	C8213	C8214
C8215	C8216	C8217	C8218	C8219	C821A	C8220	C8221
C8222	C8223	C8224	C8225	C8226	C8227	C8228	C8229
C822A	C8230	C8231	C8232	C8233	C8234	C8235	C8236
C8237	C8238	C8239	C823A	C8240	C8241	C8242	C8243
C8244	C8245	C8246	C8247	C8248	C8249	C824A	C8250
C8251	C8252	C8253	C8254	C8255	C8256	C8257	C8258
C8259	C825A	C8260	C8261	C8262	C8263	C8264	C8265
C8266	C8267	C8268	C8269	C826A	C8280	C8281	C8282
C8283	C8284	C8285	C8286	C8287	C8288	C8289	C828A
C8290	C8291	C8292	C8293	C8294	C8295	C8296	C8297
C8298	C8299	C829A					

6. The client does not have primary central nervous system lymphoma/disease.
7. The client does not have active infection or inflammatory disorder.
8. The client has not received prior CD-19 directed CAR-T therapy.
9. 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 8 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)
    - Baylor Scott & White Medical Center (Temple)

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

ATTACHMENTS:

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	02/13/2019
Ad Hoc Review	Added information and criteria step regarding Centene's Precision Drug Action Committee (PDAC) Added exclusion criteria of primary CNS lymphoma, active infection, and inflammatory disorder	10/1/2019
Ad Hoc Review	Updated list of authorized treatment centers in Texas per https://www.yescarta.com/find-a-treatment-center/	09/14/2020
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	05/04/2021
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	07/01/2022
Ad Hoc Review	Added diagnosis codes for Follicular Lymphoma indication Put applicable ICD-10 codes in table format	09/01/2022
Annual Review	Changed "pass through" to " non-risk based (NRB) in Purpose section Added separate policy section I.B. for indication of Follicular Lymphoma Removed exclusion criteria of primary CNS lymphoma/disease and prior CAR-T therapy from section I.A. Formatting changes in Purpose and Policy sections Changed "pass through" to "non-risk based (NRB)" in Purpose section Added NRB to Purpose and Definition sections Added Texas authorized center: Baylor Scott & White Medical Center (Temple), changed Texas Transplant Institute to Methodist Hospital (San Antonio)	08/14/2023

	Adjusted criteria point verbiage to “the client” for consistency throughout document Remove statement “Yescarta® is not indicated for the treatment of patients with primary central nervous system lymphoma.” from the policy section Remove specific approver names since electronic approvals are retained in Archer Updated Superior HealthPlan/Centene Pharmacy Services, CPS/SHP throughout policy Updated Functional Area to reflect Pharmacy only	
Ad Hoc Review	Added criteria steps I.A.5., 6. and 7 and I.B.7 to align with TMHP manual	11/03/2023
Ad Hoc Review	Updated to TX.CC.PHAR format Removed criteria step: 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 under both indications.	02/27/2024
Ad Hoc Review	Updated **Diagnosis Code** tables for both indications to include additional dx codes per TMHP CAD manual update effective Nov. 1, 2024	11/21/2024