Policy and Procedure

DEPARTMENT: Pharmacy, Medical Directors, Claims	**DOCUMENT NAME:** Axicabtagene Ciloleucel (Yescarta®)
PAGE: 1 of 5	**REPLACES DOCUMENT:**
APPROVED DATE: 04/16/18	**RETIRED:**
EFFECTIVE DATE: 04/18	**REVIEWED/REVISED:** 2/13/2019, 10/1/19
PRODUCT TYPE: Star, Star Health, Star Kids, Star Plus, Chip, Chip Prenate	**REFERENCE NUMBER:** TX.PHAR.48

SCOPE:

Superior HealthPlan Pharmacy Department, Medical Directors, Claims

POLICY:

It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of axicabtagene ciloleucel (Yescarta®).
Texas Health and Human Services Commission (HHSC) will account for the ingredient cost of Yescarta® coverage in managed care using a non-risk based payment process. Therefore, this drug will 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 HealthPlan 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.

There are only three 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:

- Baylor Charles A. Sammons Cancer Center (Dallas)
- The University of Texas MD Anderson (Houston)
- Texas Transplant Institute (San Antonio)

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.

BACKGROUND:

Description:
Yescarta® (axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T cell immunotherapy.

FDA APPROVED INDICATION(S)
Yescarta® is indicated for the 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. Axicabtagene ciloleucel is not indicated for the treatment of patients with primary central nervous system lymphoma.

FORMULATIONS:
Available as a single-dose unit infusion bag: frozen suspension of genetically modified autologous T cells labeled for the specific recipient.

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; deny for those under 18.

4. The patient must have a histologically confirmed diagnosis of one of the following types of aggressive non-Hodgkin's lymphoma:
   - Diffuse large B-cell lymphoma, not otherwise specified
   - High-grade B-cell lymphoma
   - Primary mediastinal large B-cell lymphoma
   - Transformed follicular lymphoma

5. The patient must have 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).

6. The patient must have received adequate prior therapy including, at a minimum, all of the following:
   - An anthracycline-containing chemotherapy regimen
   - For CD20+ disease, anti-CD20 monoclonal antibody
   - For patients with transformed follicular lymphoma, prior chemotherapy for follicular lymphoma with chemotherapy refractory disease after transformation to DLBCL

7. There must be documentation of all of the following clinical findings:
   - Eastern Cooperative Oncology Group performance status of 0 or 1 (see reference box for more information)
   - Absolute neutrophil count of 1000/uL or greater
   - Absolute lymphocyte count of greater than 100/uL
   - Platelet count of 75,000/uL or greater

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 HHSC has advised there are only 3 facilities which may provide this drug under these parameters and these are:
   - Baylor Charles A. Sammons Cancer Center (Dallas)
   - The University of Texas MD Anderson (Houston)
   - Texas Transplant Institute (San Antonio)

9. The treatment has been prescribed by an oncologist or in consultation with an oncologist.

10. The member does not have an active infection or inflammatory disorder.

11. The member does not have primary central nervous system lymphoma.

12. 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

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REFERENCES:

- Yescarta® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Yescarta® REMS.
- For information regarding the Eastern Cooperative Oncology Group performance status please see: http://ecog-acrin.org/resources/ecog-performance-status.

ATTACHMENTS:

DEFINITIONS/Abbreviations:

HHSC: Health and Human Services Commission
SCA: Single Case Agreement
REMS: Risk Evaluation and Mitigation Strategy
DLBCL: diffuse large B-cell lymphoma

REVISION LOG

REVISION	DATE
Changed "Justin M.Weiss, Sr. V.P., Pharmacy Operations" to "Karen Tadlock, V.P., Pharmacy Operations" Formatting	2/13/2019
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

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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

NOTE: The electronic approval retained in Compliance 360, Centene's P&P management software, is considered equivalent to a physical signature.