POLICY AND PROCEDURE

POLICY NAME: Tisagenlecleucel (Kymriah)	**POLICY ID:** TX.PHAR.58
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 4/8/2019	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 4/17/2019, 9/19/2019, 9/14/2020, 10/2021, 7/31/2022, 9/1/2022	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of tisagenlecleucel (Kymriah).

PURPOSE:
This medication is a pass through drug (non-risk based 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 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 Q2042 (used for Kymriah) 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.

Certified healthcare facilities must enroll and comply with the Risk Evaluation and Mitigation Strategies (REMS) requirements for each drug administered under this policy.

SCOPE:
Superior HealthPlan Pharmacy Department, Medical Directors

DEFINITIONS: NRB = non-risk based

POLICY:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of tisagenlecleucel (Kymriah).

Description:
Tisagenlecleucel (Kymriah) is a CD19-directed genetically modified autologous T cell immunotherapy (containing human cells modified with a lentivirus) in which a patient's T cells are reprogrammed with a transgene encoding a chimeric antigen receptor (CAR) to identify and eliminate CD19-expressing malignant and normal cells.

FDA Approved Indications:
Tisagenlecleucel (Kymriah) is indicated for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. Additionally, Kymriah is indicated to treat adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy (including diagnoses of diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma and DLBCL arising from follicular lymphoma). Additionally, Kymriah is approved to treat adult clients 18 years of age and older who have relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

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:

A. B-cell Precursor Acute Lymphoblastic Leukemia (second relapse 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 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 member is age 25 years or younger.

4. The member has histologically confirmed diagnosis of B-cell acute lymphoblastic leukemia

Applicable Diagnosis Codes		
C9100	C9101	C9102

5. The member has confirmed CD-19 tumor expression.

6. Disease is refractory, or in second or later relapse.

7. The member has not received prior CAR-T therapy.

8. The health-care facility has enrolled in the Kymriah® Risk Evaluation and Mitigation Strategies and training has been given to the provider on the management of cytokine release syndrome and neurological toxicities.

9. 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.

B. Diffuse Large B-cell 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 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 member is 18 years or older.

4.The member has a histologically confirmed diagnosis of large B-cell lymphoma (a., b. or c)

a. Diffuse large B-cell lymphoma, not otherwise specified
b. High grade B-cell lymphoma
c. Diffuse large B-cell lymphoma arising from follicular lymphoma

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

4. The member must have relapsed or refractory disease 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 member does not have primary central nervous system lymphoma

6. The member has not received prior CAR-T therapy.

7. The health-care facility has enrolled in the Kymriah® Risk Evaluation and Mitigation Strategies and training has been given to the provider on the management of cytokine release syndrome and neurological toxicities.

8. 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.

C. 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 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 member is 18 years or older.

4. The member has histologically confirmed diagnosis of follicular lymphoma.

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						

5. The member must have relapsed or refractory disease as progression after two or more lines of systemic therapy.

6. The member does not have primary central nervous system lymphoma/disease.

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

8. The member has not received prior CD-19 directed CAR-T therapy.

9. The health-care facility has enrolled in the Kymriah® Risk Evaluation and Mitigation Strategies and training has been given to the provider on the management of cytokine release syndrome and neurological toxicities.

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.

REFERENCES:

Kymriah (tisagenlecleucel) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2018.

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: N/A

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad Hoc Review	Added REMS statement Changed approval duration to one dose per lifetime Added exclusion criteria of primary CNS lymphoma Added PAR facility statement	9/19/2019
Ad Hoc Review	Updated criteria I.A. to specify second relapse, corrected procedure code to Q2042	9/14/2020
Ad Hoc Review	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 Removed requirement: The member does not have primary central nervous system lymphoma from criteria I.A.	10/2021
Ad Hoc Review	Changed to new P&P template Added additional FDA approved indication criteria for follicular lymphoma I.C Added “histologically”for all confirmed diagnoses	7/31/2022
Ad Hoc Review	Added diagnosis codes for Follicular Lymphoma indication Put applicable ICD-10 codes into table format	9/1/2022

POLICY AND PROCEDURE APPROVAL

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