Policy and Procedure

DEPARTMENT: Pharmacy, Medical Directors	**DOCUMENT NAME:** Tisagenlecleucel (Kymriah)
PAGE: 1 of 5	**REPLACES DOCUMENT:**
APPROVED DATE: 4/8/2019	**RETIRED:**
EFFECTIVE DATE: 4/8/2019	**REVIEWED/REVISED:** 4/17/2019, 9/19/2019, 9/14/20, 10/2021
PRODUCT TYPE: STAR, STAR Health, STAR Kids, STAR Plus, CHIP, CHIP Perinate	**REFERENCE NUMBER:** TX.PHAR.58

SCOPE:
Superior HealthPlan Pharmacy Department, Medical Directors

PURPOSE:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of Tisagenlecleucel (Kymriah). This medication should follow state guidance for medical necessity review for Medicaid/CHIP. 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.

Tisagenlecleucel (Kymriah) infusions must take place at a certified healthcare facility. Certified healthcare facilities must enroll with the Risk Evaluation and Mitigation Strategies (REMS) and comply with its requirements for each drug administered within this section. Certified healthcare facilities must ensure that providers that prescribe, dispense, or administer tisagenlecleucel (Kymriah) receive training for the management of cytokine release syndrome (CRS) and neurological toxicities.

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).

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.

BACKGROUND:
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.

Policy and Procedure

DEPARTMENT: Pharmacy, Medical Directors	**DOCUMENT NAME:** Tisagenlecleucel (Kymriah)
PAGE: 2 of 5	**REPLACES DOCUMENT:**
APPROVED DATE: 4/8/2019	**RETIRED:**
EFFECTIVE DATE: 4/8/2019	**REVIEWED/REVISED:** 4/17/2019, 9/19/2019, 9/14/20, 10/2021
PRODUCT TYPE: STAR, STAR Health, STAR Kids, STAR Plus, CHIP, CHIP Perinate	**REFERENCE NUMBER:** TX.PHAR.58

FDA Approved Indication(s)
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).

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. All prior authorization approvals or denials will be determined by a Superior HealthPlan Medical Director.
2. The member is age 25 years or younger.
3. The member has a confirmed diagnosis of B-cell acute lymphoblastic leukemia (diagnosis code: C9100, C9101, and C9102).
4. The member has confirmed CD-19 tumor expression.
5. Disease is refractory, or in second or later relapse.
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.

B. Diffuse Large B-cell Lymphoma (relapsed or refractory)

1. All prior authorization approvals or denials will be determined by a Superior HealthPlan Medical Director.
2. The member is 18 years or older.
3. The member has a confirmed diagnosis of large B-cell lymphoma (a., b. or c) (diagnosis codes: C8330, C8331, C8332, C8333, C8334, C8335, C8336, C8337, C8338, C8339):
    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
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.

REFERENCES:

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

ATTACHMENTS:

DEFINITIONS/Abbreviations:

REVISION LOG

REVISION	DATE
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
Updated criteria I.A. to specify second relapse, corrected procedure code to Q2042	9/14/2020
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

Policy and Procedure

DEPARTMENT: Pharmacy, Medical Directors	**DOCUMENT NAME:** Tisagenlecleucel (Kymriah)
PAGE: 5 of 5	**REPLACES DOCUMENT:**
APPROVED DATE: 4/8/2019	**RETIRED:**
EFFECTIVE DATE: 4/8/2019	**REVIEWED/REVISED:** 4/17/2019, 9/19/2019, 9/14/20, 10/2021
PRODUCT TYPE: STAR, STAR Health, STAR Kids, STAR Plus, CHIP, CHIP Perinate	**REFERENCE NUMBER:** TX.PHAR.58

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 RSA Archer, Centene's P&P management software, is considered equivalent to a physical signature.