TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Tisagenlecleucel (Kymriah®)	**CRITERIA ID:** TX.CC.PHAR.07
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, 8/18/2023, 02/27/2024, 11/22/2024, 10/13/2025	**REGULATOR MOST RECENT APPROVAL DATE(S): N/A**

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

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 Q2042 (used for Kymriah) will be limited to one approval 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
CPS = Centene Pharmacy Services
SHP = Superior HealthPlan

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of tisagenlecleucel (Kymriah®); procedure code: Q2042.

Description/Mechansim of Action:
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 to treat the following:

- Clients who are 25 years of age or younger with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.
- 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, 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

Formulations:
Tisagenlecleucel (Kymriah®) is available as a single-dose unit infusion bag: frozen suspension of genetically modified autologous T-cells labeled for the specific recipient.

There are authorized treatment centers to provide CAR T-cell therapies throughout the US. The following facilities are located within Texas:

- St. David's South Austin Medical Center(Austin)
- Cook Children's Medical Center (Forth Worth)
- Baylor Charles A. Sammons Cancer Center (Dallas)
- University of Texas Southwestern Medical Center, Harold C. Simmons Comprehensive Cancer Center (Dallas)
- Blood and Marrow Transplant Program at Medical City Dallas Hospital (Dallas)
- Cook Children’s Medical Center (Dallas)
- Children’s Medical Center (Dallas)
- Baylor University Medical Center (Dallas)
- Texas Transplant Institute at Methodist Hospital (San Antonio)
- The University of Texas MD Anderson Cancer Center (Houston)
- Houston Methodist Hospital Center for Cell and Gene Therapy (Houston)
- Texas Children’s Hospital (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:

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 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 25 years of age or younger.
4. The client has a histologically confirmed diagnosis of B-cell acute lymphoblastic leukemia.

Diagnosis Codes		
C9100	C9101	C9102

5. The client has a confirmed CD-19 tumor expression.
6. Documentation that the disease is refractory or in second or later relapse.
7. The client has not received prior CAR-T therapy.
8. Provider and facility attestation of all of the following monitoring parameters that the client:
    a. Receives the recommended pre-medications before treatment.
    b. Is closely monitored for at least two weeks, including daily monitoring for at least one week.
    c. Is instructed to remain within proximity of a certified healthcare facility for at least two weeks and to avoid driving for two weeks following product administration.

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 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 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

Diagnosis Codes						
C8330	C8331	C8332	C8333	C8334	C8335	C8336
C8337	C8338	C83398	C833A			

5. Documentation that 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).
6. The client does not have primary central nervous system lymphoma.
7. The client has not received prior CD-19 directed CAR-T therapy.
8. Provider and facility attestation of all of the following monitoring parameters that the client:
    a. Receives the recommended pre-medications before treatment.
    b. Is closely monitored for at least two weeks, including daily monitoring for at least one week.
    c. Is instructed to remain within proximity of a certified healthcare facility for at least two weeks and to avoid driving for two weeks following product administration.

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

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					

5. Documentation that the client has relapsed or refractory disease defined as progression after two or more lines of systemic therapy.
6. The client does not have primary central nervous system lymphoma/disease.
7. The client does not have an active infection or inflammatory disorder.
8. The client has not received prior CD-19 directed CAR-T therapy.
9. Provider and facility attestation of all of the following monitoring parameters that the client:
    a. Receives the recommended pre-medications before treatment.
    b. Is closely monitored for at least two weeks, including daily monitoring for at least one week.
    c. Is instructed to remain within proximity of a certified healthcare facility for at least two weeks and to avoid driving for two weeks following product administration.

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.

https://us.kymriah.com/treatment-center-locator

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: 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	07/31/2022

Ad Hoc Review	Added diagnosis codes for Follicular Lymphoma indication Put applicable ICD-10 codes into table format	09/01/2022
Annual Review	Rearranged verbiage order in Purpose and Policy section Changed “pass through” to “non-risk based (NRB)” in Purpose section Added Texas authorized centers: • Cook Children’s Medical Center (Dallas) • Children’s Medical Center (Dallas) • Texas Children’s Hospital (Houston) Updated Definitions section Adjusted criteria point verbiage to “the client” for consistency throughout document Added TX authorized centers to criteria points I.B.7. and I.C.9 for consistency throughout document Updated Superior HealthPlan/Centene Pharmacy Services, CPS/SHP throughout policy Added name/titles list under Policy and Procedure Approval section Minor formatting changes	08/18/2023
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement Removed criteria step: 9. If the facility is non-PAR the medical director will redirect to a PAR provider. On a case-by-case basis, the 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.	02/27/2024
Ad Hoc Review	Updated Diagnosis Code tables in sections I.B. and I.C. criteria step 4 to include additional dx codes to align with TMHP CAD Manual updated effective 11/1/2024.	11/22/2024
Ad Hoc Review	Added monitoring parameter requirements per TMHP updates Font and formatting change for 508 remediation Updated authorized treatment facilities per manufacturers website • Clarified University of Texas Southwestern Medical Center, Simmons Comprehensive Cancer Center to University of Texas Southwestern Medical Center, Harold C. Simmons Comprehensive Cancer Center • Revised St. David's Healthcare to St. David's South Austin Medical Center • Revised Medical city to Blood and Marrow Transplant Program at Medical City Dallas Hospital • Added Baylor University Medical Center (Dallas) and Texas Transplant Institute at Methodist Hospital • Removed Texas Transplant Institute • Revised Houston Methodist to Houston Methodist Hospital Center for Cell and Gene Therapy	10/13/2025

	Removed REMS statement as well as step “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.” as FDA removed REMS as of 06/2025 Added authorized treatment facility link under references	