TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: lisocabtagene Maraleucel (Breyanzi®)	**CRITERIA ID:** TX.CC.PHAR.13
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 10/18/2021	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 07/31/2022, 08/16/2023, 03/15/2024, 07/17/2024, 09/11/2024, 11/22/2024, 10/10/2025	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

POLICY STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for lisocabtagene maraleucel (Breyanzi®).

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 Q2054 (used for Breyanzi) 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:
PDAC = Precision Drug Action Committee
UM = Utilization Management
CPS = Centene Pharmacy Service
SHP = Superior HealthPlan

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of lisocabtagene maraleucel (Breyanzi®); procedure code: Q2054.

Description/Mechanism of Action:
Lisocabtagene maraleucel (Breyanzi®) is a CD19-directed genetically modified autologous T-cell immunotherapy.

FDA Approved Indications:
Lisocabtagene maraleucel (Breyanzi®) is indicated for the treatment of:

Adult clients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have one of the following:

- refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or
- refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplant (HSCT) due to comorbidities or age; or
- Relapsed or refractory disease after two or more lines of systemic therapy.

Adult clients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least two prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.

Adult clients with relapsed or refractory follicular lymphoma (FL) who have received two or more prior lines of systemic therapy.

Adult clients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least two prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.

Formulations:
Lisocabtagene maraleucel (Breyanzi®) is available as a single-dose 5 mL vial: frozen suspension of genetically modified autologous T-cells labeled for the specific recipient. Supplied in vials as separate frozen suspensions of each CD8 component and CD4 component. Each CD8 or CD4 component is packed in a carton containing up to 4 vials.

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

- St. David's Healthcare (Austin)
- Baylor Charles A. Sammons Cancer Center (Dallas)
- UT Southwestern Harold C Simmons Comprehensive Cancer Center (Dallas)
- Medical City (Dallas)
- Methodist Hospital (San Antonio)
- Sarah Cannon Transplant & Cellular Therapy Program At Methodist Hospital (San Antonio)
- The University of Texas MD Anderson Cancer Center (Houston)
- Houston Methodist Hospital (Houston)
- Covenant Health Joe Arrington Cancer Research And Treatment Center (Lubbock)
- 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:

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 CPS or SHP 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 one of the following diagnoses (a, b, c, or d):
    a. The client has a histologically confirmed diagnosis of large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B with one of the following (i, ii, or iii):
        i. Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy
        ii. Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplant (HSCT) due to comorbidities or age
        iii. Relapsed or refractory disease after receiving two or more lines of systemic therapy
    b. The client has relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and has received at least two prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.
    c. The client has relapsed or refractory follicular lymphoma (FL) after receiving two or more lines of systemic therapy.
    d. The client has relapsed or refractory mantle cell lymphoma (MCL) after receiving at least two prior lines of systemic therapy.
5. The client has one of the following lymphoma diagnosis codes:

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
C825A	C8280	C8281	C8282	C8283	C8284	C8285	C8286
C8287	C8288	C8289	C828A	C8290	C8291	C8292	C8293
C8294	C8295	C8296	C8297	C8298	C8299	C829A	C8300
C8301	C8302	C8303	C8304	C8305	C8306	C8307	C8308
C8309	C830A	C8310	C8311	C8312	C8313	C8314	C8315
C8316	C8317	C8318	C8319	C831A	C8330	C8331	C8332
C8333	C8334	C8335	C8336	C8337	C8338	C83398	C833A
C8390	C8391	C8392	C8393	C8394	C8395	C8396	C8397
C8398	C8399	C839A	C8510	C8511	C8512	C8513	C8514
C8515	C8516	C8517	C8518	C8519	C851A	C8520	C8521
C8522	C8523	C8524	C8525	C8526	C8527	C8528	C8529
C852A	C8580	C8581	C8582	C8583	C8584	C8585	C8586
C8587	C8588	C8589	C858A	C9110	C9112		

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:

Breyanzi Prescribing Information. Bothell, WA: Juno Therapeutics, Inc: February 2021. Available at: https://packageinserts.bms.com/pi/pi_breyanzi.pdf

https://www.breyanzi.com/find-a-treatment-center

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad Hoc Review	Changed to new P&P template Added additional FDA approved indications for: • Refractory disease to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy • Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplant (HSCT) due to comorbidities or age	07/31/2022
Annual Review	Formatting changes in Purpose and Policy sections Adjusted criteria point verbiage to "the client" for consistency throughout policy Removed Limitation of Use statement "Breyanzi is not indicated for the treatment of patients with primary central nervous system (CNS) lymphoma from the policy section Added regulatory references and removed reference to NRB status from Purpose section Added reference to TX authorized (REMS) centers to Policy section and criteria point I.10 Renamed Texas Transplant Institute (San Antonio) to Methodist Hospital Removed NDC reference from Policy section Adjusted criteria point verbiage to "the client" for consistency throughout policy Added table to Applicable Diagnosis Codes under criteria point I.5 Added names/titles under Policy and Procedure Approval section Updated Superior HealthPlan/Centene Pharmacy Services, CPS/SHP throughout policy Updated definitions section	08/16/2023
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement Corrected Q2504 to Q2054 Removed criteria step: 11. 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 as this is not listed in the TMHP CAD Manual	03/15/2024
Ad Hoc Review	The following prior authorization criteria for lisocabtagene maraleucel (Breyanzi) procedure code Q2054 was added: • The client has relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and has	07/17/2024

	received at least two prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor. • The client has relapsed or refractory follicular lymphoma after receiving two or more lines of systemic therapy. • The client has relapsed or refractory mantle cell lymphoma (MCL) after receiving at least two prior lines of systemic therapy Diagnosis code table was updated with additional correlating diagnosis codes	
Ad Hoc Review	Updated PURPOSE section to include NRB status effective 10/1/2024	09/11/2024
Ad Hoc Review	Updated Diagnosis Codes table in criteria step 5 to include additional dx codes to align with TMHP CAD Manual update effective 11/1/2024	11/22/2024
Ad Hoc review	Added monitoring parameter requirements per TMHP updates Font and formatting change for 508 remediation Added the following authorized treatment facilities per manufacturer website • Covenant Health Joe Arrington Cancer Research And Treatment Center (Lubbock) • Baylor Scott & White Medical Center (Temple) • Sarah Cannon Transplant & Cellular Therapy Program At Methodist Hospital (San Antonio) Revised Texas Transplant institute to Texas Transplant Institute (San Antonio) Methodist Hospital (San Antonio) Revised UT Southwestern Simmons Comprehensive Cancer Center to UT Southwestern Harold C Simmons Comprehensive Cancer Center Removed REMS statement as well as step 9. “The health-care facility has enrolled in the Breyanzi 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	10/10/2025