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: 7/31/2022, 8/16/2023, 03/15/2024	
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.

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.

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 patients 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 with 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.

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.

Certified healthcare facilities must enroll and comply with the Risk Evaluation and Mitigation Strategies (REMS) requirements for this drug. There are only seven 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:

- St. David's Healthcare (Austin)
- Baylor Charles A. Sammons Cancer Center (Dallas)
- UT Southwestern Simmons Comprehensive Cancer Center (Dallas)
- Medical City (Dallas)
- Texas Transplant Institute (San Antonio)
- The University of Texas MD Anderson Cancer Center (Houston)
- Houston Methodist (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:

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 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 (a, b, or c):
   a. Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy
   b. 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
   c. Relapsed or refractory disease after receiving two or more lines of systemic therapy
5. The client has a type of lymphoma specified by one of the following diagnosis codes:

Applicable Diagnosis Codes										
C8240	C8241	C8242	C8243	C8244	C8245	C8246	C8247	C8248	C8249	C8250
C8330	C8331	C8332	C8333	C8334	C8335	C8336	C8337	C8338	C8339	C8390
C8391	C8392	C8393	C8394	C8395	C8396	C8397	C8398	C8399	C8510	C8511
C8512	C8513	C8514	C8515	C8516	C8517	C8518	C8519	C8520	C8521	C8522

C8523	C8524	C8525	C8526	C8527	C8528	C8529	C8580	C8581	C8582	C8583
C8584	C8585	C8586	C8587	C8588	C8589					

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. 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. Currently there are only seven facilities which may provide this drug under these parameters and these are:
    - St. David's Healthcare (Austin)
    - Baylor Charles A. Sammons Cancer Center (Dallas)
    - UT Southwestern Simmons Comprehensive Cancer Center (Dallas)
    - Medical City (Dallas)
    - Texas Transplant Institute (San Antonio)
    - The University of Texas MD Anderson Cancer Center (Houston)
    - Houston Methodist (Houston)

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

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	03/15/2024

	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	