POLICY AND PROCEDURE

POLICY NAME: Lisocabtagene Maraleucel (Breyanzi)	**POLICY ID:** TX.PHAR.95
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	
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 lisocabtagene maraleucel (Breyanzi).

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 Q2504 (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.

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 lisocabtagene maraleucel (Breyanzi).

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

FDA Approved Indications:
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 relapses 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.

Limitation of use: Breyanzi is not indicated for the treatment of patients with primary central nervous system (CNS) lymphoma.

Formulations:

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 (NDC: 73153-0901-08) and CD4 component (NDC: 73153-0902-04). Each CD8 or CD4 component is packed in a carton containing up to 4 vials.

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 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 patient must have a histologically confirmed diagnosis of large B-cell lymphoma lymphoma including diffuse large B-cell lymphoma not otherwise specified (including diffuse large B-cell lymphoma arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

5. Client has a type of lymphoma specified by one of the following 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 patient must have one of the following (a, b, or c):
    a. Relapsed or refractory disease after receiving two or more lines of systemic therapy.
    b. Refractory disease to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy
    c. 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

7. The patient does not have primary central nervous system lymphoma/disease.

8. The patient does not have an active infection or inflammatory disorder.

9. Patient has not received prior CD-19 directed CAR-T therapy.

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:
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

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: 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	7/31/2022

POLICY AND PROCEDURE APPROVAL

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