Policy and Procedure

DEPARTMENT: Pharmacy, Medical Directors, Claims	**DOCUMENT NAME:** Lisocabtagene Maraleucel (Breyanzi)
PAGE: 1 of 6	**REPLACES DOCUMENT:**
APPROVED DATE:	**RETIRED:**
EFFECTIVE DATE: 10/18/2021	**REVIEWED/REVISED:**
PRODUCT TYPE: STAR, STAR Health, STAR Kids, STAR Plus, CHIP, CHIP Perinate	**REFERENCE NUMBER:** TX.PHAR.95

SCOPE:

Superior HealthPlan Pharmacy Department, Medical Directors, Claims

POLICY:

It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of lisocabtagene maraleucel (Breyanzi).

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 policy and prior authorization requirements.

All determinations will be performed by a Superior HealthPlan 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.

BACKGROUND:

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

FDA APPROVED INDICATION(S)
Breyanzi is indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma (LBCL) after two or more lines of systemic therapy, 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.

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. Age ≥ 18 years

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 relapsed or refractory disease after receiving two or more lines of systemic therapy.

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.

II. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Large B-Cell Lymphoma	Target dose: 50 to 110 × 10^6 CAR-positive viable T cells	110 × 10^6 CAR-positive viable T cells

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REFERENCES:

1. Breyanzi Prescribing Information. Bothell, WA: Juno Therapeutics, Inc: February 2021. Available at: https://packageinserts.bms.com/pi/pi_breyanzi.pdf
2. Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual, Accessed October 2021

DEFINITIONS/Abbreviations:

MCO: Managed Care Organization
HHSC: Health and Human Services Commission
SCA: Single Case Agreement
PDAC: Precision Drug Action Committee
UM: Utilization Management
SHP: Superior HealthPlan

REVISION LOG

REVISION	DATE

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

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NOTE: The electronic approval retained in RSA Archer, Centene's P&P management software, is considered equivalent to a physical signature.