POLICY AND PROCEDURE

POLICY NAME: brexucabtagene autoleucel (Tecartus)	**POLICY ID:** TX.PHAR.106
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: July 1, 2022	**PRODUCT(S):** CHIP, STAR, STAR PLUS, STAR HEALTH, STAR KIDS
REVIEWED/REVISED DATE: 9/1/22	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
The purpose of this Clinical Policy is to provide a guide to medical necessity reviews for Tecartus® (brexucabtagene autoleucel).

PURPOSE:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review Tecartus® (brexucabtagene autoleucel).

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 Q2053 (used for Tecartus) 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 this drug.

Tecartus® (brexucabtagene autoleucel) is a CD19-directed genetically modified autologous T cell immunotherapy. Tecartus® is indicated in adult patients with relapsed or refractory mantle cell lymphoma. In addition, Tecartus® is now approved to treat adult clients 18 and older with B-cell Precursor Acute Lymphoblastic Leukemia (ALL).

SCOPE:
This policy applies to Superior HealthPlan Pharmacy Department, Medical Directors, Claims.

DEFINITIONS:
PDAC = Precision Drug Action Committee
UM = Utilization Management

POLICY:

It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of Tecartus® (brexucabtagene autoleucel).

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:

A. Mantel Cell Lymphoma (relapsed or refractory):

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 relapsed or refractory mantle cell lymphoma

Applicable Diagnosis Codes							
C8310	C8311	C8312	C8313	C8314	C8315	C8316	C8317
C8318	C8319						

5. The health-care facility has enrolled in the Tecartus® 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 7 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)

6. Patient does not have primary central nervous system lymphoma/disease.

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

8. 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. Dose does not exceed 2 x 10^8 CAR-positive viable T cells (as absolute maximum).

B. B-cell Precursor Acute Lymphoblastic Leukemia (ALL) (relapsed or refractory):

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 relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

Applicable Diagnosis Codes		
C9100	C9101	C9102

5. The health-care facility has enrolled in the Tecartus® 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 7 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)

6. Patient does not have primary central nervous system lymphoma/disease.

7. Patient does not have an active infection or inflammatory disorder.

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

9. 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. Dose does not exceed 2 x 10^8 CAR-positive viable T cells (as absolute maximum).

III. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Mantle Cell lymphoma	Target dose: 2×10^6 CAR-positive viable T cells per kg body weight	2×10^8 CAR-positive viable T cells
B-cell precursor acute lymphoblastic leukemia	Target dose: 1×10^6 CAR-positive viable T cells per kg body weight	1×10^8 CAR-positive viable T cells

REFERENCES: Tecartus® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Tecartus® REMS. https://www.tecartus.com/find-a-treatment-center/

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook. September 2022.

ATTACHMENTS:

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	N/A	07/01/2022
Ad Hoc Review	Updated to separate indications Put ICD-10 codes into table format	09/01/2022

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

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