# TX CLINICAL CRITERIA & PROCEDURE

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| **CRITERIA NAME:** brexucabtagene autoleucel (Tecartus®) | **CRITERIA ID:** TX.CC.PHAR.21 |
| **BUSINESS UNIT:** Superior HealthPlan | **FUNCTIONAL AREA:** Pharmacy |
| **EFFECTIVE DATE:** July 1, 2022 | **PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate |
| **REVIEWED/REVISED DATE:** 9/1/22, 8/18/23, 03/15/2024, 10/14/2024, 11/21/2024 | |
| **REGULATOR MOST RECENT APPROVAL DATE(S):** N/A | |

**CRITERIA STATEMENT:**
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for brexucabtagene autoleucel (Tecartus®).

**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 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.

**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
NRB = Non-Risk Based
UM = Utilization Management
CPS = Centene Pharmacy Services
SHP = Superior HealthPlan

**POLICY:**
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of brexucabtagene autoleucel (Tecartus®); procedure code: Q2053.

*Description/Mechanism of Action:*
Brexucabtagene autoleucel (Tecartus®) is a CD19-directed genetically modified autologous T-cell immunotherapy.

*FDA Approved Indications:*
Brexucabtagene autoleucel (Tecartus®) is indicated to treat the following:

- Adult clients with relapsed or refractory mantle cell lymphoma (MCL)
- Adult clients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

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

**A. Mantle Cell Lymphoma (relapsed or refractory):**

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 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 must have a histologically confirmed diagnosis of relapsed or refractory mantle cell lymphoma.

| **Applicable Diagnosis Codes:** | | | | | | | |
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| C8310 | C8311 | C8312 | C8313 | C8314 | C8315 | C8316 | C8317 |
| C8318 | C8319 | C831A | | | | | |

5. The client does not have primary central nervous system lymphoma/disease.
6. The client has not received prior CD-19 directed CAR-T therapy.
7. 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 8 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)
   - Baylor Scott & White Medical Center (Temple)

**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 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 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 must have a histologically confirmed diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

| **Applicable Diagnosis Codes:** | | |
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| C9100 | C9101 | C9102 |

5. The client does not have primary central nervous system lymphoma/disease.
6. The client does not have an active infection or inflammatory disorder.
7. The client has not received prior CD-19 directed CAR-T therapy.
8. 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 8 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)
   - Methodist Hospital (San Antonio)
   - The University of Texas MD Anderson Cancer Center (Houston)
   - Houston Methodist (Houston)
   - Baylor Scott & White Medical Center (Temple)

**Approval duration: Only 1 dose per lifetime will be provided on this drug regardless of Provider. Dose does not exceed 1 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

**ATTACHMENTS:**

**REVISION LOG**

| REVISION TYPE | REVISION SUMMARY | DATE APPROVED & PUBLISHED |
|---|---|---|
| New Policy | N/A | 07/01/2022 |
| Ad Hoc Review | Updated to separate indications<br>Put ICD-10 codes into table format | 09/01/2022 |
| Annual Review | Removed reference to "NRB" status in Purpose section | 08/18/2023 |

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| | Added Texas authorized center: Baylor Scott & White Medical Center (Temple)<br>Renamed Texas Transplant Institute (San Antonio) to Methodist Hospital<br>Adjusted criteria point verbiage to “the client” for consistency throughout document<br>Replaced Karen Tadlock, Director, V.P. Regional Pharmacy with Thomas Nguyen, Sr. Pharmacy Director under Policy and Procedure Approval section<br>Corrected max does for indication of ALL to: does not exceed 1 x $10^8$ CAR-positive viable T-cells (as absolute maximum).<br>Minor formatting/spacing changes<br>Replaced Superior HealthPlan/SHP with Centene Pharmacy Services/CPS throughout document<br>Added CHIP Perinate to Products<br>Updated definitions section<br>Updated Functional Areas to just Pharmacy<br>Added CPS to Scope section | |
| Ad Hoc Review | Updated to TX.CC.PHAR format template<br>Added Centene copyright statement<br>Removed criteria step: 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 from all indications | 03/15/2024 |
| Ad Hoc Review | Updated PURPOSE section to include NRB status effective 9/1/2024 | 10/14/2024 |
| Ad Hoc Review | Updated Diagnosis Codes table under Section I.A. Mantle Cell Lymphoma to include new dx codes as outlined in TMHP CAD Manual effective November 1, 2024. | 11/21/2024 |