MEDICAL COVERAGE POLICY **SERVICE: Brexucabtagene autoleucel (Tecartus™)**	
Policy Number:	**281**
Effective Date:	**01/01/2023**
Last Review:	**12/01/2022**
Next Review Date:	**12/01/2023**

Important note
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Brexucabtagene autoleucel (Tecartus™)

PRIOR AUTHORIZATION: Required

POLICY:

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination).

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM. Texas Mandate HB1584 is applicable for Medicaid plans.

Brexucabtagene autoleucel (Tecartus™)

BSWHP may consider brexucabtagene autoleucel (Tecartus™) medically necessary for the treatment of mantel cell lymphoma when ALL of the following criteria are met:

1. Member is ≥ 18 years old; **AND**
2. Member has documentation of CD19 tumor expression; **AND**
3. Member diagnosed by a hematologist or oncologist; **AND**
4. Member will be using brexucabtagene autoleucel at a certified treatment center; **AND**
5. Member has at least 1 measurable lesion; **AND**
6. Member has relapsed or refractory disease defined as disease progression after last regimen OR refractory disease defined as failure to achieve a partial response or complete response to the last regimen; AND member must have received adequate prior therapy including **ALL** of the following:
    - Anthracycline- or bendamustine-containing chemotherapy
    - Anti-CD20 monoclonal antibody
    - BTK inhibitor therapy with ibrutinib or acalabrutinib

    AND
7. Member has or will receive lymphodepleting chemotherapy before infusion of brexucabtagene autoleucel; **AND**
8. Member will NOT be treated with more than 2 x 10^8 viable CAR-T cells; **AND**
9. Member does NOT have any of the following conditions:
    - Active hepatitis B (HBs AG-positive), active hepatitis C, or an uncontrolled infection

- History of a seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease with CNS involvement
- History of allogeneic stem cell transplantation
- Primary immunodeficiency

AND

10. The individual has NOT previously been treated with CD-19 targeted therapy or prior CD-19 targeted CAR-T cell therapy; **AND**
11. Member has been assessed by a hematologist/oncologist to be an appropriate candidate for apheresis.

BSWHP may consider brexucabtagene autoleucel (Tecartus™) medically necessary for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) when ALL of the following criteria are met:

1. Member is ≥ 18 years old; **AND**
2. Member has documentation of CD19 tumor expression; **AND**
3. Member diagnosed by a hematologist or oncologist; **AND**
4. Member will be using brexucabtagene autoleucel at a certified treatment center; **AND**
5. Member has relapsed or refractory disease defined as one of the following:
   - refractory to first-line therapy (i.e. primary refractory)
   - first relapse following a remission lasting ≤ 12 months
   - relapsed or refractory ALL after second-line or higher therapy
   - relapsed or refractory ALL at least 100 days after allogeneic stem cell transplantation (HSCT)

   AND
6. Member has or will receive lymphodepleting chemotherapy before infusion of brexucabtagene autoleucel**; AND**
7. Member will NOT be treated with more than 1 x 10^8 viable CAR-T cells**; AND**
8. Member has NOT been taking immunosuppressive medications within 4 weeks prior to infusion**; AND**
9. Member does NOT have any of the following conditions:
   - Active or serious infection including hepatitis B (HBs AG-positive), hepatitis C, or an uncontrolled infection
   - Active graft-vs-host disease
   - History of CNS disorders including CNS-2 disease with neurologic changes and CNS-3 disease irrespective of neurological changes

   AND
10. The individual has NOT previously been treated with CD-19 targeted therapy or prior CD-19 targeted CAR-T cell therapy**; AND**
11. Member has been assessed by a hematologist/oncologist to be an appropriate candidate for apheresis.

BSWHP considers repeat administration of brexucabtagene autoleucel experimental and investigational because the effectiveness of this strategy has not been established.

BSWHP considers brexucabtagene autoleucel to be experimental and investigational for all other indications.

All requests will be reviewed by a clinical pharmacist and medical director.

OVERVIEW

Chimeric antigen receptor (CAR) T cells and genetically engineered T-cell receptor (TCR T) cells are manufactured by collecting lymphocytes from a patient or donor and modifying them using gene transfer techniques. Viral vectors are introduced that express cell receptors that are highly specific for tumor antigens. CAR T and TCR T cells are then infused back into the patient where they direct a targeted immune response to cancerous tissue. CAR T cells express a hybrid receptor with an extracellular single-chain antibody fragment, a transmembrane domain, and at least 1 intracellular signaling domain. CAR T cells are most often used to treat hematological malignancies, and a common target is B-cell cluster of differentiation antigen 19 (CD19).

The U. S. Food and Drug Administration (FDA) granted accelerated approval for brexucabtagene autoleucel (Tecartus™) on July 24, 2020 for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). The indication is approved under accelerated approval based on overall response rate and durability of response and continued approval for this indication may be contingent upon a confirmatory trial. The boxed warning includes the clarification that brexucabtagene autoleucel is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) because of the risk of cytokine release syndrome (CRS) and neurological toxicities.

In a multicenter phase two trial, a total of 74 patients were enrolled to evaluate the safety and efficacy of brexucabtagene autoleucel. To be eligible, patients had to have MCL that had relapsed or was refractory and had previous therapy that included anthracycline- or bendamustine-containing chemotherapy, an anti-CD20 monoclonal antibody, and BTK inhibitor therapy with ibrutinib or acalabrutinib. It was found that 85% of patients had an objective response and 59% had a complete response. Regarding estimated progression-free survival and overall survival, the percentages of patients were 61% and 83% respectively. With respect to the safety of brexucabtagene autoleucel, 99% of patients had an adverse event of grade 3 or higher with the most common types being cytopenias (94%) and infections (32%). For serious adverse events, it was found that 68% of patients experienced these types of adverse events.

In October 2021 the FDA approved brexucabtagene autoleucel for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) based on an open-label, single-arm, multicenter phase 1/2 trial. Eligible patients were adults with primary refractory ALL, first relapse following a remission lasting ≤ 12 months, relapsed or refractory ALL after second-line or higher therapy, or relapsed or refractory ALL at least 100 days after allogeneic stem cell transplantation (HSCT). Of 71 patient enrolled and leukapheresed, 54 were efficacy-evaluable. The primary end points were the percentage of participants experiencing dose-limiting toxicities (DLTs) and overall complete remission (CR) rate. 28 (51.9%) of the 54 evaluable patients achieved a complete remission (CR) with 3 months after the infusion. No DLTs occurred in the DLT-evaluable cohort.

CODES:

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	
CPT Not Covered:	

HCPCS	Q2053 Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
ICD10 codes:	C83.10-C83.19 Mantle cell lymphoma
ICD10 Not covered:	

CMS: NCD 110.24 - Chimeric Antigen Receptor (CAR) T-cell Therapy: Medicare covers autologous treatment for cancer with T-cells expressing at least one chimeric antigen receptor (CAR) when administered at healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies (REMS) and used for a medically accepted indication as defined at Social Security Act section 1861(t)(2) -i.e., is used for either an FDA-approved indication (according to the FDA-approved label for that product), or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia.
Effective date: 08/07/2019. Implementation date: 09/20/2021

POLICY HISTORY:

Status	Date	Action
New	11/19/2021	New policy
Updated	01/28/2021	Minor updates to criteria and excluded sections
Updated	04/22/2021	Medicaid instructions added.
Updated	05/27/2021	Removed Oncology Analytics line, added apheresis criteria, reformatted criteria
Updated	07/22/2021	Added clinician reviewer criteria
Updated	06/23/2022	Added NCD information
Updated	12/01/2022	Removed language with CMS LCD since NCD applies. Removed Texas Mandate HB1584 language from main policy section as the policy is compliant. Added criteria for ALL.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

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Note: Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plans.

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs. Individual HMO plans are offered through FirstCare in West Texas.