MEDICAL COVERAGE POLICY SERVICE: Brexucabtagene autoleucel (Tecartus™)	
Policy Number:	**281**
Effective Date:	**03/01/2021**
Last Review:	**01/28/2021**
Next Review Date:	**01/28/2022**

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: Adoptive Immunotherapy

PRIOR AUTHORIZATION: Required. This policy provides guidelines for medical review when that review is NOT performed by vendor Oncology Analytics®.

POLICY:

For Medicare plans, please refer to appropriate Medicare LCD (Local Coverage Determination). If there is no applicable LCD, use the criteria set forth below.

Brexucabtagene autoleucel (Tecartus™)

SWHP/FirstCare 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
4. Member will be using brexucabtagene autoleucel at a REMS-certified treatment center
5. Member has at least 1 measurable lesion; **AND**
6. Member has histologically confirmed relapsed or refractory disease; **AND EITHER:**
   a. For members of Plans subject to Texas Mandate HB1584: the member has stage 4 advanced metastatic disease; **OR**
   b. There is 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

In addition, the member has or will receive lymphodepleting chemotherapy (fludarabine 30 mg/m2 IV daily and cyclophosphamide 500mg/m2 IV daily) on each of the fifth, fourth, and third days before infusion of brexucabtagene autoleucel.

The member will NOT be treated with more than 2 x 10^8 viable CAR-T cells

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

SWHP/FirstCare considers brexucabtagene autoleucel to be experimental and investigational for all other indications.

Members with the following conditions are NOT eligible for treatment with brexucabtagene autoleucel (Tecartus™):

- 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
- Has received prior CD-19 targeted therapy AND/OR prior CD-19 targeted CAR-T cell therapy
- Primary immunodeficiency, primary central nervous system lymphoma/disease, active infection, or inflammatory disorder

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.

CODES:

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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	C9399 Unclassified drugs or biologicals J9999 Not otherwise classified, antineoplastic drugs
ICD10 codes:	C83.10-C83.19 Mantle cell lymphoma
ICD10 Not covered:	

CMS:

POLICY HISTORY:

Status	Date	Action
New	11/19/2021	New policy
Updated	1/28/2021	Minor updates to criteria and excluded sections

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP/FirstCare 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 SWHP/FirstCare 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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