Medical Policy

Tecartus™ (brexucabtagene autoleucel)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_027
ORIGINAL EFFECTIVE DATE	May 24, 2021
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Tecartus™ (brexucabtagene

autoleucel) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Coverage of Tecartus™ (brexucabtagene autoleucel) is approved for members with a diagnosis of relapsed or refractory mantle cell lymphoma (MCL)

Relapsed or refractory mantle cell lymphoma (MCL)

1. Tecartus is prescribed by, or in consultation with, an oncologist; **AND**
2. Patient is 18 years of age and older; **AND**
3. Patient has disease that is relapsed or refractory to all other treatment options; **AND**
4. Patient did not receive prior allogeneic hematopoietic stem cell transplantation (HSCT); **AND**
5. Patient has an ECOG performance status of 0-1; **AND**
6. Patient has CD19-positive disease; **AND**
7. Patient must not be currently pregnant and sexually active females of reproductive potential should have pregnancy status verified through a pregnancy test; **AND**
8. Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
9. Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during Tecartus treatment, and will not receive live vaccines until immune recovery following treatment; **AND**
10. Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
11. Prophylaxis for infection has been followed according to local guidelines; **AND**
12. Patient will be using Tecartus in conjunction with lymphodepleting chemotherapy cyclophosphamide 500 mg/m2 intravenously and fludarabine 30 mg/m2 intravenously on each of the fifth, fourth, and third days before infusion of Tecartus; **AND**
13. Healthcare facility has enrolled in the Tecartus REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
14. Patient will be using Tecartus at a treatment center that is certified to administer Tecartus; **AND**
15. Patient will be monitored for signs and symptoms of Cytokine Release Syndrome (CRS) for at least 7 days after treatment with Tecartus and will be counselled to seek immediate medical attention should signs and symptoms of CRS or a neurological event occur at any time; **AND**
16. Patient will stay within proximity of the Tecartus infusion center for at least 4 weeks following infusion; **AND**

17. Max dose (per dose and over time): 2×10^8 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells; **AND**
18. Coverage will be provided for one treatment course (1 dose of Tecartus) and may not be renewed.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

BACKGROUND

Brexucabtagene autoleucel is a chimeric antigen receptor (CAR) T-cell gene therapy. It is CD19-directed immunotherapy that works by using a patient's own genetically altered immune cells to kill B-cell cancer cells in the blood. Brexucabtagene autoleucel is indicated for use in adult patients with mantle cell lymphoma who have not responded to or who have relapsed following other therapy.

CODING

Applicable NDC Codes	
71287-0219-01	Tecartus™ (brexucabtagene autoleucel) suspension for infusion; 1 infusion bag (68 mL)

Applicable Procedure Code	
J9999	Not otherwise classified, antineoplastic drugs
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose. Effective Date: 04/01/2020

Applicable ICD-10 Codes	
C83.10	Mantle cell lymphoma
C83.11	Mantle cell lymphoma, lymph nodes of head, face and neck
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen

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EVIDENCE BASED REFERENCES

1. TECARTUS™ (brexucabtagene autoleucel). Prescribing information. Kite Pharma, Inc; 2020.

POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	September 23, 2021 - Added Q-Code (Q2053): Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose February 2, 2022 – Annual Review and approval (no policy revisions made) March 1, 2023 – Adopted by MA UM Committee January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics 2/22/2022