Tecartus (brexucabtagene autoleucel)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Adult patients with relapsed or refractory mantle cell lymphoma (MCL)
2. Adult relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. For all indications: Chart notes, medical record documentation or claims history supporting previous lines of therapy.
B. For Acute Lymphoblastic Leukemia: Testing or analysis confirming morphological disease in the bone marrow (≥ 5% blasts).

Criteria for Initial Approval

A. Mantle Cell Lymphoma

Authorization of 3 months may be granted for a one-time treatment of mantle cell lymphoma in members 18 years of age or older when ALL of the following criteria are met:

1. The disease is relapsed or refractory.

2. The member has had previous treatment with ALL of the following:
   a. Bendamustine OR anthracycline containing chemotherapy; and
   b. Anti-CD20 monoclonal antibody, such as rituximab; and
   c. Bruton's Tyrosine Kinase (BTK) Inhibitors (e.g., acalabrutinib, ibrutinib, zanubrutinib)
3. The member has not received a previous treatment course of brexucabtagene autoleucel or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.
4. The member has an ECOG performance status of 0 to 2. Member is ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours).
5. The member has adequate bone marrow reserve defined by all of the following:
   a. Platelet count ≥ 75,000/μL
   b. Absolute neutrophil count (ANC) ≥ 1000 cells/μL
   c. Absolute lymphocyte count (ALC) ≥ 100 cells/μL
6. The member has adequate and stable kidney, liver, pulmonary and cardiac function as demonstrated by all of the following:
   a. Creatinine clearance ≥ 60 mL/minute
   b. Left ventricular ejection fraction ≥ 50% and there is no evidence of pericardial effusion as determined by an echocardiogram
7. The member does not have any active infections including hepatitis B (HBsAG negative) or hepatitis C virus (anti-HCV negative); (a history of hepatitis B or hepatitis C virus is permitted if the viral load is undetectable per quantitative PCR and/or nucleic acid testing).
8. The member does not have an active inflammatory disorder.
9. The member will receive Tecartus at a treatment center that is certified to administer Tecartus per Yescarta and Tecartus REMS requirements

B. Adult Relapsed or Refractory B-cell precursor Acute Lymphoblastic Leukemia (ALL)

Authorization of 3 months may be granted for a one-time treatment of B-cell precursor acute lymphoblastic leukemia (ALL) in members 18 years of age or older when all of the following criteria are met:

1. The member has not received a previous treatment course of the requested medication or another CD19-directed chimeric antigen receptor (CAR-T) therapy, or any prior CD19 directed therapy other than blinatumomab.
2. The member meets either of the following criteria:
   a. Member has Philadelphia chromosome-negative disease that is relapsed or refractory as defined as one of the following:
      i. Primary refractory disease
      ii. First relapse with remission of 12 months or less
      iii. Relapsed or refractory disease after at least 2 previous lines of systemic therapy
      iv. Relapsed or refractory disease after allogeneic stem cell transplant (ASCT)
   b. Member has Philadelphia chromosome-positive disease and meets any of the following:
      i. The member has relapsed or refractory disease despite treatment with at least 2 different tyrosine kinase inhibitors (TKIs) (e.g., bosutinib, dasatinib, imatinib, nilotinib, ponatinib)
      ii. The member is intolerant to TKI therapy
3. The member has morphological disease in the bone marrow (≥5% blasts).
4. The member has an ECOG performance status of 0 to 2. (Member is ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours).
5. The member has adequate bone marrow reserve defined by all of the following:
   a. Absolute neutrophil count (ANC) ≥ 1000 cells/μL
   b. Absolute lymphocyte count (ALC) ≥ 300 cells/μL
   c. Platelet count ≥ 75,000/μL
   d. Hemoglobin > 8.0 g/dL

6. The member has adequate and stable kidney, liver, pulmonary, and cardiac function as demonstrated by all of the following:
    a. Creatinine clearance ≥ 60 mL/minute
    b. Serum creatinine of < 1.5 times upper limit of normal
    c. Left ventricular ejection fraction ≥ 50% and there is no evidence of pericardial effusion as determined by an echocardiogram
    d. Alanine aminotransferase (ALT)/aspartate aminotransferase (AST) ≤ 2.5 times upper limit of normal for age
    e. Total bilirubin ≤ 1.5 mg/dL with the exception of patients with Gilbert-Meulengracht syndrome; patients with Gilbert-Meulengracht syndrome may be included if their total bilirubin is < 3.0 times the upper limit of normal
7. The member does not have any active infections including hepatitis B (HBsAG negative) or hepatitis C virus (anti-HCV negative); (a history of hepatitis B or hepatitis C virus is permitted if the viral load is undetectable per quantitative PCR and/or nucleic acid testing).
8. The member does not have active graft versus host disease.
9. The member does not have an active inflammatory disorder.
10. The member will receive Tecartus at a treatment center that is certified to administer Tecartus per Yescarta and Tecartus REMS requirements.

Continuation of Therapy

Repeat treatment of Tecartus for any indication is considered investigational, as the safety and efficacy beyond one dose has not been studied. The evidence is insufficient to determine the effects on net health outcomes.

Dosing and Administration

Tecartus will be provided based on the FDA recommended dosing and administration:

A. Mantle Cell Lymphoma
The patient will receive weight-based dosing of 2×10^6 CAR-positive viable T-cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T-cells in approximately 68mL.

B. Adult Relapsed or Refractory B-cell precursor Acute Lymphoblastic Leukemia (ALL)
The patient will receive weight-based dosing of 1×10^6 CAR-positive viable T-cells per kg body weight, with a maximum of 1×10^8 CAR-positive viable T-cells in approximately 68mL.

Quantity Limits

Tecartus approvals will be limited to one treatment per lifetime.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Q2053 – Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR-positive viable T-cells, including leukapheresis and dose preparation procedure, per therapeutic dose

REFERENCES

- Tecartus [package insert]. Los Angeles, CA: Kite Pharma; October 2021.
- The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 16, 2022.
- The NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas (Version4.2022).© 2022 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 16, 2022.
- The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 2.2021).).© 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org.

- Wang M, Munoz J, Goy A, et al. KTE-X19 CAR T-Cell Therapy in Relapsed or Refractory Mantle-Cell Lymphoma. NEJM 2020; 382:1331-1342.
- Shah BD, Ghobadi A, Oluwole OO, et al. KTE-X19 for relapsed or refractory adult B-cell acute lymphoblastic leukaemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study. Lancet. 2021;398(10299):491-502.
- Yescarta and Tecartus REMS also available at https://www.yescartatecartusrems.com/
- U.S. FDA Approves Kite's Tecartus as the First and Only Car T for Adults With Relapsed or Refractory B-cell Acute Lymphoblastic Leukemia. https://gilead.com
- MedScape. For Patients with R/R B-cell Disease. Nick Mulcahy. October 4, 2021https://www.medscape.com/viewarticle/960191
- ASCO 2021: Tecartus Zuma-3 Trial to Support a First Label in Adult R/R ALL. Last updated June 10, 2021 14:33
- Wierda W, Bishop M, Oluwole O, et. al. Updated Phase 1 Results of Zuma-3: KteX19, and Anti-CD19 Chimeric Antigen Receptor T Cell Therapy, in Adult Patients with Relapsed/Refractory Acute Lymphoblastic Leukemia. Abstract Biol Blood Marrow Transplant 25 (2019) S100S289
- Clinical Trial NCT02614066. A Study Evaluating Brexucabtagene Autoleucel (KTE-X19) in Adult Subjects With Relapsed/Refractory B-precursor Acute Wellmark Blue Cross and Blue Shield is an independent licensee of the Blue Cross and Blue Shield Association. 18 © Wellmark, Inc. Lymphoblastic Leukemia (ZUMA-3). Also available at https://clinicaltrials.gov/ct2/show/study/NCT02614066

POLICY HISTORY

Policy #: 05.04.78
Original Effective Date: January 1, 2023
Reviewed: August 2023
Revised:
Current Effective Date: January 1, 2023