Draft Revised Policy: Do Not Implement

Brexucbtagene Autoleucel (Tecartus®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

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

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

EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:

- ECOG performance status greater than or equal to 3 (member is not ambulatory and not capable of all self-care, confined to bed or chair more than 50% of waking hours)
- Inadequate and unstable kidney, liver, pulmonary or cardiac function
- Active hepatitis B, active hepatitis C or any active uncontrolled infection
- Active inflammatory disorder

COVERAGE CRITERIA ~~FOR INITIAL APPROVAL~~

Mantle Cell Lymphoma

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

- The disease is relapsed or refractory.

- The member has received had previous treatment with a covalent ~~both chemoimmunotherapy and a~~ Bruton tyrosine kinase inhibitor (e.g., acalabrutinib [Calquence], ibrutinib [Imbruvica], zanubrutinib [Brukinsa]).
- The member has not received a previous treatment course of brexucabtagene autoleucel or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.

Adult Relapsed or Refractory B-cell precursor Acute Lymphoblastic Leukemia (ALL)
Authorization of 3 months may be granted for the 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:

- 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.
- The member meets either of the following criteria:
  - Member has Philadelphia chromosome-negative disease that is relapsed or refractory as defined as one of the following:
    - Primary refractory disease
    - First relapse with remission of 12 months or less
    - Relapsed or refractory disease after at least 2 previous lines of systemic therapy
    - Relapsed or refractory disease after allogeneic stem cell transplant (allo-SCT)
  - Member has Philadelphia chromosome-positive disease and meets any of the following:
- 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)
- The member is intolerant to TKI therapy
- The member has morphological disease in the bone marrow (≥5% blasts)
- The member does not have active graft versus host disease.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Tecartus [package insert]. Santa Monica, CA: Kite Pharma, Inc.; June 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 17, 2024.
3. 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.

4. Shah BD, Ghobadi A, Oluwole OO, et al. KTE-X19 for relapsed or refractory adult B-cell acute lymphoblastic leukemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study. Lancet. 2021;398(10299):491-502.

EFFECTIVE DATE

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