Reference number(s)
4042-A

SPECIALTY GUIDELINE MANAGEMENT

TECARTUS (brexucabtagene autoleucel)

POLICY

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

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

II. 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).

III. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:
A. 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)
B. Inadequate and unstable kidney, liver, pulmonary or cardiac function
C. Active hepatitis B, active hepatitis C or any active uncontrolled infection
D. Active inflammatory disorder

IV. CRITERIA FOR INITIAL APPROVAL

A. 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:
1. The disease is relapsed or refractory.
2. The member has had previous treatment with both chemoimmunotherapy and a bruton tyrosine kinase inhibitor (e.g., ibrutinib).
3. The member has not received a previous treatment course of brexucabtagene autoleucel or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.

B. 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:

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

V. REFERENCES

1. Tecartus [package insert]. Santa Monica, CA: Kite Pharma, Inc.; October 2021.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 6, 2023.
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 leukaemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study. Lancet. 2021;398(10299):491-502.