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 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. 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.
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 and stable kidney, liver, pulmonary and cardiac function.
6. The member does not have active hepatitis B, active hepatitis C or any active uncontrolled infection.
7. The member does not have an active inflammatory disorder.

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 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 and stable kidney, liver, pulmonary, and cardiac function.
6. The member does not have active hepatitis B, active hepatitis C, or any active uncontrolled infection.
7. The member does not have active graft versus host disease.
8. The member does not have an active inflammatory disorder.

IV. REFERENCES

1. Tecartus [package insert]. Los Angeles, CA: Kite Pharma; October 2021.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 1, 2021.
3. The NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas (Version4.2021).© 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 1, 2021.
4. 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.
5. 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.