

# Specialty Guideline Management

## Tecartus

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tecartus	brexucabtagene autoleucel

### 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 ( $\geq$  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

### 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 previous treatment with a covalent 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:

Reference number(s)
4042-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)
- The member is intolerant to TKI therapy
- The member has morphological disease in the bone marrow ( $\geq 5\%$  blasts)
- The member does not have active graft versus host disease.

## 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 leukaemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study. *Lancet*. 2021;398(10299):491-502.