Reference number(s)
4044-A

STANDARD MEDICARE PART B 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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. EXCLUSIONS

Coverage will not be provided for members less than 18 years of age.

III. DOCUMENTATION

The following documentation must be available, upon request, for all submissions: Chart notes, medical record documentation or claims history supporting previous lines of therapy.

IV. CRITERIA FOR INITIAL APPROVAL

A. Mantle Cell Lymphoma
Authorization of 3 months may be granted for treatment of mantle cell lymphoma 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 does not have active hepatitis B, active hepatitis C, or any active uncontrolled infection.
4. 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 acute lymphoblastic leukemia (ALL) when all of the following criteria are met:
1. The disease is relapsed or refractory meeting either of the following criteria:

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i. Member has Philadelphia chromosome-negative disease
ii. Member has Philadelphia chromosome-positive disease following therapy that has included tyrosine kinase inhibitors (TKIs) (e.g., bosutinib, dasatinib, imatinib, nilotinib, ponatinib)

2. The member does not have active hepatitis B, active hepatitis C, or any active uncontrolled infection.
3. The member does not have active graft versus host disease.
4. The member does not have an active inflammatory disorder.

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Tecartus.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Acute lymphoblastic leukemia
4. NCCN Guideline: B-cell lymphomas
5. National Coverage Determination: Chimeric Antigen Receptor (CAR) T-cell Therapy

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Tecartus are covered.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

All FDA-approved indications are covered according to the conditions outlined in National Coverage Determination Manual section 110.24 (Chimeric Antigen Receptor [CAR] T-cell Therapy).

VII. 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. National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24-Version 1). https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=344&ncdver=1&DocID=110.22&from2=search.asp&bc=gAAAAAgAAAAA& Accessed June 9, 2023.

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