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
Tecartus is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

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

Submission of the following information is necessary to initiate the prior authorization review: Testing or analysis confirming CD19 protein on the surface of the B-cell.

IV. CRITERIA FOR INITIAL APPROVAL

Mantle Cell Lymphoma
Authorization of 3 months may be granted for treatment of mantle cell lymphoma when all of the following criteria are met:

A. The disease is relapsed or refractory.
B. The member has had previous treatment with both chemoimmunotherapy and a bruton tyrosine kinase inhibitor (e.g., ibrutinib).
C. The member has not received a previous treatment course of brexucabtagene autoleucel or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.
D. The B-cells must be CD19-positive as confirmed by testing or analysis.

V. REFERENCES

1. Tecartus [package insert]. Los Angeles, CA: Kite Pharma; July 2020.
2. The NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas (Version 2.2020).© 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed August 06, 2020.