Reference number(s)
2471-A

STANDARD MEDICARE PART B MANAGEMENT

KADCYLA (ado-trastuzumab emtansine)

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.

A. FDA-Approved Indications

1. Metastatic Breast Cancer (MBC)
   Kadcyla, as a single agent, is indicated for the treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either received prior therapy for metastatic disease, or developed disease recurrence during or within six months of completing adjuvant therapy.

2. Early Breast Cancer (EBC)
   Kadcyla, as a single agent, is indicated for the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neo adjuvant taxane and trastuzumab-based treatment.

B. Compendial Uses
1. Single-agent therapy for recurrent or stage IV (M1) HER2-positive breast cancer
2. Non-small cell lung cancer with HER2 mutations
3. HER2-positive recurrent salivary gland tumors

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. DOCUMENTATION

The following documentation must be available, upon request, for all submissions: human epidermal growth factor receptor 2 (HER2) status.

III. CRITERIA FOR INITIAL APPROVAL

Breast cancer
Authorization of 12 months may be granted for the treatment of HER2-positive breast cancer.

Non-small cell lung cancer
Authorization of 12 months may be granted for treatment of non-small cell lung cancer with HER2 mutations.

Salivary gland tumor
Authorization of 12 months may be granted for treatment of HER2-positive salivary gland tumors.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who are continuing with Kadcyla therapy when all of the following criteria are met. Adjuvant treatment of breast cancer will be approved for a total of 12 months of therapy.

A. The member is currently receiving treatment with Kadcyla.
B. Kadcyla is being used to treat a diagnosis or condition enumerated in Section III.
C. The member is receiving benefit from therapy. Benefit is defined as:
    i. No evidence of unacceptable toxicity while on the current regimen AND
    ii. No evidence of disease progression while on the current regimen

V. REFERENCES

1. Kadcyla [package insert]. South San Francisco, CA: Genentech, Inc.; September 2020.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed December 20, 2020.
3. Clinical Pharmacology [database online]. Atlanta, GA: Elsevier, Inc.; 2020. https://www.clinicalkey.com/pharmacology/. Accessed December 20, 2020.