Reference number(s)
1906-A

SPECIALTY GUIDELINE 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 neoadjuvant 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 are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of human epidermal growth factor receptor 2 (HER2) status is necessary to initiate the prior authorization review.

III. CRITERIA FOR INITIAL APPROVAL

A. Breast cancer
1. Authorization of 12 months may be granted for subsequent treatment of HER2-positive metastatic or recurrent breast cancer when used as a single agent.
2. Authorization of up to 12 months may be granted for adjuvant treatment of HER2-positive early breast cancer.

B. Non-small cell lung cancer

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

C. Salivary Gland Tumor
Authorization of 12 months may be granted for treatment of recurrent HER2-positive salivary gland tumors as a single agent.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. Adjuvant treatment of breast cancer will be approved for a total of 12 months of therapy.

V. REFERENCES

1. Kadcyla [package insert]. South San Francisco, CA: Genentech, Inc.; September 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed December 6, 2021.