

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 Indications¹

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.

B. Compendial Use²⁻⁴

1. Recurrent HER2-positive breast cancer
2. Non-small cell lung cancer with HER2 mutations

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Breast cancer**¹⁻³

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

B. **Non-small cell lung cancer**^{2,4}

Authorization of 12 months may be granted for treatment of lung cancer with HER2 mutations.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Kadcyla [package insert]. South San Francisco, CA: Genentech, Inc.; July 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2018 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 15, 2018.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: breast cancer. Version 3.2017. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 15, 2018.
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: non-small cell lung cancer. Version 2.2018 https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed January 15, 2018.