

## 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<sup>1</sup>

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 Use<sup>2-4</sup>

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**<sup>1-3</sup>

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

B. **Non-small cell lung cancer**<sup>2,4</sup>

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](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](https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf). Accessed January 15, 2018.