

## SPECIALTY GUIDELINE MANAGEMENT

### KADCYLA (ado-trastuzumab)

#### 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

Kadcyla, as a single agent, is indicated for the treatment of patients with 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

Recurrent HER2-positive breast cancer

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

##### II. CRITERIA FOR INITIAL APPROVAL

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

##### 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™ © 2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed January 9, 2017.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: breast cancer. Version 2.2016. [http://www.nccn.org/professionals/physician\\_gls/pdf/breast.pdf](http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf). Accessed January 18, 2017.