

## SPECIALTY GUIDELINE MANAGEMENT

### TYKERB (lapatinib)

#### 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

Tykerb is indicated in combination with:

1. Capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress human epidermal growth factor receptor 2 (HER2) and who have received prior therapy including an anthracycline, a taxane, and trastuzumab
2. Letrozole for the treatment of postmenopausal women with hormone receptor (HR)-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated

###### B. Compendial Uses

1. Recurrent or metastatic HER2-positive breast cancer in combination with trastuzumab
2. Recurrent or stage IV estrogen receptor-positive, HER2-positive breast cancer in combination with aromatase inhibition in postmenopausal women
3. Metastatic central nervous system (CNS) lesions if active against primary tumor (breast)

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

##### II. CRITERIA FOR INITIAL APPROVAL

###### A. **Breast cancer**

Authorization of 12 months may be granted for the treatment of HER2-positive breast cancer when Tykerb is used in combination with an aromatase inhibitor (eg, letrozole, anastrozole, exemestane), trastuzumab, or capecitabine.

###### B. **Metastatic CNS lesions**

Authorization of 12 months may be granted for the treatment of metastatic CNS lesions from 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. Tykerb [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2015.
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.