

## **Specialty Pharmacy Program**

### **Tykerb<sup>®</sup> (lapatinib)**

#### **DESCRIPTION**

Tykerb is an oral tyrosine kinase inhibitor that is indicated for the treatment of breast cancer in patients whose tumors overexpress the HER2 protein.

#### **APPROVAL DURATION**

Approval duration: 1 year

#### **APPROVAL CRITERIA**

##### **FDA-Approved Indication(s)**

1. Treatment of advanced or metastatic breast cancer, in combination with capecitabine, in patients whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.

##### **Off-Label Indication(s)**

Requests for off-label use of Tykerb will be reviewed and approved when sufficiently supported by evidence from major compendia, published peer-reviewed medical literature, nationally accepted practice guidelines, or expert consensus statements. The major compendia that are recognized include AHFS<sup>®</sup> Drug Information, Thomson Micromedex<sup>®</sup>, National Comprehensive Cancer Network Drugs and Biologics Compendium<sup>™</sup>, and Clinical Pharmacology.