

### Clinical Pharmacy Program Guidelines for Tykerb

Program	Prior Authorization
Medication	Tykerb <sup>®</sup> (lapatinib)
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

**1. Background:**

Tykerb<sup>®</sup> (lapatinib) is a kinase inhibitor indicated for use in combination with Femara<sup>®</sup> (letrozole) for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated. Tykerb is also indicated in combination with Xeloda<sup>®</sup> (capecitabine) for treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy, including an anthracycline, a taxane, and the HER2 receptor antagonist Herceptin<sup>®</sup> (trastuzumab). Patients should have disease progression on Herceptin prior to initiation of treatment with Tykerb in combination with Xeloda. The National Cancer Comprehensive Network (NCCN) also approves the use of Tykerb in metastatic central nervous system (CNS) lesions with primary tumor of the breast and EGFR-positive chordoma.

**2. Coverage Criteria:**

**A. Breast Cancer**

**1. Initial Authorization**

**a. Tykerb** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Diagnosis of recurrent or stage IV estrogen receptor positive (ER+), human epidermal growth factor receptor 2-positive (HER2+) breast cancer

-AND-

(b) **One** of the following:

- i. Patient is postmenopausal
- ii. Patient is receiving testicular steroidogenesis suppression

-AND-

(c) Used in combination with an aromatase inhibitor [eg, Aromasin

(exemestane), Femara (letrozole), Arimedex (anastrozole)]

**-OR-**

(2) **All** of the following:

(a) Diagnosis of recurrent or metastatic HER2+ breast cancer

**-AND-**

(b) Patient has been previously treated with Herceptin (trastuzumab)

**-AND-**

(c) Used in combination with **one** of the following:

- i. Herceptin (trastuzumab)
- ii. Xeloda (capecitabine)

**Authorization will be issued for 12 months.**

## **2. Reauthorization**

**a. Tykerb** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tykerb therapy

**Authorization will be issued for 12 months.**

## **B. Central Nervous System (CNS) Cancers (off-label)**

### **1. Initial Authorization**

**a. Tykerb** will be approved based on **all** of the following criteria:

(1) Diagnosis of recurrent, central nervous system (CNS) cancer with metastatic lesions

**-AND-**

(2) Tykerb is active against primary (breast) tumor

**-AND-**

(3) Used in combination with Xeloda (capecitabine)

**Authorization will be issued for 12 months.**

**2. Reauthorization**

**a. Tykerb** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Tykerb therapy

**Authorization will be issued for 12 months.**

**C. Chordoma (off-label)**

**1. Initial Authorization**

**a. Tykerb** will be approved based on the following criterion:

- (1) Diagnosis of EGFR-positive, recurrent chordoma

**Authorization will be issued for 12 months.**

**2. Reauthorization**

**a. Tykerb** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Tykerb therapy

**Authorization will be issued for 12 months.**

**3. References:**

1. Tykerb [package insert]. Research Triangle Park, NC: Novartis Pharmaceuticals Corp; April 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [http://www.nccn.org/professionals/drug\\_compendium/content/contents.asp](http://www.nccn.org/professionals/drug_compendium/content/contents.asp). Accessed August 3, 2017.

Program	Prior Authorization–Tykerb (lapatinib)
<b>Change Control</b>	
Date	Change
9/2013	New guideline.

12/2015	Annual Review
9/2016	Updated clinical criteria to align with E&I notification policy and updated policy template.
9/2017	Annual Review. Updated references.