UnitedHealthcare Community Plan

# Clinical Pharmacy Program Guidelines for Tykerb

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| Program | Prior Authorization |
| Medication | Tykerb® (lapatinib) |
| Markets in Scope | Arizona, Colorado, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina |
| Issue Date | 9/2013 |
| Pharmacy and Therapeutics Approval Date | 9/2020 |
| Effective Date | 11/2020 |

## 1. Background:

Tykerb® (lapatinib) is a kinase inhibitor indicated for use in combination with Femara® (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® (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 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, intracranial and spinal ependymomas, EGFR-positive chordoma and colon and rectal cancers not previously treated with HER2 inhibitors.

Tykerb has a black box warning for hepatotoxicity. Please see full prescribing information for additional details.

## 2. Coverage Criteria:

**A. <u>Breast Cancer</u>**

**1. <u>Initial Authorization</u>**

**a. Tykerb** will be approved based on **<u>one</u>** of the following criteria:

(1) **<u>Both</u>** of the following:

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

**-AND-**

(b) Used in combination with an aromatase inhibitor [e.g., Aromasin

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

**-OR-**

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

(a) Diagnosis of advanced or stage IV HER2+ breast cancer

**-AND-**

(b) 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**

**1. Initial Authorization**

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

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

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

**-AND-**

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

**-AND-**

(c) Used in combination with Xeloda (capecitabine)

**-OR-**

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

(a) Diagnosis of recurrent intracranial or spinal ependymoma (excluding subependymoma)

**-AND-**

(b) Patient has received previous radiation therapy

**-AND-**

(c) Patient has received **one** of the following:

i. Gross total or subtotal resection
ii. Localized recurrence
iii. Evidence of metastasis (brain, spine, or cerebral spinal fluid)

**-AND-**

(d) Used in combination with Temodar (temozolomide)

**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**

**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.**

**D. Colon Cancer**

**1. Initial Authorization**

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

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

(a) Diagnosis of unresectable, advanced or metastatic colon cancer (HER2-amplified and RAS wild type)

**-AND-**

(b) Patient has not previously been treated with a HER2 inhibitor [e.g., Kanjinti (trastuzumab), Perjeta (pertuzumab), Nerlynx (neratinib)]

**-AND-**

(c) Patient has previously been treated with **one** of the following regimens:

i. Oxaliplatin-based therapy without irinotecan
ii. Irinotecan-based therapy without oxaliplatin
iii. FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen
iv. A fluoropyrimidine without irinotecan or oxaliplatin

**-AND-**

(d) Used in combination with trastuzumab.

**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.**

**E. Rectal Cancer**

**1. Initial Authorization**

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

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

(a) Diagnosis of unresectable, advanced or metastatic rectal cancer (HER2-amplified and RAS wild type)

**-AND-**

(b) Patient has not previously been treated with a HER2 inhibitor [e.g., Kanjinti (trastuzumab), Perjeta (pertuzumab), Nerlynx (neratinib)]

**-AND-**

(c) Patient has previously been treated with **one** of the following regimens:

i. Oxaliplatin-based therapy without irinotecan
ii. Irinotecan-based therapy without oxaliplatin
iii. FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen
iv. A fluoropyrimidine without irinotecan or oxaliplatin

**-AND-**

(d) Used in combination with trastuzumab

**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.**

**F. NCCN Recommended Regimens**

**1. Initial Authorization**

a. **Tykerb** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

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

**2. Reauthorization**

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

(1) Documentation of positive clinical response to Tykerb therapy

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

**3. References:**


1. Tykerb [package insert]. Research Triangle Park, NC: Novartis Pharmaceuticals Corp; December 2018.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 30,2020.


| Program | Prior Authorization–Tykerb (lapatinib) |
|---|---|
| **Change Control** | |
| 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. |
| 9/2018 | Updated criteria for breast cancer. Added NCCN Recommended Regimen criteria. Updated references. |
| 9/2019 | Updated background and criteria to align with NCCN guidance. Updated references. |
| 9/2020 | Annual review. No changes to coverage criteria. Updated reference. Added Additional Clinical Rules section. |