UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1112-11
Program	Prior Authorization/Notification
Medication	Tykerb® (lapatinib)
P&T Approval Date	8/2008, 6/2009, 9/2010, 12/2010, 9/2011, 8/2012, 7/2013, 11/2014, 11/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 10/2021, 10/2022, 10/2023
Effective Date	1/1/2024

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 human epidermal growth factor receptor 2 (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 trastuzumab prior to initiation of treatment with Tykerb in combination with Xeloda. The National Cancer Comprehensive Network (NCCN) also recommends 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.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <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 recurrent 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.

C. 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.

D. 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.

E. 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 and BRAF wild type)

-AND-

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

-AND-

(c) One of the following:

i. Patient has previously been treated with **one** of the following regimens:
- Oxaliplatin-based therapy without irinotecan
- Irinotecan-based therapy without oxaliplatin
- FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen
- A fluoropyrimidine without irinotecan or oxaliplatin

-OR-

ii. Patient is not appropriate for intensive therapy

-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. 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 and BRAF wild type)

-AND-

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

-AND-

(c) Used in combination with trastuzumab

-AND-

(d) One of the following:

i. Patient has previously been treated with **one** of the following regimens:
- Oxaliplatin-based therapy without irinotecan
- Irinotecan-based therapy without oxaliplatin
- FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen
- A fluoropyrimidine without irinotecan or oxaliplatin

-OR-

ii. Patient is not appropriate for intensive therapy

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.

G. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific

benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limit may be in place.

4. References:

1. Tykerb [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; March 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 29, 2023.

Program	Prior Authorization/Notification –Tykerb (lapatinib)
Change Control	
11/2014	Annual review. Added coverage criteria for chordoma. Updated background & references.
11/2015	Annual review. Increased authorization from 7 months to 12 months. Revised breast cancer & CNS cancer criteria. Updated background & references.
9/2016	Annual review. Changed Member to Patient. Revised breast cancer criteria. Updated references.
9/2017	Annual review. Updated references.
9/2018	Annual review. Updated coverage criteria for breast cancer. Updated references.
9/2019	Annual review. Updated coverage criteria to align with NCCN guidelines. Updated references. Added general NCCN recommended review criteria.
9/2020	Annual review. No changes to coverage criteria.
10/2021	Annual review. Updated coverage criteria for rectal cancer to align with NCCN guidelines. Updated references.
10/2022	Annual review. Updated coverage criteria for colon cancer to align with NCCN guidelines. Added state mandate. Updated references.
10/2023	Annual review. Updated coverage criteria for colon cancer.