



Commercial/Healthcare Exchange PA Criteria Effective: January 1, 2021

Prior Authorization: Lapatinib

Products Affected: Tykerb and lapatinib oral tablets

Medication Description: Tyrosine kinase (dual kinase) inhibitor; inhibits EGFR (ErbB1) and HER2 (ErbB2) by reversibly binding to tyrosine kinase, blocking phosphorylation and activation of downstream second messengers (Erk1/2 and Akt), regulating cellular proliferation and survival in ErbB- and ErbB2-expressing tumors.

Covered Uses:

1. Breast Cancer – Human Epidermal Growth Factor Receptor 2 (HER2)-Positive

Exclusion Criteria:

Lapatinib has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval in the following circumstances.

1. Monotherapy
2. HER2-negative breast cancer
3. Breast cancer, advanced or metastatic, HER2 overexpression – treatment naïve patients
4. Breast cancer, advanced or metastatic, HER2 overexpression – Herceptin naïve patients

Required Medical Information:

1. Human epidermal growth factor receptor 2 (HER 2) status
2. Menopausal status
3. Prior therapies tried
4. Dose and frequency

Age Restrictions: None

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist

Coverage Duration: 3 years

Other Criteria:

1. **Breast Cancer** Approve if the patient meets one of the following criteria (A or B):

- A) Patient has a diagnosis of advanced or metastatic HER2+ breast cancer; **AND**
- i. Lapatinib will be used in combination with capecitabine or trastuzumab; **AND**
 - ii. Patient has received prior therapy including an anthracycline, a taxane, and trastuzumab; **OR**

- B) Patient has a diagnosis of hormone receptor positive, human epidermal growth factor receptor 2-positive (HER2+) breast cancer; **AND**
- i. Patient is postmenopausal; **AND**

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ii. Lapatinib will be used in combination with an aromatase inhibitor

References:

1. Tykerb [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2020.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 6.2020). National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on December 15, 2020.

Policy Revision History:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	Retired Tykerb NCH policy and adopted EH Tykerb policy	All	1/1/2021