

Tykerb (lapatinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Tykerb (lapatinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Tykerb (lapatinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Breast Cancer, with HER 2 overexpression confirmed by one of the following:
 - A. Immunohistochemistry (IHC) is 3+; **OR**
 - B. In situ hybridization (ISH) positive;

AND
 - II. The following criteria applies:
 - A. Individual has advanced or metastatic breast cancer and is using in combination with capecitabine; **AND**
 - B. Individual has received prior therapy including an anthracycline, a taxane, and trastuzumab; **AND**
 - C. Individual has had disease progression on trastuzumab prior to initiation of treatment with Tykerb;

OR

 - D. Individual has hormone receptor (HR) positive metastatic breast cancer and is using in combination with letrozole;

OR

 - E. Individual has recurrent or stage IV disease and is using in combination with trastuzumab or capecitabine, as third-line therapy or beyond (NCCN 2A);

OR

 - F. Individual has recurrent or stage IV disease and is using in combination with an Aromatase Inhibitor with or without trastuzumab (NCCN 2A);
- OR**
- III. Individual has a diagnosis of metastatic Breast Cancer with asymptomatic, recurrent, or relapsed brain metastases; **AND**
- IV. The primary tumor (breast cancer) is HER2-positive confirmed by one of the following:
 - A. Immunohistochemistry (IHC) is 3+; **OR**
 - B. In situ hybridization (ISH) positive;

AND

- V. Individual is using in combination with capecitabine;

OR

- VI. Individual has a diagnosis of Bone Cancer- EGFR-positive recurrent chordoma (NCCN 2A).

Note:

Tykerb (lapatinib) has a black box warning for hepatotoxicity. Hepatotoxicity has been observed in clinical trials and post marketing experience. The hepatotoxicity may be severe and deaths have been reported. Causality of the deaths is uncertain.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 1, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. Sartore- bianchi A, trusolino L, Martino C, et al. Dual-targeted therapy with trastuzumab and lapatinib in treatment-refractory, KRAS codon 12/13 wild-type, HER2-positive metastatic colorectal cancer (HERACLES): a proof-of-concept, multicentre, open-label, phase 2 trial. *Lancet Oncol* 2016;17:738-746.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed April 1, 2022.
 - a. Breast Cancer. V2.2022. Revised December 20, 2021.
 - b. Central Nervous System Cancers. V2.2021. Revised September 8, 2021.
 - c. Colon Cancer. V1.2022. Revised February 25, 2022.
 - d. Rectal Cancer. V1.2022. Revised February 25, 2022.
 - e. Bone Cancer. V2.2022. Revised October 8, 2021.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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