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 (or trastuzumab biosimilar); **AND**
   C. Individual has had disease progression on trastuzumab (or trastuzumab biosimilar) 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 unresectable or stage IV disease and is using in combination with trastuzumab (or trastuzumab biosimilar) or capecitabine, as fourth-line therapy or beyond (NCCN 2A);

   OR

   F. Individual has recurrent unresectable or stage IV hormone receptor (HR) positive disease and is using in combination with an Aromatase Inhibitor with or without trastuzumab (or trastuzumab biosimilar) (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);

OR

VII. Individual has a diagnosis of HER2-amplified (HER2+) colon cancer, rectal cancer, or appendiceal adenocarcinoma verified by one of the following:
   A. Immunohistochemistry (IHC) is 3+; **OR**
   B. In situ hybridization (ISH) positive;

AND

VIII. Individual has unresectable, advanced, or metastatic disease that is RAS and BRAF wild-type; **AND**

IX. Individual is using in combination with trastuzumab (or trastuzumab biosimilar); AND

X. Individual is using as primary/initial therapy or as second-line and subsequent therapy.

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. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. 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 trail. Lancet Oncol 2016;17:738-746.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed March 21, 2024
   a. Breast Cancer. V2.2024. Revised March 11, 2024.
   b. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.
   c. Colon Cancer. V1.2024. Revised January 29, 2024.
   d. Rectal Cancer. V1.2024. Revised January 29, 2024.
   e. Bone Cancer. V2.2024. Revised March 12, 2024.