

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

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

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

- I. Individual has a diagnosis of Breast Cancer, with HER 2 overexpression; **AND**
 - 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

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

OR

 - D. Individual has recurrent or stage IV disease and is using in combination with trastuzumab (NCCN 2A);

OR

 - E. Individual has recurrent or stage IV disease and is using in combination with an Aromatase Inhibitor (NCCN 2A);
- OR**
- II. Individual has a diagnosis of Central Nervous System Cancers; **AND**
 - III. Individual has recurrent disease for brain metastases if active against the primary tumor (breast cancer) (NCCN 2A);

OR

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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IV. Individual has a diagnosis of Bone Cancer-chordoma (NCCN 2A).

Limitation of use: Individuals should have disease progression on trastuzumab prior to initiation of treatment with Tykerb in combination with capecitabine.

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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. 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: October 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. The NCCN Drugs & Biologics Compendium (NCCN Compendium™) © 2018 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.

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