Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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 (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

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

III. Individual has a diagnosis ofmetastatic Breast Cancer with asymptomatic, recurrent, or relapsed brain metastases; **AND**

IV. The primary tumor (breast cancer) is HER2-positive;

OR

V. Individual has a diagnosis of Bone Cancer- 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.: 2020. 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 19, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; 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 trail. Lancet Oncol 2016;17:738-746.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed April 2020.
    a. Breast Cancer. V3.2020. Revised March 6, 2020.
    b. Central Nervous System Cancers. V1.2020. Revised March 10, 2020.