

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

## Tukysa (tucatinib)

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

Medications	Quantity Limit
Tukysa (tucatinib)	May be subject to quantity limit

### APPROVAL CRITERIA

Requests for Tukysa (tucatinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of HER2-positive (HER2+) breast cancer (NCCN 1) confirmed by *one* of the following:
  - A. Immunohistochemistry (IHC) is 3 +;
  - OR**
  - B. In situ hybridization (ISH) positive;
- AND**
- II. Individual has advanced unresectable or metastatic breast cancer, including brain metastases; **AND**
- III. Individual has received one or more prior anti-HER2 based regimens in the metastatic setting; **AND**
- IV. Individual is using as second-line or greater in combination with oral capecitabine and trastuzumab (or trastuzumab biosimilars).

### 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 20, 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. Murthy RK, Loi S, Okines A, et. al. Tucatinib, Trastuzumab, and Capecitabine for HER2-Positive Metastatic Breast Cancer. N Engl J Med. 2020; 382 (7): 597-609. Accessed April 20, 2020.

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PAGE 1 of 2 06/09/2020  
New Program Date 06/09/2020

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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6. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 20, 2020.

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