

# 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 (Label, 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);
- OR**
- V. Individual has a diagnosis of RAS wild-type HER2-positive unresectable or metastatic colorectal cancer (Label); **AND**
  - VI. Individual is using in combination with trastuzumab (or its biosimilars); **AND**
  - VII. Individual has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-, based chemotherapy.

## **Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. 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: January 14, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; 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 January 14, 2023.

6. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 14, 2023
- a. Breast Cancer. V4.2022. Revised June 21, 2022.
  - b. Central Nervous System. V2.2022. Revised September 29, 2022.

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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