

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, 2A) 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, including Appendiceal Adenocarcinoma (Label); **AND**
 - VI. Individual is using in combination with trastuzumab (or trasztuzumab biosimilars); **AND**
 - VII. One of the following:
 - A. Individual has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-, based chemotherapy (Label, NCCN 2A); **OR**
 - B. Individual has prior FOLFOX or CapeOX therapy within the past 12 months in those with proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease (NCCN 2A); **OR**
 - C. Individual is ineligible for or progression on checkpoint inhibitor immunotherapy for deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) and if intensive therapy is not recommended and no prior treatment with a HER2 inhibitor (NCCN 2A);
- OR**
- VIII. Individual has a diagnosis of Biliary Tract Cancers (NCCN 2A); **AND**

- A. Individual has HER2-positive unresectable or resected gross residual disease or metastatic disease; **AND**
- B. Individual is using as subsequent treatment; **AND**
- C. Individual is using in combination with trastuzumab (or trastuzumab bisoimilars).

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.; 2025; Updated periodically.
4. 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.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 18, 2025.
 - a. Breast Cancer. V6.2024. Revised November 11, 2024.
 - b. Central Nervous System Cancers. V3.2024. Revised September 30, 2024.
 - c. Colon Cancer V6.2024. Revised January 17, 2025.
 - d. Rectal Cancer. V5. 2024. Revised January 17, 2025.

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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