

# Specialty Guideline Management

## Tukysa

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tukysa	tucatinib

### Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-approved Indications<sup>1</sup>

- Tukysa is indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.
- Tukysa is indicated in combination with trastuzumab for the treatment of adult patients with RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

#### Compendial Uses<sup>2-6</sup>

- Breast Cancer
- Colorectal Cancer
- Biliary Tract Cancers

Reference number(s)
3782-A

- Gallbladder cancer
- Intrahepatic cholangiocarcinoma
- Extrahepatic cholangiocarcinoma
- Appendiceal Neoplasms and Cancers
  - Appendiceal adenocarcinoma
  - Goblet cell adenocarcinoma
  - Undifferentiated carcinoma not otherwise specified

All other indications are considered experimental/investigational and not medically necessary.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review, where applicable:

- Human epidermal growth factor receptor 2 (HER2) status
- RAS mutation status
- BRAF mutation status
- HER2 activating mutation

## Coverage Criteria

### Breast Cancer<sup>1,2</sup>

Authorization of 12 months may be granted for treatment of HER2-positive breast cancer in combination with trastuzumab and capecitabine when any of the following criteria are met:

- As subsequent therapy for members with no response to preoperative systemic therapy, recurrent unresectable, advanced unresectable, or metastatic disease including limited or extensive brain metastases; or
- As initial therapy for members with small asymptomatic brain metastases

Authorization of 12 months may be granted for treatment of metastatic breast cancer with HER2 activating mutation as third-line or later when used in combination with trastuzumab with or without fulvestrant.

### Colorectal Cancer<sup>1-4</sup>

Authorization of 12 months may be granted for treatment of advanced, unresectable, inoperable, or metastatic colorectal cancer, including anal adenocarcinoma, with HER2-amplified and RAS and BRAF wild-type disease in combination with trastuzumab when the member has not previously received treatment with HER2 inhibitor.

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3782-A

## Biliary Tract Cancers<sup>2,5</sup>

Authorization of 12 months may be granted for subsequent treatment of locally advanced, unresectable, resected gross residual (R2) or metastatic HER2-positive biliary tract cancers (including gallbladder cancer, intrahepatic and extrahepatic cholangiocarcinoma) when used in combination with trastuzumab.

## Appendiceal Neoplasms and Cancers<sup>2,6</sup>

Authorization of 12 months may be granted for subsequent treatment of appendiceal neoplasms and cancers (including appendiceal adenocarcinoma, goblet cell adenocarcinoma, and undifferentiated carcinoma not otherwise specified) when all of the following criteria are met:

- The disease is HER2 positive and RAS and BRAF wild-type (negative)
- The requested medication will be used in combination with trastuzumab
- The member has not received previous treatment with HER2 inhibitor

## Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

## References

1. Tukysa [package insert]. Bothell, WA: Seagen, Inc.; January 2023.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed January 23, 2026.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Colon Cancer. Version 5.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/colon.pdf](https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf). Accessed November 5, 2025.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 5.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/anal.pdf](https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf). Accessed November 10, 2025.
5. Tucatinib. Lexi-Drugs. UpToDate Lexidrug. UpToDate Inc. <https://online.lexi.com>. Accessed November 4, 2025.
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Appendiceal Neoplasms and Cancers. Version 1.2026. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/appendiceal.pdf](https://www.nccn.org/professionals/physician_gls/pdf/appendiceal.pdf). Accessed November 4, 2025.