

TUKYSA (tucatinib)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

- 1. Advanced unresectable or metastatic breast cancer
 - a. Patient has previously received one or more anti-HER2-based regimens
 - b. Used in combination with trastuzumab and capecitabine
- 2. Unresectable or metastatic colorectal cancer
 - a. RAS wild-type, as determined by an FDA-approved test
 - b. Cancer has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
 - c. Used in combination with trastuzumab

AND ALL of the following:

- 1. Human epidermal growth factor receptor 2 (HER2)-positive
- 2. Prescriber agrees to obtain baseline AST, ALT, and bilirubin and to monitor levels during treatment
- Females of reproductive potential only: patient will be advised to use effective contraception during treatment with Tukysa and for 1 week after the last dose
- 4. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Tukysa and for 1 week after the last dose

Prior - Approval Limits

Quantity

Strength	Quantity Limit per 90 days
50 mg	1080 tablets per 90 days OR
150 mg	360 tablets per 90 days

Maximum daily limit of any combination: 600mg



TUKYSA (tucatinib)

Duration 12 months

Prior – Approval Renewal Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

- 1. Advanced unresectable or metastatic breast cancer
 - a. Used in combination with trastuzumab and capecitabine
- 2. Unresectable or metastatic colorectal cancer
 - a. Used in combination with trastuzumab

AND ALL of the following:

- 1. **NO** disease progression or unacceptable toxicity
- 2. Prescriber agrees to monitor AST, ALT, and bilirubin during treatment
- Females of reproductive potential only: patient will be advised to use effective contraception during treatment with Tukysa and for 1 week after the last dose
- 4. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Tukysa and for 1 week after the last dose

Prior - Approval Renewal Limits

Same as above