Seagen Secure®
Patient Assistance Program

TUKYSA® (tucatinib) Tablets Prior Authorization Process Guide

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Monday-Friday, 8 AM-8 PM ET

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Seagen Secure® Oncology Access Advocates help you through the prior authorization (PA) process

They will also evaluate your patient for a free short-term supply of TUKYSA if the PA determination is delayed

Seagen Secure®
Patient Assistance Program

Help Your Patients Access TUKYSA (tucatinib) Tablets

Seagen Secure, Seagen's patient support and reimbursement assistance program, may be able to help patients access their prescribed Seagen therapy in a timely manner.

Seagen helps by

Informing

Providing education on PA requirements, including payer-specific PA policy and submission information

Connecting

Helping you connect with your local Field Reimbursement Manager (FRM) to understand PA and payer processes

Assisting

Helping eligible patients access TUKYSA through benefits investigations, appeal support, and financial assistance programs

Seagen does not guarantee that enrollment in Seagen Secure will result in patient assistance, coverage, and/or reimbursement. Seagen Secure is not intended to provide medical advice or replace medical advice from the patient's healthcare provider (HCP).

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Documentation You May Need to Complete a PA Request for TUKYSA (tucatinib) Tablets

Complete the Appropriate PA Form

- Verify and record that every PA requirement for the plan has been met
- Accurate and appropriate completion of clinical documentation can help expedite claims processing and facilitate timely access to TUKYSA
- If a PA requirement has not been met, indicate why, including providing additional patient medical information supporting why the requirement has not been or cannot be met

Ensure You Have Provided This Information

- ✔ Diagnosis details with proper metastatic breast cancer (MBC) or metastatic colorectal cancer (mCRC) diagnosis codes: ICD-10-CM codes and CPT codes*
- ✔ For patients with MBC, previous HER2-directed therapies and how TUKYSA will be used
- ✔ Payer-specific PA forms
- ✔ Supporting clinical references for your treatment recommendation

*Specific plan requirements may vary.

CPT = Current Procedural Terminology; HER2 = human epidermal growth factor receptor 2; ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification.

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Available Resources From Seagen Secure

Prior Authorization Request Guide


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TUKYSA® (tucatinib) 50 mg and 150 mg tablets
Prior Authorization Request Guide

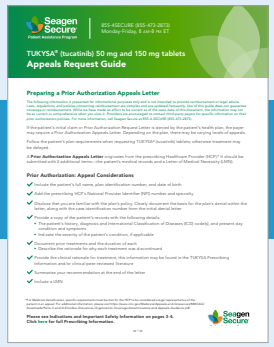
Drafting a Prior Authorization Request Letter

Prior Authorization Requests: Guidance and Recommendations

Prior Authorization Considerations

Please see Indications and Important Safety Information on pages 3-4.
Click here for full Prescribing Information.

Appeals Request Guide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TUKYSA® (tucatinib) 50 mg and 150 mg tablets
Appeals Request Guide

Preparing a Prior Authorization Appeals Letter

Prior Authorization: Appeal Considerations

Please see Indications and Important Safety Information on pages 3-4.
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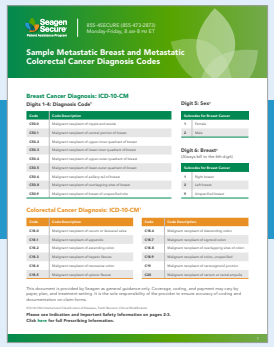
Sample Metastatic Breast and Metastatic Colorectal Cancer Diagnosis Codes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Sample Metastatic Breast and Metastatic Colorectal Cancer Diagnosis Codes

Breast Cancer Diagnosis: ICD-10-CM

Colorectal Cancer Diagnosis: ICD-10-CM†

Please see Indication and Important Safety Information on pages 2-3.
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Common Documentation Requirements for Patients Prescribed TUKYSA (tucatinib)

Diagnosis	Clinical Details	Documentation Examples
Primary diagnosis	HER2+ MBC or mCRC, including metastases	ICD-10 code from Seagen Secure Sample Metastatic Breast and Metastatic Colorectal Cancer Diagnosis Codes Select primary codes used: C18.0-C20, C50.1-6, C50.8-9 (Example: C50.011 Malignant neoplasm of nipple and areola, female, right breast)[1]
Secondary diagnosis	Secondary and unspecified malignant neoplasms	Secondary ICD-10 code from Seagen Secure Sample Metastatic Breast Cancer Diagnosis Codes (Example: C79.31 Secondary malignant neoplasm of brain)[1]
Diagnostic findings	Relevant details may be found in patient's medical record, including: • Physical symptoms of MBC • Blood tests • Scans • Biopsy	Diagnostic tests for breast and colorectal cancer • Locally advanced • Unresectable • Metastatic • Hormone receptor (HR) status • Brain malignancy
Previous therapies and intolerance	• Hormone therapy • Chemotherapy • Targeted therapy (monoclonal antibodies; trastuzumab; tyrosine kinase inhibitors, or combination therapy) • Local treatments, such as surgery or radiation • Intolerance to therapy	• Duration/dates of therapy • Efficacy/response • Association of adverse events/reactions • Development of resistance and mutations • Intolerance • Documented lab results • Symptoms/duration of symptoms
Experience with TUKYSA	• TUKYSA in combination with trastuzumab and capecitabine • TUKYSA in combination with trastuzumab	• Duration/dates of therapy • Efficacy/response • Association of adverse events/reactions • Development of resistance and mutations • Intolerance • Documented lab results • Symptoms/duration of symptoms • Questionnaires

NDC Codes[2]

TUKYSA (tucatinib) tablets

150-mg tablets/60 count	51144-002-60
150-mg tablets/120 count	51144-002-12
50-mg tablets/60 count	51144-001-60

Coverage, coding, and payment may vary by payer, plan, and treatment setting. It is the sole responsibility of the provider to ensure accuracy of coding and documentation on claim forms.

Note: Payer requirements regarding use of a 10-digit or 11-digit NDC may vary.

NDC = National Drug Code.

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TUKYSA (tucatinib) PA Journey

STEP 1

Enroll the patient in Seagen Secure for Oncology Access Advocate Support*

Submit the Seagen Secure Enrollment Form and Patient Authorization Form to Seagen Secure via fax at 855-557-2480. Forms can also be submitted via email at CaseManager@seagensecure.com or online at SeagenSecure.com

Seagen Secure enrollment evaluates your patient's eligibility for a Quick Start supply if there is a delay in gaining coverage from the patient's insurance

STEP 2

Benefits investigation begins for your patients

Seagen Secure will evaluate the patient's insurance coverage to determine eligibility for coverage as well as the patient's responsible cost share

A complete benefits investigation will be faxed to you with the patient's plan and coverage information, including patient's deductible and OOP amount for the regimen

The benefits investigation will also include additional patient assistance support that may be available through Seagen Secure, including copay assistance for commercially insured patients

STEP 3

Seagen Secure or FRMs can help with PA and appeals (if needed)

Seagen Secure can

- Obtain and send the appropriate PA form to the HCP to review, complete,and sign
- Inform the HCP of how to submit the completed PA form to the insurer
- Follow up with the insurer to confirm receipt, check status, and obtain the outcome

  Note: Some plans do not allow third-party groups to check status

If the patient's initial claim or Prior Authorization Request Letter is denied by the patient's health plan, the payer may require a Prior Authorization Appeals Letter; depending on the plan, there may be varying levels of appeals

- Seagen Secure will review the appeal denial reason(s) and relay this information to the HCP

The Quick Start Program provides 15 days of TUKYSA free of charge.

Quick Start is a short-term, free product that may be available to patients who face a delay of at least 5 days in insurance determination of coverage for TUKYSA.

While the payer decision is being made, all patients enrolled into Seagen Secure will be evaluated for this program. Acceptance of enrollment into the program is optional and will be discussed with the prescriber prior to dispensing.

Quick Start is not available through Specialty Pharmacies.

OOP = out of pocket.

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STEP 4

Seagen Secure helps eligible patients with copay assistance

For eligible patients, Seagen Secure offers a Commercial Copay Assistance Program to support all phases of a patient's benefit

Oncology Access Advocates may be able to refer patients with third-party organizations for additional assistance, if needed†

STEP 5

Insurance is confirmed and TUKYSA is delivered

Once insurance coverage is confirmed, the specialty pharmacy will process the claim, prepare the medication, and contact the patient to arrange delivery

TUKYSA is provided free of charge for qualifying patients who are uninsured or underinsured.

*Seagen does not guarantee that enrollment will result in coverage or reimbursement. Seagen reserves the right to make eligibility determinations and to modify or discontinue the program at any time.

†Support is provided through third-party organizations that operate independently and are not controlled by Seagen Secure or Seagen. Information provided by the Oncology Access Advocate is not intended to be a substitute for the patient's HCP. Patients are always encouraged to speak with their HCP about all medication issues or concerns.

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Indication

TUKYSA is a kinase inhibitor 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.
- 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.

  This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Important Safety Information

Warnings and Precautions

- **Diarrhea:** TUKYSA can cause severe diarrhea including dehydration, hypotension, acute kidney injury, and death. If diarrhea occurs, administer antidiarrheal treatment as clinically indicated. Perform diagnostic tests as clinically indicated to exclude other causes of diarrhea. Based on the severity of the diarrhea, interrupt dose, then dose reduce or permanently discontinue TUKYSA.

  In HER2CLIMB, when TUKYSA was given in combination with trastuzumab and capecitabine, 81% of patients who received TUKYSA experienced diarrhea, including 0.5% with Grade 4 and 12% with Grade 3. Both patients who developed Grade 4 diarrhea subsequently died, with diarrhea as a contributor to death. Median time to onset of the first episode of diarrhea was 12 days and the median time to resolution was 8 days. Diarrhea led to TUKYSA dose reductions in 6% of patients and TUKYSA discontinuation in 1% of patients. Prophylactic use of antidiarrheal treatment was not required on HER2CLIMB.

  In MOUNTAINEER, when TUKYSA was given in combination with trastuzumab, diarrhea occurred in 64% of patients, including Grade 3 (3.5%), Grade 2 (10%), and Grade 1 (50%).
- **Hepatotoxicity:** TUKYSA can cause severe hepatotoxicity. Monitor ALT, AST, and bilirubin prior to starting TUKYSA, every 3 weeks during treatment, and as clinically indicated. Based on the severity of hepatotoxicity, interrupt dose, then dose reduce or permanently discontinue TUKYSA.

  In HER2CLIMB, 8% of patients who received TUKYSA had an ALT increase >5 × ULN, 6% had an AST increase >5 × ULN, and 1.5% had a bilirubin increase >3 × ULN (Grade ≥3). Hepatotoxicity led to TUKYSA dose reductions in 8% of patients and TUKYSA discontinuation in 1.5% of patients.

  In MOUNTAINEER, 6% of patients had a bilirubin increase > 3 × ULN (Grade ≥3), 6% had an AST increase > 5 × ULN, and 4.7% had an ALT increase > 5 × ULN. Hepatotoxicity led to dose reduction of TUKYSA in 3.5% of patients and discontinuation of TUKYSA in 2.3% of patients.
- **Embryo-Fetal Toxicity:** TUKYSA can cause fetal harm. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential, and male patients with female partners of reproductive potential, to use effective contraception during TUKYSA treatment and for 1 week after the last dose.

Adverse Reactions

In HER2CLIMB, serious adverse reactions occurred in 26% of patients; the most common (in ≥2% of patients) were diarrhea (4%), vomiting (2.5%), nausea (2%), abdominal pain (2%), and seizure (2%). Fatal adverse reactions occurred in 2% of patients who received TUKYSA including sudden death, sepsis, dehydration, and cardiogenic shock. Adverse reactions led to treatment discontinuation in 6% of patients who received TUKYSA; the most common (in ≥1% of patients) were hepatotoxicity (1.5%) and diarrhea (1%). Adverse reactions led to dose reduction in 21% of patients who received TUKYSA; the most common (in ≥2% of patients) were hepatotoxicity (8%) and diarrhea (6%). The most common adverse reactions in patients who received TUKYSA (≥20%) were diarrhea, palmar-plantar erythrodysesthesia, nausea, hepatotoxicity, vomiting, stomatitis, decreased appetite, anemia, and rash.

In MOUNTAINEER, serious adverse reactions occurred in 22% of patients; the most common (in ≥2% of patients) were intestinal obstruction (7%), urinary tract infection (3.5%), pneumonia, abdominal pain, and rectal perforation (2.3% each). Adverse reactions leading to permanent discontinuation of TUKYSA occurred in 6% of patients; the most common (in ≥2% of patients) was increased ALT (2.3%). Adverse reactions leading to dosage interruption occurred in 23% of patients; the most common (in ≥3% of patients) were increased ALT and diarrhea (3.5% each). Adverse reactions leading to dose reduction occurred in 9% of patients; the most common (in ≥2% of patients) were increased ALT and diarrhea (2.3% each). The most common adverse reactions (≥20%) in patients treated with TUKYSA and trastuzumab were diarrhea, fatigue, rash, nausea, abdominal pain, infusion-related reactions, and pyrexia. Other adverse reactions (<10%) include epistaxis (7%), weight decreased (7%), oropharyngeal pain (5%), oral dysesthesia (1%), and stomatitis (1%).

Lab Abnormalities

In HER2CLIMB, Grade ≥3 laboratory abnormalities reported in ≥5% of patients who received TUKYSA were decreased phosphate, increased ALT, decreased potassium, and increased AST. The mean increase in serum creatinine was 32% within the first 21 days of treatment with TUKYSA. The serum creatinine increases persisted throughout treatment and were reversible upon treatment completion. Consider alternative markers of renal function if persistent elevations in serum creatinine are observed.

In MOUNTAINEER, Grade ≥3 laboratory abnormalities reported in ≥5% of patients who received TUKYSA were decreased lymphocytes, decreased sodium, increased AST, and increased bilirubin. The mean increase in serum creatinine was 32% within the first 21 days of treatment with TUKYSA. The serum creatinine increases persisted throughout treatment and were reversible in 87% of patients with values outside normal lab limits upon treatment completion. Consider alternative markers of renal function if persistent elevations in serum creatinine are observed.

Drug Interactions

- **Strong CYP3A/Moderate CYP2C8 Inducers:** Concomitant use may decrease TUKYSA activity. Avoid concomitant use of TUKYSA.
- **Strong or Moderate CYP2C8 Inhibitors:** Concomitant use of TUKYSA with a strong CYP2C8 inhibitor may increase the risk of TUKYSA toxicity; avoid concomitant use. Increase monitoring for TUKYSA toxicity with moderate CYP2C8 inhibitors.
- **CYP3A Substrates:** Concomitant use may increase the toxicity associated with a CYP3A substrate. Avoid concomitant use of TUKYSA with a CYP3A substrate, where minimal concentration changes may lead to serious or life-threatening toxicities. If concomitant use is unavoidable, decrease the CYP3A substrate dosage.
- **P-gp Substrates:** Concomitant use may increase the toxicity associated with a P-gp substrate. Consider reducing the dosage of P-gp substrates, where minimal concentration changes may lead to serious or life-threatening toxicities.

Use in Specific Populations

- **Lactation:** Advise women not to breastfeed while taking TUKYSA and for 1 week after the last dose.
- **Renal Impairment:** Use of TUKYSA in combination with capecitabine and trastuzumab is not recommended in patients with severe renal impairment (CLcr < 30 mL/min), because capecitabine is contraindicated in patients with severe renal impairment.
- **Hepatic Impairment:** Reduce the dose of TUKYSA for patients with severe (Child-Pugh C) hepatic impairment.

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Enroll Your Patient Today and Help Them Get Access

There are 3 ways to contact Seagen Secure for assistance

Call	**855-4SECURE** (855-473-2873), Monday-Friday, 8 AM-8 PM ET
Go online	SeagenSecure.com
Fax	855-557-2480

For more information on Seagen Secure, contact your FRM

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References: 1. CMS.gov. ICD-10-CM tabular list of diseases and injuries. Centers for Medicare and Medicaid Services; 2022. https://www.cms.gov/files/zip/2022-code-tables-tabular-and-index-updated-02012022.zip. File name: icd10cm_tabular_2022.pdf. Accessed 04-05-2022. **2.** TUKYSA [Prescribing Information]. Bothell, WA: Seagen Inc. January 2023.

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