Seagen Secure®
Patient Assistance Program

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Monday-Friday, 8 AM-8 PM ET

Sample Metastatic Breast and Metastatic Colorectal Cancer Diagnosis Codes

Breast Cancer Diagnosis: ICD-10-CM

Digits 1-4: Diagnosis Code[1]

Code	Code Description
C50.0	Malignant neoplasm of nipple and areola
C50.1	Malignant neoplasm of central portion of breast
C50.2	Malignant neoplasm of upper-inner quadrant of breast
C50.3	Malignant neoplasm of lower-inner quadrant of breast
C50.4	Malignant neoplasm of upper-outer quadrant of breast
C50.5	Malignant neoplasm of lower-outer quadrant of breast
C50.6	Malignant neoplasm of axillary tail of breast
C50.8	Malignant neoplasm of overlapping sites of breast
C50.9	Malignant neoplasm of breast of unspecified site

Digit 5: Sex[1]

Subcodes for Breast Cancer	
1	Female
2	Male

Digit 6: Breast[1]

(Always bill to the 6th digit)

Subcodes for Breast Cancer	
1	Right breast
2	Left breast
9	Unspecified breast

Colorectal Cancer Diagnosis: ICD-10-CM[1]

Code	Code Description
C18.0	Malignant neoplasm of cecum or ileocecal valve
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure

Code	Code Description
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum or rectal ampulla

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ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

Please see Indication and Important Safety Information on pages 2-3.
Click here for full Prescribing Information.

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NDC Codes[2]

TUKYSA® (tucatinib) tablets

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

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

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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.

Please see additional Important Safety Information on page 3.
Click here for full Prescribing Information.

NDC=National Drug Code.

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Important Safety Information (cont'd)

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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Click here for full Prescribing Information.

References: 1. Centers for Medicare & Medicaid Services. ICD-10-CM 2022 code tables, tabular and index. https://www.cms.gov/medicare/icd-10/2022-icd-10-cm. File name: Iicd10cm_tabular_2022.pdf. Accessed September 7, 2022. **2.** TUKYSA [prescribing information]. Bothell, WA: Seagen Inc. January 2023.

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