TUKYSA™
tucatinib
50 mg | 150 mg tablets

DOSING AND ADMINISTRATION GUIDE

TUKYSA + TRASTUZUMAB + CAPECITABINE

Indication

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.

Select Safety Information

Warnings and Precautions

- **Diarrhea:** TUKYSA can cause severe diarrhea including dehydration, hypotension, acute kidney injury, and death. In HER2CLIMB, 81% of patients who received TUKYSA experienced diarrhea, including 12% with Grade 3 and 0.5% with Grade 4. 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.

  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.

Please see Important Safety Information on pages 2-3 and the accompanying full Prescribing Information.

Important Safety Information

Warnings and Precautions

- **Diarrhea:** TUKYSA can cause severe diarrhea including dehydration, hypotension, acute kidney injury, and death. In HER2CLIMB, 81% of patients who received TUKYSA experienced diarrhea, including 12% with Grade 3 and 0.5% with Grade 4. 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.

  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.

- **Hepatotoxicity:** TUKYSA can cause severe hepatotoxicity. 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.

  Monitor ALT, AST, and bilirubin prior to starting TUKYSA, every 3 weeks during treatment, and as clinically indicated. Based on the severity of hepatoxicity, interrupt dose, then dose reduce or permanently discontinue TUKYSA.

- **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 at least 1 week after the last dose.

Adverse Reactions

Serious adverse reactions occurred in 26% of patients who received TUKYSA; those occurring 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; those occurring in ≥1% of patients were hepatotoxicity (1.5%) and diarrhea (1%). Adverse reactions led to dose reduction in 21% of patients who received TUKYSA; those occurring 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, fatigue, hepatotoxicity, vomiting, stomatitis, decreased appetite, abdominal pain, headache, anemia, and rash.

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.

Please see additional Important Safety Information on page 3 and the accompanying full Prescribing Information.

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Important Safety Information (cont'd)

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.

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 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 toxicity.

Use in Specific Populations

- **Lactation:** Advise women not to breastfeed while taking TUKYSA and for at least 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.

Please see additional Important Safety Information on page 2 and the accompanying full Prescribing Information.

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GETTING STARTED WITH TUKYSA

This guide provides an overview of appropriate dosing and administration of TUKYSA and includes:

- Getting started with TUKYSA
- Preventing drug interactions
- Monitoring for adverse events
- Managing diarrhea
- Modifying dosing
- Accessing patient support resources

TUKYSA is an oral medication taken twice daily as part of a regimen containing trastuzumab and capecitabine[1]

	DOSAGE FORM AND STRENGTHS	HOW SUPPLIED
 50 mg*	Round, yellow, film-coated, debossed with "TUC" on one side and "50" on the other side	60 count in 75 cc bottle: NDC 51144-001-60
 150 mg*	Oval-shaped, yellow, film-coated, debossed with "TUC" on one side and "150" on the other side	60 count in 75 cc bottle: NDC 51144-002-60 120 count in 150 cc bottle: NDC 51144-002-12†

*Images are not to size.
†Anticipated availability: July 2020.

Storage

- Store at controlled room temperature, 20°C to 25°C (68°F to 77°F); excursions permitted from 15°C to 30°C (59°F to 86°F)

Special handling

- Dispense to patient in original container only. Store in original container to protect from moisture. Replace cap securely each time after opening. Do not discard desiccant
- Once opened, the product must be used within 3 months. Discard any unused tablets 3 months after opening the bottle

Please see Important Safety Information on pages 2-3 and the accompanying full Prescribing Information.

TUKYSA™ tucatinib 50 mg | 150 mg tablets

GETTING STARTED WITH TUKYSA

TUKYSA and capecitabine are oral regimens taken twice daily. Trastuzumab is given every 3 weeks as an infusion or injection.[1]

Dosing of the TUKYSA regimen should continue until disease progression or unacceptable toxicity.[1]

21-DAY REPEATING REGIMEN[1,2]		DAY 1	DAYS 2-14	DAYS 15-21
TUKYSA • 300 mg orally, twice daily • At about the same time each day; each TUKYSA dose should be taken 12 hours apart • With or without food • Do not chew, crush, or split tablet before swallowing • If the patient vomits or misses a dose of TUKYSA, instruct the patient to take the next dose at its usual scheduled time	AM	●	●	●
	PM	●	●	●
TRASTUZUMAB* • 8 mg/kg intravenously on Day 1, followed by 6 mg/kg intravenously, every 21 days *OR* • 600 mg subcutaneously, every 21 days	ANY TIME	●		
CAPECITABINE* • 1000 mg/m^2 orally, twice daily on Days 1 through 14 • Within 30 minutes of eating when taken with TUKYSA	AM	●	●	
	PM	●	●	

*Refer to full Prescribing Information for trastuzumab and capecitabine for dose modifications.

- For patients with severe hepatic impairment (Child-Pugh C), reduce the recommended dosage to 200 mg orally twice daily[1]
- Avoid concomitant use with strong CYP2C8 inhibitors during treatment with TUKYSA. If concomitant use with a strong CYP2C8 inhibitor cannot be avoided, reduce the starting TUKYSA dose to 100 mg orally twice daily[1]

Learn more about dose modifications for adverse events on pages 8-9.

Please see Important Safety Information on pages 2-3 and the accompanying full Prescribing Information.

TUKYSA™ tucatinib
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MONITORING FOR ADVERSE EVENTS

Adverse reactions in ≥10% of patients who received TUKYSA and ≥5% compared with placebo in HER2CLIMB[1]

	TUKYSA + trastuzumab + capecitabine (n = 404)			Placebo + trastuzumab + capecitabine (n = 197)		
	All Grades %	Grade 3 %	Grade 4 %	All Grades %	Grade 3 %	Grade 4 %
GASTROINTESTINAL DISORDERS						
Diarrhea	81	12	0.5	53	9	0
Nausea	58	3.7	0	44	3	0
Vomiting	36	3	0	25	3.6	0
Stomatitis*	32	2.5	0	21	0.5	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS						
PPE syndrome	63	13	0	53	9	0
Rash†	20	0.7	0	15	0.5	0
HEPATOBILIARY DISORDERS						
Hepatotoxicity‡	42	9	0.2	24	3.6	0
METABOLISM AND NUTRITION DISORDERS						
Decreased appetite	25	0.5	0	20	0	0
BLOOD AND LYMPHATIC SYSTEM DISORDERS						
Anemia§	21	3.7	0	13	2.5	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS						
Arthralgia	15	0.5	0	4.6	0.5	0
INVESTIGATIONS						
Creatinine increased¶	14	0	0	1.5	0	0
Weight decreased	13	1	0	6	0.5	0
NERVOUS SYSTEM DISORDERS						
Peripheral neuropathy**	13	0.5	0	7	1	0
RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS						
Epistaxis	12	0	0	5	0	0

*Stomatitis includes stomatitis, oropharyngeal pain, oropharyngeal discomfort, mouth ulceration, oral pain, lip ulceration, glossodynia, tongue blistering, lip blister, oral dysesthesia, tongue ulceration, and aphthous ulcer.

†Rash includes rash maculo-papular, rash, dermatitis acneiform, erythema, rash macular, rash papular, rash pustular, rash pruritic, rash erythematous, skin exfoliation, urticaria, dermatitis allergic, palmar erythema, plantar erythema, skin toxicity, and dermatitis.

‡Hepatotoxicity includes hyperbilirubinemia, blood bilirubin increased, bilirubin conjugated increased, alanine aminotransferase increased, transaminases increased, hepatotoxicity, aspartate aminotransferase increased, liver function test increased, liver injury, and hepatocellular injury.

§Anemia includes anemia, hemoglobin decreased, and normocytic anemia.

¶Due to inhibition of renal tubular transport of creatinine without affecting glomerular function.

**Peripheral neuropathy includes peripheral sensory neuropathy, neuropathy peripheral, peripheral motor neuropathy, and peripheral sensorimotor neuropathy.

ALT = alanine aminotransferase; AST = aspartate aminotransferase; PPE = palmar-plantar erythrodysesthesia.

Please see Important Safety Information on pages 2-3 and the accompanying full Prescribing Information.

MONITORING FOR ADVERSE EVENTS

Diarrhea[1,2]

- Prophylactic support to manage diarrhea was not required per HER2CLIMB protocol
- 81% of patients who received TUKYSA experienced diarrhea, including 12% with Grade 3 and 0.5% with Grade 4
- The median time to onset of diarrhea was 12 days, and the median time to resolution was 8 days
- The median duration of antidiarrheal use was 3 days for each 21-day repeating regimen
- If diarrhea occurs, as clinically indicated, administer antidiarrheal treatment and perform diagnostic tests to exclude other causes; based on the severity, interrupt dose then dose reduce or permanently discontinue TUKYSA
- Refer to the full Prescribing Information for capecitabine for information about dosage modifications

See pages 8–9 for dose modifications to manage diarrhea and hepatotoxicity.

Hepatotoxicity[1,3]

- In the HER2CLIMB trial, in patients treated with TUKYSA, 8% had an ALT increase >5 × ULN, 6% had an AST increase >5 × ULN, and 1.5% had a bilirubin increase >3 × ULN (Grade ≥3)
- The median time to onset of any grade of increased ALT, AST, or bilirubin was 36 days
- Most events resolved, with a median time to resolution of 22 days

Monitor ALT, AST, and bilirubin before starting treatment with TUKYSA, and every 3 weeks during treatment, and as clinically indicated[1]

Discontinuation of TUKYSA due to adverse events was infrequent (6%)*[1-3]

AGENT DISCONTINUED	TUKYSA + trastuzumab + capecitabine (n = 404)	Placebo + trastuzumab + capecitabine (n = 197)
TUKYSA/placebo	6%	3%
Trastuzumab	5%	3%
Capecitabine	10%	9%

*Discontinuation rates are descriptive data that are not intended to provide conclusions about safety and should be interpreted with caution.

ALT = alanine aminotransferase; AST = aspartate aminotransferase.

Dose reductions and discontinuations[1]

- Adverse reactions leading to dose reduction of TUKYSA in ≥2% of patients were hepatotoxicity (8%) and diarrhea (6%)
- Adverse reactions leading to treatment discontinuation of TUKYSA in ≥1% of patients were hepatotoxicity (1.5%) and diarrhea (1%)

Please see Important Safety Information on pages 2–3 and the accompanying full Prescribing Information.

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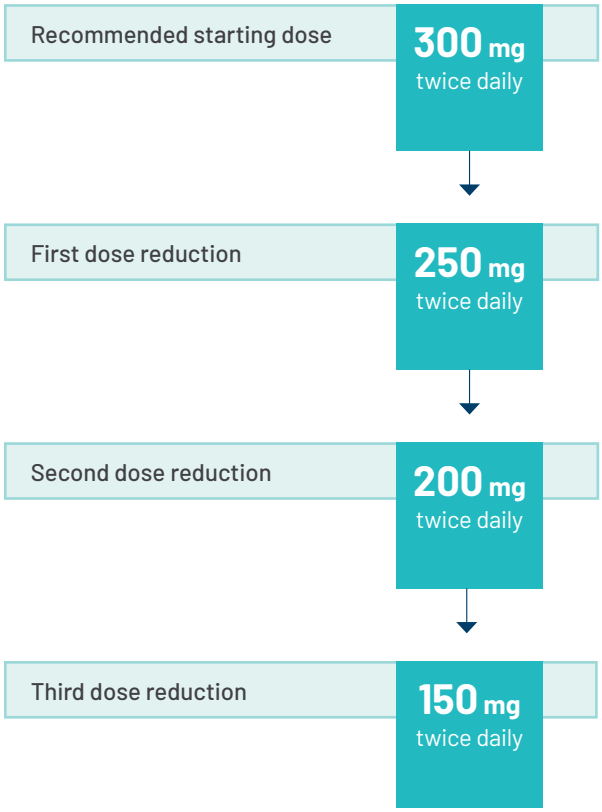
MODIFYING THE TUKYSA DOSE

Some patients may require dose modifications or discontinuation of therapy to manage adverse events. In HER2CLIMB, 21% of patients had their TUKYSA dose modified and 6% discontinued TUKYSA.[1]

Reduce TUKYSA in increments of 50 mg to manage adverse events[1]



Permanently discontinue TUKYSA in patients unable to tolerate 150 mg orally twice daily.

Refer to full Prescribing Information for trastuzumab and capecitabine for dose modifications

Please see Important Safety Information on pages 2-3 and the accompanying full Prescribing Information.

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MODIFYING THE TUKYSA DOSE

TUKYSA dose should be reduced, held, or discontinued to manage hepatotoxicity, diarrhea, and Grade 3 or 4 adverse reactions[1]

Diarrhea	TUKYSA dose modifications
Grade 3 without antidiarrheal treatment	Initiate or intensify appropriate medical therapy. Hold TUKYSA until recovery to Grade 1 or lower, then resume TUKYSA at the same dose level.
Grade 3 with antidiarrheal treatment	Initiate or intensify appropriate medical therapy. Hold TUKYSA until recovery to Grade 1 or lower, then resume TUKYSA at the next lower dose level.
Grade 4	Permanently discontinue treatment with TUKYSA.

Hepatotoxicity	
Grade 2 bilirubin (>1.5 to ≤ 3 × ULN)	Hold TUKYSA until recovery to Grade 1 or lower, then resume TUKYSA at the same dose level.
Grade 3 ALT or AST (>5 to ≤20 × ULN) **or** Grade 3 bilirubin (>3 to ≤10 × ULN)	Hold TUKYSA until recovery to Grade 1 or lower, then resume treatment at the next lower dose level.
Grade 4 ALT or AST (>20 × ULN) **or** Grade 4 bilirubin (>10 × ULN)	Permanently discontinue treatment with TUKYSA.
ALT or AST >3 × ULN **and** bilirubin >2 × ULN	Permanently discontinue treatment with TUKYSA.

Other adverse reactions*	
Grade 3	Hold TUKYSA until recovery to Grade 1 or lower, then resume treatment at the next lower dose level.
Grade 4	Permanently discontinue treatment with TUKYSA.

*Grading per CTCAE (Common Terminology Criteria for Adverse Events) v4.03.

ULN = upper limit of normal.

Please see Important Safety Information on pages 2-3 and the accompanying full Prescribing Information.

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PREVENTING DRUG INTERACTIONS

Drug interactions that affect TUKYSA[1]

Strong CYP3A Inducers or Moderate CYP2C8 Inducers	
Clinical impact	Strong CYP3A inducers or moderate CYP2C8 inducers may reduce TUKYSA activity.
Management	Avoid prescribing TUKYSA with a strong CYP3A inducer or a moderate CYP2C8 inducer.
Strong or Moderate CYP2C8 Inhibitors	
Clinical impact	Strong CYP2C8 inhibitors may increase the risk of TUKYSA toxicity.
Management	Avoid prescribing TUKYSA with a strong CYP2C8 inhibitor. Increase monitoring for TUKYSA toxicity with moderate CYP2C8 inhibitors.

TUKYSA drug interactions that affect other drugs[1]

CYP3A Substrates	
Clinical impact	Prescribing TUKYSA with a CYP3A substrate may increase CYP3A substrate toxicity.
Management	Avoid prescribing TUKYSA with CYP3A substrates, where minimal concentration changes may lead to serious or life-threatening toxicities. If unavoidable, decrease the CYP3A substrate dosage in accordance with approved product labeling.
P-glycoprotein (P-gp) Substrates	
Clinical impact	Prescribing TUKYSA with a P-gp substrate may increase P-gp substrate toxicity.
Management	Consider reducing the dosage of P-gp substrates, where minimal concentration changes may lead to serious or life-threatening toxicities.

For additional drug interactions, please refer to full Prescribing Information

Please see Important Safety Information on pages 2-3 and the accompanying full Prescribing Information.

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TIPS FOR HELPING TO MANAGE DIARRHEA

Ensure your patients know that TUKYSA has been associated with severe diarrhea, and to inform their healthcare provider immediately if they experience symptoms. Discuss with them ways to help manage symptoms of diarrhea.[1]

Strategies that may help manage the symptoms of diarrhea[4,5]:

Dietary interventions

- Avoid high-fiber foods like whole grains, nuts, beans, and raw fruits; also avoid spicy, sugary, fatty, or fried foods, dairy products, caffeinated beverages, alcohol, and acidic foods such as citrus fruit and juices
- Drink plenty of clear liquids including water, apple juice, sports drinks, clear broth or bouillon, and weak decaffeinated tea
- Eat and drink small amounts all day, rather than full meals and large amounts of fluids; focus on easy-to-digest foods like rice, bananas, yogurt, and dry toast

Please see Important Safety Information on pages 2-3 and the accompanying full Prescribing Information.

RESOURCES TO SUPPORT YOUR PATIENTS

Your patients may find these resources helpful as they receive treatment with TUKYSA.

TUKYSA Patient Brochure

- Provides your patients with a guide to treatment with TUKYSA

Treatment Tracker

- Tips and a calendar to help your patients start and stay on the TUKYSA treatment regimen

Frequently Asked Questions

- Answers to frequently asked questions about treatment with TUKYSA

Download materials from TUKYSAhcp.com/resources or talk to your Seattle Genetics Account Representative

Please see Important Safety Information on pages 2-3 and the accompanying full Prescribing Information.

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SEATTLE GENETICS IS HERE TO HELP YOUR PATIENTS ACCESS TUKYSA

TUKYSA prescriptions are filled through specialty pharmacies in the TUKYSA network or through dispensing physician practices and hospital pharmacies that can purchase the product through their specialty distributors.

SPECIALTY PHARMACIES	IN-OFFICE DISPENSERS (MEDICALLY INTEGRATED DISPENSARIES)	IDN SPECIALTY PHARMACIES AND HOSPITAL PHARMACIES
• Biologics • Onco360		

Physician practices can obtain TUKYSA from one of the following specialty distributors:

ASD HEALTHCARE
CALL 800-746-6273
FAX 800-547-9413
VISIT asdhealthcare.com

CARDINAL HEALTH SPECIALTY DISTRIBUTION
CALL 855-740-1871
FAX 888-345-4916
VISIT cardinalhealth.com

MCKESSON PLASMA AND BIOLOGICS, LLC
CALL 877-625-2566
FAX 888-752-7626
VISIT mckesson.com

MCKESSON SPECIALTY HEALTH
CALL 800-482-6700
FAX 800-800-5673
VISIT mckessonspecialtyhealth.com

ONCOLOGY SUPPLY
CALL 800-633-7555
FAX 800-248-8205
VISIT oncologysupply.com

These Specialty Pharmacies are authorized to dispense TUKYSA:

Biologics By McKesson

CALL 800-850-4306
FAX 800-823-4506
VISIT biologics.mckesson.com

Onco360 ONCOLOGY PHARMACY

CALL 877-662-6633
FAX 877-662-6355
VISIT onco360.com

Please see Important Safety Information on pages 2-3 and the accompanying full Prescribing Information.

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SeaGen Secure® offers comprehensive services and patient support

SeaGen Secure® is a comprehensive, personalized reimbursement and support program for TUKYSA™ (tucatinib) tablets that can help your patients navigate treatment. SeaGen Secure® offers individualized services for your patients including:

- Benefits investigation
- Prior authorization support
- Assistance appealing denied insurance claims
- Access to limited Quick Start product for qualifying patients facing a coverage delay
- Out-of-Pocket assistance for qualifying patients
- Product free of charge to qualifying patients

3 Simple Ways to Enroll Your Patients

Enroll by Fax

Download and complete the Healthcare Provider Request Form and Patient Authorization Form at **SeaGenSecure.com** and fax to **855-557-2480**

Enroll by Phone

Contact SeaGen Secure® to enroll over the phone

Call **855-4-SECURE**, Monday-Friday, 8 AM-8 PM ET

Enroll Online

Download and complete the Healthcare Provider Request Form and Patient Authorization Form at **SeaGenSecure.com** and email to **CaseManager@seagensecure.com**

Your patients can receive dedicated support from an Oncology Nurse Advocate*

An oncology nurse advocate is an experienced nurse who can answer your patients' questions, offer personalized resources, help your patients enroll in SeaGen Secure®, and refer patients to additional external services.

* Above support is provided through third-party organizations that operate independently and are not controlled by SeaGen Secure® or Seattle Genetics.

Information provided by the Oncology Nurse Advocate is not intended to be a substitute for the patient's healthcare provider. Patients are always encouraged to speak with their HCP about all medication issues or concerns. Seattle Genetics does not guarantee that enrollment will result in coverage or reimbursement.

SeaGen Secure® Access. Advocates. Answers.
Patient Assistance & Reimbursement Support

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References: 1. TUKYSA [Prescribing Information]. Bothell, WA: Seattle Genetics, Inc. April 2020. **2.** Murthy RK, Loi S, Okines A, et al. Tucatinib, trastuzumab, and capecitabine for HER2-positive metastatic breast cancer. *N Engl J Med*. 2020;382:597-609. **3.** Data on file. Seattle Genetics, Inc. 2020. **4.** American Cancer Society. Diarrhea. https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/stool-or-urine-changes/diarrhea.html. Accessed February 13, 2020. **5.** Mayo Clinic. Diarrhea: cancer-related causes and how to cope. https://www.mayoclinic.org/diseases-conditions/cancer/in-depth/diarrhea/art-20044799?p=1. Accessed February 13, 2020.

Please see Important Safety Information on pages 2-3 and the accompanying full Prescribing Information.

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