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855-4-SECURE (855-473-2873)
Monday-Friday, 8 AM-8 PM ET

Prior Authorization Request Guide

Drafting a Prior Authorization Request Letter

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their prior authorization policies. For more information, call SeaGen Secure at 855-4-SECURE (855-473-2873).

Most health plans require a prior authorization request and supporting documentation to process and cover a claim for biologic treatments. A request allows the payer to review the reason for the requested treatment and determine its medical appropriateness.

Plans often have specific Prior Authorization Request Forms that must be used for requests. These forms may be downloaded from each plan's website. Follow the plan's requirements when requesting TUKYSA™ (tucatinib) 50 mg and 150 mg tablets; otherwise, treatment may be delayed.

Prior Authorization Requests: Guidance and Recommendations

1. Your SeaGen Secure Case Manager may be able to provide you with prior authorization requirements for specific plans and pharmacy benefit managers. Benefit verifications performed by the SeaGen Secure and/or specialty pharmacies can assist with identifying prior authorization criteria, including any previous therapies and other plan-specific requirements
2. All Prior Authorization Request Forms should be completed and submitted to the plan by the office of the healthcare provider (HCP)
3. Fax the completed Prior Authorization Request Form to the health plan
4. Fax the SeaGen Secure Enrollment Form to SeaGen Secure at 855-557-2480
5. If a prior authorization is denied and the HCP wishes to submit an appeal, the SeaGen Secure Case Manager can identify which payer appeal form may be required. SeaGen Secure can track appeals with a payer once submitted
6. Plans will usually allow up to 3 levels of appeal for prior authorization denials. The third appeal may include a review by an external review board or hearing. Refer to the SeaGen Secure Preparing a Prior Authorization Appeals Letter document

Prior Authorization Considerations

- ✔ Verify and record that all of the prior authorization requirements for the plan have been met
- ✔ If applicable, provide evidence that all plan-specified prerequisites have been met. For exception requests, when medically appropriate, explain why a particular requirement is not medically appropriate for the patient
- ✔ Review the attached sample letter as an example
- ✔ If required, use the health plan's Prior Authorization Request Form that can be found on the plan's website. Your SeaGen Secure Case Manager may also be able to assist you in locating the plan-specific form

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

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Sample Prior Authorization Request Letter

Most health plans require a prior authorization request and supporting documentation to cover a claim for TUKYSA™ (tucatinib) tablets. This resource, Drafting a Prior Authorization Request Letter, provides general information to HCPs when drafting the necessary letter.

[Date]
[Prior authorization department]
[Name of health plan]
[Mailing address]

Re: [Patient's name]
[Plan identification number]
[Date of birth]

To whom it may concern:

This letter serves as a prior authorization request for TUKYSA™ (tucatinib) for [patient's name, plan identification number, and group number] for the treatment of [diagnosis and ICD code].

Indicate the patient's diagnosis:

Breast cancer
- ☐ Locally advanced, unresectable
- ☐ Metastatic

Hormone receptor (HR) status
- ☐ Positive
- ☐ Negative

Brain malignancy
- ☐ Yes
- ☐ No

Indicate previous HER2-directed therapies: _____

Indicate how TUKYSA will be used:

In combination with trastuzumab and capecitabine for adult patients who have received one or more prior anti-HER2-based regimens in the metastatic setting
- ☐ Yes ☐ No

Other pertinent information (please specify):

_____

If this is a prior authorization (PA) renewal for continuation of therapy, please indicate if the patient has experienced disease progression or unacceptable toxic effects:

[Insert rationale for prescribing TUKYSA here, including your professional opinion of the patient's likely prognosis without TUKYSA treatment.]

Provide supporting references for your recommendation:

[Provide clinical rationale for treatment; this information may be found in the TUKYSA Prescribing Information and/or clinical peer-reviewed literature.]

Physician contact information:

The ordering physician is [physician name, NPI #]. The prior authorization decision may be faxed to [fax #] or mailed to [physician office mailing address]. Please send a copy of the prior authorization determination decision to [patient's name, street address, state, ZIP].

Sincerely,

_____

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI]
[Physician's practice name]
[Phone #]
[Fax #]

Encl: Medical records, supporting documentation, photo(s), clinical references.

Reauthorization of TUKYSA

[If the prior authorization request is for a patient who is currently taking TUKYSA, which may be due to a change in payer coverage, sample copy may include the following: [Describe the diagnosis and symptoms of metastatic breast cancer at the time when the patient was first prescribed TUKYSA. In addition, include a summary of the patient's clinical response to TUKYSA. It may be necessary to review past medical records to gather this information.]

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

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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.

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.

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.

Please see continuing Important Safety Information on page 4.
Click here for full Prescribing Information.

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Important Safety Information (cont'd)

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.

Click here for full Prescribing Information.

Reference: TUKYSA [package insert]. Bothell, WA: Seattle Genetics, Inc. April 2020.

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