



Positive Quality Intervention: Capivasertib (Truqap™) Patient Management

Description: This document will help in the identification and management of patients taking capivasertib.

Background: Capivasertib is a kinase inhibitor indicated in combination with fulvestrant for the treatment of adult patients with HR positive, HER2 negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following progression on at least one endocrine-based regimen in the metastatic setting or recurrence \leq 12 months of completing adjuvant therapy.¹ In the phase III CAPItello-291 study, the median progression-free survival (mPFS) was 7.2 months in the capivasertib–fulvestrant group, as compared with 3.6 months in the placebo–fulvestrant group (hazard ratio (HR), 0.60; 95% confidence interval (CI), 0.51-0.71; $P < 0.001$). In the AKT pathway–altered population, the mPFS was 7.3 months in the capivasertib–fulvestrant group, as compared with 3.1 months in the placebo–fulvestrant group (HR 0.50; 95% CI, 0.38-0.65; $P < 0.001$). The most frequent adverse events of \geq Grade 3 in patients receiving capivasertib–fulvestrant were rash (12.1% vs. 0.3%) and diarrhea (9.3% vs. 0.3%). Adverse events leading to discontinuation were reported in 13% of the patients receiving capivasertib and in 2.3% with placebo.²

PQI Process:³

- For pre- and peri-menopausal patients, a luteinizing hormone-releasing hormone (LHRH) agonist (according to current clinical practice standards) should be administered; for males, consider administering an LHRH agonist (according to current clinical practice standards)
- Dosage guidance: Evaluate fasting blood glucose, HbA1c and then optimize blood glucose prior to capivasertib initiation
- Table 1. Dosing considerations for Capivasertib³

Dosage form	Tablet, Oral – 160 mg, 200 mg Blister pack – 160 mg, 200 mg (each carton has 4 blister packs (64 tabs total) - each blister pack contains 16 tabs)
Usual starting dose	400 mg twice daily (~12 hours apart) for 4 consecutive days, followed by 3 days off (administer capivasertib on days 1 to 4 of each week); in combination with fulvestrant; continue until disease progression or unacceptable toxicity
Dose adjustments (renal/hepatic)	Capivasertib has not been studied in patients with severe hepatic or renal impairment
Dose reductions for toxicity	400 mg BID □ 320 mg BID □ 200 mg BID □ permanently discontinue if unable to tolerate the final dose reduction

- Once medication delivery is scheduled, ensure complete counseling on administration, proper handling, storage, missed dose management, side effect information, and all other pertinent information
- Assess the patient’s understanding of the regimen complexity and provide tools to assist with adherence
- Monitor for signs/symptoms of cutaneous adverse reactions, diarrhea, and hyperglycemia; monitor for adverse reactions in patients with moderate hepatic impairment
- Monitor adherence
- Monitoring parameters¹
 - FBG prior to treatment, at least every two weeks during the first month and at least every month starting from the second month of treatment
 - HbA1C prior to treatment and every 3 months of treatment

Patient-Centered Activities:³

IMPORTANT NOTICE: NCODA has developed this Positive Quality Intervention platform. This platform is intended as an educational aid, does not provide individual medical advice, and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication. The materials contained in this platform do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA. NCODA does not ensure the accuracy of the information presented and assumes no liability relating to its accuracy. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional. It is the individual’s sole responsibility to seek guidance from a qualified healthcare professional. Updated 2.14.25

- Administer with or without food, approximately every 12 hours on scheduled days; swallow whole; do not chew, crush, or split tablets
- If a dose is missed within 4 hours of the scheduled time, administer the missed dose; if a dose is missed by more than 4 hours of the scheduled time, skip the dose and administer the next dose at its usual scheduled time
- If a dose is vomited, do not administer an additional dose; administer the next dose at usual scheduled time
- Avoid grapefruit, star fruit, pomegranate and Seville oranges products
- This medication is considered hazardous - counsel on appropriate precautions for handling, administration, and disposal
 - Wash hands before and after handling; caregivers should wear gloves while handling
 - Do not dispose of any medication in trash or flush down sink or toilet – contact pharmacist for disposal locations
- Store in the original bottle at room temperature
- Check blood glucose levels more frequently as medication can cause high blood sugar
- Significant drug interactions exist, requiring dose/frequency adjustment or avoidance – let healthcare team know of any new medications
- Side effects to monitor
 - Skin changes that include inflammation, redness, rash, hives, itching, discoloration, sun sensitivity
 - Decreased appetite, diarrhea, nausea, vomiting, mouth sores
 - Signs of urinary tract infection (fever, burning or pain when passing urine, lower stomach, or pelvic pain)
 - Signs of hyperglycemia (confusion, fatigue, flushing, fast breathing, unusual thirst or hunger, urinating more frequently)
 - Fatigue, headache
- Ensure patient has access to supportive medications such as loperamide, moisturizing cream and antihistamine treatment
- Consider providing a blood glucose meter to the patient
- [MyTRUQAP](#) Support Program– patients can enroll to receive helpful resources, emails, and a starter kit⁴
- Patient Assistance: [NCODA Financial Assistance Tool](#)

References:

1. [Truqap \(capivasertib\) Prescribing Information.](#)
2. Turner NC, et al. Capivasertib in Hormone Receptor–Positive Advanced Breast Cancer. *New England Journal of Medicine*. 2023;388(22):2058-2070. doi:<https://doi.org/10.1056/nejmoa2214131>.
3. [Lexicomp. Capivasertib \(Lexi-Drugs\).](#)
4. Truqap website. <https://www.truqap.com/>.

Supplemental Information:³

Capivasertib Dose Reduction Levels	
Dose level	Capivasertib dose and schedule
Initial (usual) dose	400 mg twice daily for 4 days, followed by 3 days off
First dose reduction	320 mg twice daily for 4 days, followed by 3 days off
Second dose reduction	200 mg twice daily for 4 days, followed by 3 days off
Permanently discontinue if unable to tolerate the second dose reduction.	

Recommended Capivasertib Dosage Modifications		
Adverse reaction	Severity	Capivasertib dosage modification ^a
Dermatologic toxicity: Cutaneous adverse reactions	Any	Early consultation with a dermatologist is recommended. May require corticosteroids (topical or systemic, depending on the severity) to manage.
	Grade 2	Withhold capivasertib until recovery to \leq Grade 1. Resume capivasertib at the same dose. <i>Persistent or recurrent Grade 2 toxicity:</i> Reduce capivasertib by one dose level.
	Grade 3	Withhold capivasertib until recovery to \leq Grade 1. <i>Resolution \leq28 days after interruption:</i> Resume capivasertib at the same dose. <i>Resolution >28 days after interruption:</i> Resume capivasertib at one lower dose level. <i>Recurrent Grade 3 toxicity:</i> Permanently discontinue capivasertib.
	Grade 4	Permanently discontinue capivasertib.
GI toxicity: Diarrhea	Any	May require antidiarrheal medications to manage symptoms. Advise patients to increase oral fluids and start antidiarrheal treatment at the first sign of diarrhea.
	Grade 2	Withhold capivasertib until recovery to \leq Grade 1. <i>Resolution \leq28 days after interruption:</i> Resume capivasertib at the same or at one lower dose level as clinically indicated.

Recommended Capivasertib Dosage Modifications		
Adverse reaction	Severity	Capivasertib dosage modification ^a
		<i>Resolution >28 days after interruption:</i> Resume capivasertib at one lower dose level as clinically indicated. <i>Recurrence:</i> Reduce capivasertib by one dose level.
	Grade 3	Withhold capivasertib until recovery to \leq Grade 1. <i>Resolution \leq28 days after interruption:</i> Resume capivasertib at the same or at one lower dose level as clinically indicated. <i>Resolution >28 days after interruption:</i> Permanently discontinue capivasertib.
	Grade 4	Permanently discontinue capivasertib.
Hyperglycemia	Any	Consider consultation with a health care practitioner with expertise in hyperglycemia management. Counsel patients on lifestyle modifications.
	FBG ^b > ULN to 160 mg/dL or FBG > ULN to 8.9 mmol/L or HbA _{1c} >7%	Consider initiation or intensification of oral antidiabetic therapy.
	FBG 161 to 250 mg/dL or FBG 9 to 13.9 mmol/L	Withhold capivasertib until FBG decreases to \leq 160 mg/dL (or \leq 8.9 mmol/L). <i>Resolution \leq28 days after interruption:</i> Resume capivasertib at the same dose. <i>Resolution >28 days after interruption:</i> Resume capivasertib at one lower dose level.
	FBG 251 to 500 mg/dL or FBG 14 to 27.8 mmol/L	Withhold capivasertib until FBG decreases to \leq 160 mg/dL (or \leq 8.9 mmol/L). <i>Resolution \leq28 days after interruption:</i> Resume capivasertib at one lower dose level. <i>Resolution >28 days after interruption:</i> Permanently discontinue capivasertib.
	FBG >500 mg/dL or FBG >27.8 mmol/L or Life-threatening hyperglycemia sequelae at any FBG level	<i>If FBG is \leq500 mg/dL (or \leq27.8 mmol/L) within 24 hours:</i> Follow the guidance in this table for the relevant FBG. <i>Life-threatening hyperglycemia sequelae or if FBG persists at \geq500 mg/dL after 24 hours:</i> Permanently discontinue capivasertib.
Other adverse reactions [see	Grade 2	Withhold capivasertib until recovery to \leq Grade 1. Resume capivasertib at the same dose.

Recommended Capivasertib Dosage Modifications		
Adverse reaction	Severity	Capivasertib dosage modification ^a
Adverse Reactions (6.1) in Package Insert] ¹	Grade 3	Withhold capivasertib until recovery to \leq Grade 1. <i>Resolution ≤ 28 days after interruption:</i> Resume capivasertib at the same dose. <i>Resolution > 28 days after interruption:</i> Resume capivasertib at one lower dose level.
	Grade 4	Permanently discontinue capivasertib.

a. Fulvestrant may also require dosage modification.

b. FBG = fasting blood glucose.