PQI IN ACTION

Positive Quality Intervention

Capivasertib (Truqap) Patient Management

April 2026

INTRODUCTION

NCODA developed the peer-reviewed Positive Quality Intervention (PQI) as an easy-to-use and relatable clinical guidance resource for healthcare providers. By consolidating quality standards, real-world effective practices, clinical trial results, package inserts and other guidance, PQIs equip the entire multidisciplinary care team with a comprehensive yet concise resource for managing patients receiving oral or IV oncolytics.

This PQI in Action is a follow-up to the Capivasertib (Truqap) Patient Management PQI and explores how medically integrated teams collaborate and utilize the information found in the PQI as part of their daily practice.

Capivasertib (Truqap) Patient Management PQI

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CAPIVASERTIB FOR METASTATIC BREAST CANCER

Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer represents the most common subtype of breast cancer and is frequently driven by dysregulation of the PI3K/AKT/PTEN signaling pathway, which is activated in approximately 50% of tumors. Genomic alterations in this pathway, including mutations in PIK3CA, AKT1, or loss of PTEN, are associated with endocrine resistance and disease progression in the advanced or metastatic setting. As a result, targeting this pathway has become a key treatment strategy in patients with disease progression following endocrine-based therapies.

Capivasertib is an oral, selective inhibitor of AKT, a central component of the PI3K/AKT signaling pathway involved in tumor cell proliferation, survival, and resistance mechanisms. By inhibiting AKT activity, capivasertib helps restore sensitivity to endocrine therapy and suppress tumor growth in patients with tumors driven by PI3K/AKT pathway mutations.

Capivasertib, in combination with fulvestrant, is FDA-approved for the treatment of adult patients with HR-positive, HER2-negative, locally advanced or metastatic breast cancer harboring one or more PIK3CA, AKT1, or PTEN mutations following progression on at least one prior endocrine-based regimen in the metastatic setting or recurrence within 12 months of completing adjuvant therapy. This biomarker-driven approach aligns with current National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines, which emphasize molecular testing and incorporation of targeted therapies for patients with actionable mutations in the recurrent or metastatic setting.

Clinical benefit of capivasertib was demonstrated in the phase 3 CAPItello-291 trial, which evaluated capivasertib in combination with fulvestrant in patients with HR-positive, HER2-negative advanced breast cancer whose disease had progressed during or after aromatase inhibitor therapy, with or without prior CDK4/6 inhibitor treatment.

The addition of capivasertib resulted in significantly improved progression-free survival compared with fulvestrant alone in both the overall population and in patients whose tumors harbored PIK3CA, AKT1, or PTEN alterations, supporting its role as a targeted treatment option in this setting.

The safety profile of capivasertib is consistent with its mechanism of action. The most common adverse reactions (≥20%) include diarrhea, cutaneous adverse reactions, hyperglycemia, nausea, fatigue, and hematologic abnormalities. Clinically significant toxicities such as hyperglycemia, diarrhea, and dermatologic reactions may require dose modifications, treatment interruptions, or discontinuation, highlighting the importance of proactive monitoring and multidisciplinary management.

By targeting the PI3K/AKT signaling pathway, capivasertib represents a targeted therapeutic advancement, improving outcomes for patients with HR-positive, HER2-negative advanced breast cancer.

INSIGHTS ON PATIENT SELECTION AND GENOMIC TESTING

Appropriate patient selection for capivasertib begins with a clear understanding of disease biology, prior therapy, and the presence of actionable genomic alterations. Across institutions, providers emphasized that confirming eligibility through molecular testing is a critical first step before initiating therapy.

Jing Du, MD, PhD, described how genomic testing is incorporated into treatment decision making at the time of disease progression. Patients are typically evaluated after progression on first line therapy, such as a CDK4/6 inhibitor combined with an aromatase inhibitor. Liquid biopsy is commonly utilized to identify PIK3CA mutations and determine candidacy for therapy. This approach allows for timely identification of actionable alterations while minimizing delays in care.

Nicole Bentivegna, PharmD, BCOP, underscored the pharmacist's role in ensuring appropriate patient selection. Pharmacists are actively involved in reviewing molecular and genetic testing to confirm that therapy aligns with the

Insights on Patient Selection and Genomic Testing - continued

indication, including verification of hormone receptor positive, HER2 negative disease and the presence of a PIK3CA, AKT1, or PTEN alteration. This additional layer of review helps reinforce accuracy and supports appropriate use of targeted therapy.

Beyond mutation status, Dr. Du emphasized the importance of assessing the full clinical picture, including performance status and disease pace. Patients with slower progressing disease may benefit from continued endocrine based strategies, allowing time to incorporate targeted therapy such as capivasertib. In contrast, patients with more rapidly progressing disease may require transition to alternative approaches. Comorbid conditions, including diabetes, are also considered carefully given the metabolic effects associated with therapy.

"Patient selection starts with confirming HR positive, HER2 negative disease and the presence of a PIK3CA, AKT1, or PTEN alteration."

– Nicole Bentivegna, PharmD, BCOP

VALUE OF THE MEDICALLY INTEGRATED PHARMACY TEAM IN CAPIVASERTIB MANAGEMENT

Managing capivasertib requires coordinated oversight across several clinical domains within a relatively short timeframe, particularly early in therapy when adverse events are most likely to emerge. Providers emphasized that success with this therapy depends on proactive education, structured monitoring, and timely intervention.

Ilicia Shugarman, MD, described the medically integrated pharmacy model as central to making this possible. Pharmacists reinforce education at first fill, ensure patients have supportive medications available, and help coordinate monitoring such as glucose checks and laboratory follow up. Early outreach, especially within the first few weeks of treatment, allows for rapid identification and management of emerging toxicities.

"That combination of proactive education, structured monitoring, and early pharmacist follow up is what allows us to intervene quickly and keep patients safely on therapy," Dr. Shugarman explained. "Managing a therapy like capivasertib really highlights the value of a medically integrated pharmacy model."

This approach allows multiple components of care to occur simultaneously, including symptom monitoring, lab coordination, dose adjustments, and supportive care. Within a medically integrated setting, the care team has access to the full clinical picture, including laboratory trends, comorbidities, and treatment plans. This enables more informed recommendations, whether addressing rising glucose levels, adjusting supportive medications, or identifying when dose modifications or treatment interruptions are needed.

Dr. Du highlighted the importance of real time collaboration in managing these complexities. Pharmacists are routinely consulted prior to initiation to evaluate for drug interactions, particularly in patients with multiple concomitant medications. Ongoing communication supports management of adverse events as they arise. "If a patient develops toxicity or we are considering dose reduction or a treatment break, we will reach out to our pharmacists for guidance," she shared.

From an operational perspective, adherence teams also play a key role in maintaining continuity of therapy. Anita Shields, CPhT, RPhT, described how close coordination across the care team supports timely access and minimizes disruptions. Her team conducts

Value of the Medically Integrated Pharmacy Team in Capivasertib Management - continued

proactive outreach to ensure refills are aligned with the current treatment plan, reviewing provider documentation to confirm dosing and identify any holds or modifications. When questions arise, they communicate directly with clinical staff and escalate concerns to pharmacists for further evaluation.

This level of coordination supports earlier intervention, reduces delays in care, and helps patients navigate therapy with greater confidence. As Dr. Shugarman noted, consistent communication and support ultimately help patients remain on therapy longer and achieve the intended clinical benefit.

CAPIVASERTIB IN PRACTICE:
ROLE-BASED RESPONSIBILITIES

PHYSICIAN

Physicians identify appropriate candidates for capivasertib based on disease progression, biomarker status, and overall clinical context. This includes confirming HR positive, HER2 negative disease and the presence of a PIK3CA, AKT1, or PTEN alteration, often through liquid biopsy at progression.

They assess disease pace, performance status, and comorbidities such as diabetes to guide treatment sequencing. Physicians also initiate therapy and define the treatment plan, including dose modifications or treatment interruptions when higher grade toxicities occur.

PHARMACIST

Pharmacists play a central role in managing capivasertib by ensuring therapy is appropriate, safe, and supported from the start. At initiation, they review disease characteristics and genomic testing, confirm dosing and schedule, assess for drug interactions including CYP3A, and verify that baseline labs support treatment. They also provide individualized patient education on administration, expected adverse events, and management strategies, while ensuring supportive medications are in place prior to therapy.

Throughout treatment, pharmacists remain highly proactive, monitoring lab trends and toxicities such as hyperglycemia, assessing adherence, and completing clinical checks before each cycle is dispensed. Their frequent patient touchpoints allow early identification of new medications, side effects, or adherence challenges, with concerns addressed directly or escalated as needed. “The pharmacist is often the first to recognize when a patient is starting to struggle and can escalate concerns quickly,” Dr. Shugarman stated.

NURSE

Nurses provide continuity of care throughout the capivasertib treatment journey, supporting patient education, monitoring, and early identification of adverse events. They reinforce key counseling at initiation and ensure patients understand dosing schedules, including the importance of on and off treatment days. According to Jessica Carraway, RN, nursing plays a central role in maintaining consistency across the care process through standardized workflows, proactive outreach, and early identification of side effects, allowing for timely intervention, especially during the first weeks of therapy when toxicities are most likely to emerge.

Nurses often spend more time with patients than other providers, creating opportunities for patients to share concerns they may not otherwise express. Marlene Lichatz, RN, emphasized this unique role, noting that patients often share important clinical, adherence, and psychosocial information with nurses that may not surface elsewhere. This ongoing engagement is particularly important for patients on oral therapies at home, where monitoring is less visible.

PHARMACY TECHNICIAN

Pharmacy technicians support the operational and patient facing components of capivasertib therapy, with a focus on adherence, access, and early identification of issues. Karina Rodriguez, CPhT, described a proactive refill process that includes outreach prior to each cycle, during which technicians assess remaining medication supply, review dosing schedules, and confirm how the patient

Capivasertib in Practice: Role-Based Responsibilities - continued

is taking therapy. Open ended questions help uncover discrepancies such as missed doses or confusion around dosing, including the on and off treatment days. These conversations also create opportunities to identify financial barriers, with technicians assisting in copay support enrollment and helping patients understand coverage and out of pocket costs.

Shields emphasized the structured nature of adherence support, with outreach occurring five to seven days before each cycle to verify prescription details and assess medication use. By confirming remaining tablets and reviewing how therapy is being taken, technicians can identify potential adherence concerns early. When issues arise, patients are escalated to pharmacists for clinical evaluation and coordinated with the provider team as needed.

CAPIVASERTIB IN PRACTICE: ROLE-BASED CARE MODEL

PHYSICIAN

INITIATION
- Confirm HR positive, HER2 negative disease
- Verify PIK3CA, AKT1, or PTEN mutation
- Assess disease pace and comorbidities
- Initiate capivasertib plus fulvestrant

EARLY WEEKS
- Evaluate emerging toxicities
- Determine need for dose modification or hold

ONGOING
- Reassess response and tolerability
- Guide long term treatment strategy

PHARMACIST

INITIATION
- Verify therapy and genomic criteria
- Review labs including glucose and A1C
- Screen for drug interactions including CYP3A
- Ensure supportive medications are in place
- Provide patient counseling and blister pack education

EARLY WEEKS
- Monitor labs and glucose trends
- Identify early toxicities
- Recommend supportive care and dose adjustments
- Escalate concerns to provider

ONGOING
- Complete clinical check prior to each cycle
- Review new medications and adherence
- Continue toxicity monitoring

NURSE

INITIATION
- Reinforce education and dosing schedule
- Ensure understanding of on and off treatment days
- Identify barriers to starting therapy

EARLY WEEKS
- Conduct early follow up and symptom check ins
- Identify side effects patients may not otherwise report
- Provide real time patient support

ONGOING
- Continue monitoring and education
- Serve as key patient contact between visits
- Escalate clinical concerns to care team

PHARMACY TECHNICIAN

INITIATION
- Support access and affordability
- Assist with copay programs and onboarding

EARLY WEEKS
- Confirm dosing schedule and medication supply
- Identify early adherence issues
- Reinforce correct administration schedule

ONGOING
- Conduct refill outreach prior to each cycle
- Verify remaining tablets and adherence
- Identify missed doses or confusion
- Route concerns to pharmacist and care team

SHARED GOAL: Early identification of adverse events, timely intervention, minimize treatment disruptions, support adherence, and keep patients on therapy longer

USING THE CAPIVASERTIB PQI TO GUIDE PATIENT MANAGEMENT

The NCODA Capivasertib Patient Management PQI provides a standardized, practical framework to guide care from initiation through ongoing therapy. It outlines key steps for baseline assessment, patient education, monitoring, and adverse event management, helping teams stay aligned and consistent.

In practice, the PQI functions as both a roadmap and a checklist. Bentivenga explained that at FCS it is used to confirm baseline labs are completed, ensure patient education is delivered, and establish a clear monitoring plan. It also supports cycle based reassessment of labs, toxicity, and adherence, which is especially important for capivasertib given the need for frequent monitoring and dose adjustments.

For nursing workflows, the PQI helps standardize patient conversations and clinical assessments. Carraway noted, "We use it to guide patient conversations around dosing, toxicity expectations, and escalation pathways." This consistency supports early identification of adverse events and timely communication across the care team.

Because the PQI is accessible across roles, it reinforces a shared approach to patient management and supports coordinated care. The following section walks through key elements of the PQI process, including initiation, monitoring, and adverse event management.

PQI PROCESS: INITIATION AND EARLY MONITORING

Prior to initiating capivasertib, key clinical and supportive measures should be in place. This includes use of a luteinizing hormone-releasing hormone (LHRH) agonist for appropriate patients according to clinical practice standards. Baseline assessment is critical, particularly for metabolic parameters such as fasting blood glucose and hemoglobin A1C, with optimization of glucose control prior to starting therapy given the risk of early onset hyperglycemia, which has a median time to first occurrence of approximately 15 days.[1] Additional baseline labs, including complete blood count, metabolic panel, and hepatic and renal function, should be reviewed.

Territo emphasized establishing these baseline values is essential to guide future decisions. Having a clear starting point allows the team to identify changes over time and determine when dose adjustments or treatment holds may be necessary. Medication reconciliation is also a key step, as pharmacists assess for potential drug interactions and determine whether therapy can safely proceed or requires modification prior to initiation.

Once medication delivery is scheduled, comprehensive patient counseling is imperiative. This includes education on administration, handling, storage, missed dose management, and expected adverse events. Patients should be assessed for understanding of the regimen, including the complexity of dosing schedules, and provided with tools to support adherence.

Early in treatment, close and proactive monitoring is required. Patients should be monitored for cutaneous reactions, diarrhea, and hyperglycemia, with additional attention to those with moderate hepatic impairment. As Carraway described, this monitoring occurs through scheduled follow up calls, patient self reporting, and ongoing chart review, with targeted questions focused on blood sugar symptoms, bowel habits, and skin changes. Patients are encouraged to report symptoms early, allowing for prompt escalation and intervention.

Pharmacists play a key role in ongoing lab review and coordination of care during this phase. Bentivegna shared that her team reviews labs at each fill and the results are used to guide patient specific management. When abnormalities are identified, pharmacists collaborate with providers to recommend dose adjustments and supportive care strategies. Coordinating lab schedules with existing visits when possible can help reduce patient burden and improve adherence to monitoring.

PQI PROCESS:
DOSING AND ADMINISTRATION

Capivasertib dosing requires clear education and reinforcement given its intermittent schedule and specific administration considerations.

STARTING DOSE AND SCHEDULE

The recommended starting dose of capivasertivb is 400 mg twice daily, administered approximately every 12 hours, with or without food, on a 4 days on, 3 days off schedule.[1] Bentivegna highlighted the importance of pharmacist oversight at initiation to confirm appropriate dosing and ensure patients understand the structure of the regimen. Because the regimen is not continuous, clear communication is essential. As Territo stressed, intermittent medications require additional focus on directions to prevent confusion and dosing errors.

ADMINISTRATION AND MISSED DOSE GUIDANCE

Tablets should be swallowed whole and not chewed, crushed, or split. If a dose is missed within 4 hours, it may be taken; if more than 4 hours have passed, the dose should be skipped. If vomiting occurs, an additional dose should not be taken. Patients should also avoid grapefruit, star fruit, pomegranate, and Seville orange products.[1]

SUPPORTING ADHERENCE

Given the complexity of the schedule, tools such as calendars are often used to reinforce adherence. Lichatz explained that non-daily regimens can be challenging for patients, and aligning the start of therapy with a consistent day, such as Monday, along with use of a visual calendar, can help patients stay on track and better understand on and off days.

DOSE MODIFICATIONS

Dose interruptions and reductions follow a stepwise approach based on tolerability. Dr. Shugarman outlined, "We follow the recommended dose modification strategy, starting at 400 mg twice daily on a 4 days on, 3 days off schedule, with stepwise reductions as needed." Decisions to hold, reduce, or add supportive care are individualized based on patient specific factors and toxicity.

DOSING CONSIDERATIONS FOR CAPIVASERTIB[1]

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

ADVERSE EVENT MANAGEMENT

Capivasertib is associated with a distinct adverse event profile driven by its mechanism of action. As an AKT inhibitor, it affects physiologic PI3K/AKT pathway signaling, leading to on target, off tumor toxicities that require proactive monitoring and management.[8]

Stomatitis is an early toxicity that, while not typically dose limiting, can significantly impact quality of life. Dr. Du noted the importance of reinforcing oral hygiene and encouraging patients to report symptoms early. Supportive care, including dexamethasone mouthwash or compounded rinses, may help reduce discomfort and maintain adherence.

Fatigue should also be monitored throughout treatment. In contrast to earlier toxicities, Joyce O'Shaughnessy, MD explained that fatigue often develops over time and may build with continued therapy. She shared dose reduction can be an effective strategy for managing persistent fatigue and improving tolerability.

This proactive approach to early symptom management sets the foundation for addressing three of the most common and clinically impactful toxicities with capivasertib, including hyperglycemia, diarrhea, and rash.

Hyperglycemia

Hyperglycemia is one of the most clinically significant and early toxicities associated with capivasertib, requiring proactive monitoring, patient education, and early intervention. As an on target effect of AKT inhibition, disruption of glucose homeostasis can occur quickly, often within the first few weeks of therapy.[8]

BASELINE RISK AND PREVENTION

Assessment begins prior to initiation. Fasting blood glucose and hemoglobin A1C should be evaluated and optimized, with particular attention to patients with prediabetes, elevated A1C, or higher BMI. Dr. O'Shaughnessy emphasized the importance of setting expectations early, including counseling on a low carbohydrate, low sugar diet and assessing baseline risk. Patients with higher A1C values or suboptimal glycemic control may benefit from a short period of optimization prior to starting therapy.

Proactive strategies, including lifestyle modifications and early use of agents such as metformin, may help mitigate risk and support treatment persistence.[8] The Yale team also highlighted the value of early endocrinology involvement for patients with preexisting diabetes or higher risk features to support co-management and optimize glycemic control.

MONITORING AND EARLY DETECTION

Frequent monitoring is critical, particularly early in treatment. Fasting blood glucose should be assessed prior to treatment, then during weeks 1, 2, 4, 6, and 8, followed by monthly monitoring. If hyperglycemia develops, monitoring should increase to at least twice weekly until values return to baseline.[1,8]

Dr. O'Shaughnessy noted that hyperglycemia often emerges early, particularly during the first cycle, and recommends home glucose monitoring during the first few weeks, especially on days 2 through 4 of the dosing cycle. Dr. Du similarly described routine use of glucometers and daily monitoring in higher risk patients to prevent more severe complications.

MANAGEMENT AND INTERVENTION

Management includes close monitoring, early pharmacologic intervention, and coordination with the care team. Dr. Shugarman detailed assessing baseline risk, monitoring closely, and initiating or intensifying agents such as metformin when appropriate. If hyperglycemia occurs, anti diabetic therapy should be initiated or escalated, with continued monitoring at least weekly for the first two months.

Lichatz also underscored the importance of patient engagement, including maintaining glucose logs, recognizing symptoms, and reporting concerns early. If severe hyperglycemia or ketoacidosis is suspected, capivasertib should be held and permanently discontinued if confirmed. Dr. O'Shaughnessy pointed out that insulin should generally be avoided unless medically necessary, as it may counteract the intended pathway effects of therapy. She further cautioned that patients with insulin dependent diabetes may not be appropriate candidates due to the risk of significant hyperglycemia and challenges with management.

> "I have patients monitor their blood glucose early, particularly in the first cycle, and focus on a low carbohydrate, low sugar diet because hyperglycemia can emerge quickly."
>
> — Joyce O'Shaughnessy, MD

Adverse Event Management - continued

HYPERGLYCEMIA MANAGEMENT WITH CAPIVASERTIB[8]

01 Baseline Risk Assessment

- Evaluate fasting blood glucose and HbA1C prior to initiation
- Identify high risk patients (prediabetes, elevated A1C, higher BMI)
- Optimize glycemic control before starting therapy
- Consider early involvement of endocrinology for higher risk patients

02 Early Monitoring (First Cycles = Highest Risk)

- Monitor FBG prior to treatment and frequently during weeks 1–8
- Encourage home glucose monitoring, especially early in therapy
- Focus on early onset, often within the first cycle
- Increase monitoring frequency if elevations occur

03 Prevention and Patient Education

- Set expectations that hyperglycemia is an early and common toxicity
- Counsel on low carbohydrate, low sugar diet
- Reinforce when and how to check blood glucose at home
- Encourage early reporting of symptoms

Adverse Event Management - continued

04 Intervention and Management

- Initiate or escalate anti diabetic therapy (for example, metformin)
- Coordinate care with endocrinology when appropriate
- Adjust monitoring based on response
- Use a patient specific approach based on baseline risk and trends

05 Escalation and Safety

- Hold therapy for severe hyperglycemia
- Evaluate for ketoacidosis if suspected
- Avoid insulin unless medically necessary
- Resume therapy based on clinical recovery and guidance

GOAL:
EARLY DETECTION ➲ PROACTIVE MANAGEMENT ➲ MINIMIZE DOSE DISRUPTIONS ➲ SUPPORT TREATMENT PERSISTENCE

Diarrhea

Diarrhea is one of the most common and anticipated toxicities with capivasertib, requiring early education and proactive management. Symptoms often emerge within the first 1 to 2 weeks and can impact adherence if not addressed promptly.[8]

PREVENTION AND PATIENT EDUCATION

Patients should be counseled before starting therapy on what to expect and when to act. This includes distinguishing mild symptoms from those requiring escalation, such as fever, severe cramping, or signs of dehydration.[8] Dietary guidance, including small frequent meals and avoiding high fiber or irritating foods, can help reduce severity.[8] Encouraging use of a stool diary to track frequency, patterns, and response to medications can support early intervention and guide management.[8]

Dr. O'Shaughnessy sets patient expectations early. The intermittent dosing schedule often helps, with symptoms improving during the 3 days off therapy. Patients should be counseled to hold treatment and contact the care team if diarrhea becomes severe or persistent. She added that use of loperamide during the dosing cycle is expected and manageable.

PROACTIVE SUPPORT AND MONITORING

Ensuring patients have supportive medications on hand is critical. The PQI recommends access to agents such as loperamide at initiation, allowing patients to treat symptoms at the first sign. Territo described embedding this approach into treatment plans, with antidiarrheals and antiemetics dispensed alongside the initial prescription and

Adverse Event Management - continued

reinforced through patient counseling.

Monitoring includes assessing risk factors such as prior gastrointestinal issues, concomitant medications, and comorbidities that may increase susceptibility.[8] Dr. Du explained that diarrhea is frequently observed in practice but is typically manageable with early use of loperamide and supportive care. If symptoms persist or are not controlled, she may further evaluate to rule out infectious or alternative causes.

MANAGEMENT AND ESCALATION

Management follows a stepwise approach, starting with antidiarrheal therapy such as loperamide at the first sign of symptoms, along with hydration and dietary modifications.[8] Most cases can be controlled with these measures. For grade 2 or higher diarrhea, capivasertib should be held until recovery, with dose adjustments implemented as needed.[8]

If diarrhea persists despite initial management, escalation to additional agents or further clinical evaluation may be required. Severe or prolonged cases may require hospitalization for supportive care, including fluid and electrolyte management and diagnostic workup.[8] Dose reduction may also be effective in improving tolerability, "diarrhea is responsive to dose reduction, however in my experience not that many people need it" Dr. O'Shaughnessy shared.

DIARRHEA MANAGEMENT WITH CAPIVASERTIB8

01 Set Expectations Early

- Common and early toxicity (often weeks 1–2)
- Typically mild to moderate, but can escalate
- Educate on when to treat vs when to call

02 Prevention and Preparation

- Ensure access to loperamide at initiation
- Counsel on taking with food
- Review diet modifications (small meals, avoid irritants)
- Consider baseline risk (GI history, medications)

Adverse Event Management - continued

03 Early Monitoring

- Encourage stool diary (frequency, pattern, response)
- Reinforce early symptom reporting
- Watch for ≥4 stools above baseline or dehydration

04 First-Line Management

- Start loperamide at first sign (do not delay)
- Hydration and dietary adjustments
- Most cases manageable without interruption

05 Escalation and Safety

- Hold therapy for grade ≥2 until recovery
- Resume at same or reduced dose based on timing
- Escalate to additional agents if persistent

Rash

Rash is a common toxicity with capivasertib that often occurs early, typically within the first treatment cycle, and requires proactive prevention and rapid intervention.[8] While often manageable, it can become difficult to treat once established, making early education and prophylaxis critical.

PREVENTION AND PATIENT EDUCATION

Patients should be counseled at initiation on expected skin changes, including redness, itching, hives, and photosensitivity, and instructed to report symptoms at first onset. Early prevention strategies include use of gentle moisturizers, avoidance of skin irritants, and initiation of non drowsy antihistamines. Bentivegna stressed the importance of establishing prophylactic skin care routines at the start of therapy to reduce risk and improve tolerability.

Dr. O'Shaughnessy strongly emphasized prevention as the most effective strategy. "The rash is difficult to treat, but it is much easier to prevent," she explained, highlighting routine use of antihistamines early, sometimes twice daily, to reduce risk. She also reinforced the need for repeated education, as patients may not consistently follow recommendations without reinforcement from multiple members of the care team.

Adverse Event Management - continued

Close monitoring during the first cycle is essential. Patients should be encouraged to report symptoms early and, when possible, share photos through the patient portal to allow for real time assessment. Clinical evaluation includes assessing rash characteristics and estimating body surface area involvement to guide management.[8]

Dr. Du incorporates dermatology early when needed, with rapid access to dermatology specialists for co management of more significant skin toxicities. This allows for timely evaluation and escalation of care when symptoms progress.

MANAGEMENT AND ESCALATION

Management is guided by severity and typically follows a stepwise approach. Initial strategies include antihistamines and topical therapies, with escalation to topical or systemic steroids for more significant reactions. Dr. Shugarman outlined using antihistamines early and adding steroids as needed based on severity. If rash worsens or becomes more extensive, dose interruption or reduction may be required.

> "The rash is difficult to treat, but it is much easier to prevent."
>
> — Joyce O'Shaughnessy, MD

RASH MANAGEMENT WITH CAPIVASERTIB[8]

01 Prevent Early

- Start non drowsy antihistamine
- Use gentle moisturizers
- Avoid skin irritants

02 Monitor Closely

- Common in first cycle
- Report rash at first sign
- Share photos when possible

Capivasertib AE Management Expert Guidance

Adverse Event Management - continued

03 Treat Promptly

- Antihistamines → topical steroids
- Escalate to systemic steroids if needed
- Consider dermatology consult

04 Adjust Therapy

- Hold or reduce dose for severe rash
- Resume based on recovery

PATIENT EDUCATION AND PATIENT-CENTERED ACTIVITIES

Effective patient education is foundational to successful capivasertib therapy and begins before the first dose, continuing throughout treatment. Given the complexity of the dosing schedule and the need for proactive toxicity management, education must be clear, reinforced, and tailored to the individual patient.

Initial education focuses on safe and accurate medication use, including dosing schedule, missed dose guidance, handling precautions, and avoidance of key food and drug interactions. Pharmacists play a central role at initiation, with Territo explaining that patients receive comprehensive counseling before the medication is dispensed to ensure readiness and understanding. This includes reviewing administration, potential adverse events, proper blister pack use, and when to contact the care team, while also recognizing that patients may need information delivered in stages based on their readiness to engage.

Reinforcement across the care team is essential. In Carraway's clinic, education is not a single interaction but an ongoing process, with nursing teams supporting follow up assessments, addressing emerging concerns, and reinforcing key concepts such as adherence, symptom recognition, and the importance of laboratory monitoring. Patients are often asked to explain the dosing schedule in their own words to confirm understanding, helping to identify confusion early and build confidence before starting therapy.

Practical tools and anticipatory guidance support adherence and reduce barriers. Bentivegna conveyed the importance of medication reconciliation, counseling on drug interactions, and providing clear guidance on hydration, symptom reporting, and lab monitoring. Tools such as pill calendars, reminders, and caregiver involvement can be especially helpful for patients managing a non-daily dosing schedule or polypharmacy. Dr. O'Shaughnessy reinforced the need to revisit these concepts frequently, noting that patients can easily become confused with dosing and benefit from ongoing support and reassurance, particularly around dose adjustments and tolerability.

Ongoing engagement remains critical throughout therapy. Lichatz under-

Patient Education and Patient-Centered Activities - continued

scored the importance of continuous, real-time education, including confirming correct dosing, reinforcing side effect management, and ensuring patients have access to medication and support resources. She also highlighted common barriers that can impact understanding and adherence, including cost, language differences, and varying levels of health literacy. Addressing these challenges requires meeting patients where they are, using interpreter services when needed, simplifying education materials, and reinforcing key concepts over time to ensure understanding.

The NCODA-led Patient Education Sheet for capivasertib serves as a key resource to standardize and reinforce patient understanding across the care team. It provides clear, patient-friendly guidance on dosing, side effects, and management strategies. Lichatz shared, "I've used a lot of education materials over my 30 plus years, and NCODA's are the best in terms of making it simple for patients to understand and providing clear information on side effects and how to manage them."

Together, consistent education, practical tools, and coordinated support empower patients to manage therapy at home, report concerns early, and remain engaged in their care, ultimately supporting adherence and improving outcomes.

CONCLUSION

Capivasertib offers an important targeted option for patients with HR positive, HER2 negative advanced breast cancer, but its success in practice depends on more than prescribing. Effective use requires structured workflows, proactive adverse event management, and consistent patient-centered education.

The NCODA capivasertib PQI provides a clear, practical framework to support this process. By standardizing patient selection, monitoring, and management, it helps align the care team and enables timely, consistent interventions that support safety and adherence.

The medically integrated pharmacy model brings this to life. With pharmacy services embedded in the care team and access to real-time clinical information, patients benefit from faster medication access, closer monitoring, and coordinated support. According to Territo, patients are often surprised by how quickly therapy is initiated, with many receiving medication within days rather than the delays often seen with traditional specialty pharmacy models.

Together, capivasertib, the PQI framework, and the medically integrated pharmacy model create a coordinated, patient-centered approach that supports adherence, minimizes disruptions, and helps patients achieve the intended clinical benefit

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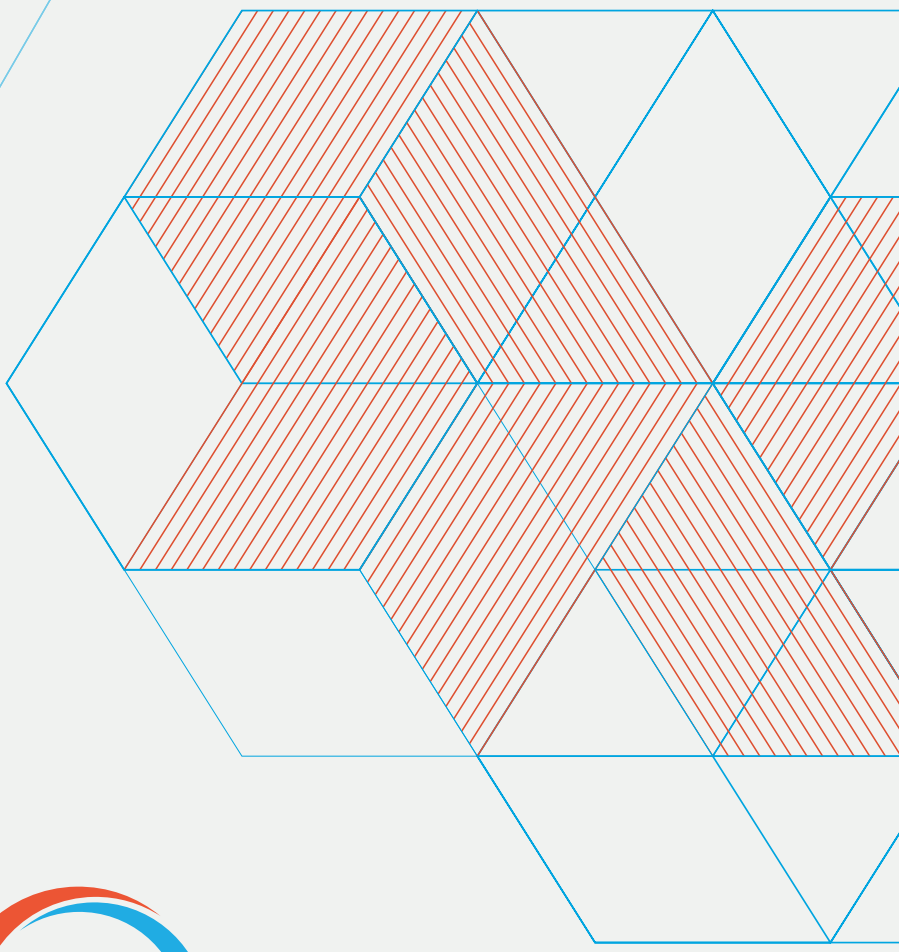

Practice panelist's comments reflect their experiences and opinions and should not be used as a substitute for medical judgment.