PQI IN ACTION

Positive Quality Intervention

NCODA

Darolutamide (Nubeqa®)

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-life effective practices, clinical trial results, package insert 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 Darolutamide PQIs and explores how medically integrated teams collaborate and utilize the information found in the PQI as part of their daily practice.

Scan or click here to access Darolutamide (Nubeqa) in combination with Docetaxel (Taxotere) for Metastatic Hormone Sensitive Prostate Cancer

Scan or click here to access Darolutamide (Nubeqa) In the Treatment of Non-Metastatic Castration Resistant Prostate Cancer

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CLINICAL BACKGROUND: DAROLUTAMIDE (NUBEQA®)

Prostate cancer leads as the most common cancer and the second leading cause of cancer death in men in the United States.[1] In addition, marked racial and ethnic disparities persist in prostate cancer incidence and outcomes. Black men have the highest incidence rate of prostate cancer (191.5 per 100,000), which is 67% higher than White men and nearly double that of American Indian/Alaska Native and Hispanic men. They are also diagnosed at a younger median age and have higher incidence across every age group. The causes of these disparities are multifactorial and are thought to include a complex interplay of genetic, environmental, and social determinants of health.[1]

Given the significant disease burden and the importance of optimizing outcomes across diverse patient populations, effective management strategies for prostate cancer remain a key clinical priority. Darolutamide, an androgen receptor inhibitor, offers an important therapeutic option for patients with non-metastatic and metastatic castration-resistant prostate cancer, as well as metastatic hormone-sensitive prostate cancer.

Darolutamide is indicated for the treatment of adult patients with[2]:

- non-metastatic castration-resistant prostate cancer (nmCRPC)
- metastatic castration-sensitive prostate cancer (mCSPC). *(approved in June 2025)*
- metastatic castration-sensitive prostate cancer (mCSPC) in combination with docetaxel

In clinical trials, the most common adverse reactions associated with darolutamide varied by indication. In patients with nmCRPC and mCSPC, the most frequent adverse reactions (greater than 10% and at least 2% more common than with placebo), including laboratory test abnormalities, were increased aspartate aminotransferase (AST), decreased neutrophil count, increased bilirubin, fatigue, and increased alanine aminotransferase (ALT). In patients with mCSPC receiving darolutamide in combination with docetaxel, the most common adverse reactions (10% or more and at least 2% greater than with placebo) were constipation, rash, decreased appetite, hemorrhage, increased weight, and hypertension.

The most frequent laboratory abnormalities (30% or more) included anemia, hyperglycemia, decreased lymphocyte and neutrophil counts, increased AST and ALT, and hypocalcemia.[2] The recommended darolutamide dose is 600 mg (two 300 mg tablets) taken orally, twice daily, with food.[2]

HCP INSIGHTS: PATIENT SELECTION, ACCESS CONSIDERATIONS, AND THE IMPACT OF THE EXPANDED DAROLUTAMIDE INDICATION

Clinicians emphasized that patient selection for darolutamide is guided primarily by indication, comorbidities, drug interactions, and the overall safety profile of the medication. Jason Stinnett, MD, medical oncologist at Utah Cancer Specialists, underscored that prescribing remains aligned with approved indications but noted that payer formularies still shape treatment choices. “Insurance may still dictate a preferred formulary product per their own pharmacy benefit manager,” he explained. Dr. Stinnett added that darolutamide can offer advantages for patients with diabetes because “abiraterone requires concomitant glucocorticoid use,” which may complicate glycemic control.

Advanced practice providers described similar considerations. Nerina McDonald, PA-C, shared that their team at Fred Hutch evaluates a patient’s comorbidities, performance status, and potential drug interactions when determining whether darolutamide is appropriate. “We rely a lot on concomitant medical conditions and how fit patients are,” she said. Because darolutamide is generally well tolerated, the team “has not run into a lot of issues,” although interactions with statins are monitored closely and are typically “easy to adjust.”

HCP Insights: Patient Selection, Access Considerations, and the Impact of the Expanded Darolutamide Indication - continued

CLINICAL PERSPECTIVE ON THE EXPANDED INDICATION

The recent (June, 2025) expanded indication for darolutamide in mCSPC has been well received by clinicians and pharmacists who had already incorporated the agent into practice. Andrew Ruplin, PharmD, described the latest approval as confirmation of what many teams were already doing. "The pivotal trial revealed something we were not surprised about," he said. "An androgen receptor inhibitor would work quite well in the metastatic castrate-sensitive setting." He added that darolutamide's safety features, including a lower potential for interactions and lower blood-brain barrier penetration, have provided advantages for patients who experienced fatigue or neurocognitive side effects with other agents.

Dr. Stinnett highlighted new evidence supporting the expanded indication. He referenced the ARANOTE trial, a randomized phase III study showing that darolutamide plus androgen deprivation therapy (ADT) significantly improved radiographic progression free survival compared to ADT alone. "This was observed in both high volume and lower volume disease without a meaningful increase in side effects," he explained. In the treatment group, the median time to radiographic progression was not reached, compared to 25 months in the ADT-only group. Dr. Stinnett added, "It gives those of us who treat prostate cancer an additional option for our patients." He shared that he has used darolutamide in triplet therapy with excellent tolerance and long-standing benefit, and that the broadened approval gives an additional indication for patients.

Ruplin echoed that the expanded indication aligns with clinical practice patterns. The update helps ensure "affordable coverage" for patients, particularly those who were previously receiving darolutamide off-label due to drug interaction concerns with other agents. He explained that while the approval does not change management for patients who are already chemotherapy candidates, it "opened up additional opportunities" for patients who are not eligible for docetaxel.

McDonald added that as familiarity with the drug has increased, so has its use across a wider range of clinical presentations. "We are expanding the treatment and applying it to more patients," she said. Their team is now using darolutamide in mCSPC with docetaxel upfront, as well as in nmCRPC, reflecting the growing comfort and experience within the multidisciplinary team. Collectively, these insights highlight how clinicians across roles are incorporating darolutamide more broadly, balancing patient-level considerations with payer dynamics, and leveraging new evidence to support informed, individualized treatment decisions.

THE VALUE OF THE MEDICALLY INTEGRATED PHARMACY AND THE ONCOLOGY CARE TEAM

The implementation of Medically Integrated Pharmacy (MIP) practices within oncology care has transformed how patients experience and manage complex treatment regimens. With a growing emphasis on collaborative, patient-centered care, MIP structures aim to streamline communication, enhance medication safety, and improve treatment adherence, resulting in improvements across clinical outcomes. A defining strength of MIP is its multidisciplinary nature, where physicians, pharmacists, nurses, advanced practice providers, financial advocates, and pharmacy technicians work together to provide coordinated and comprehensive support.

The importance of this model is reinforced in the ASCO/NCODA Patient-Centered Standards for Medically Integrated Oncology Practices, which outline best practices that advance safety, efficiency, and equity in cancer care. These standards highlight key elements such as integrated clinical and pharmacy communication, proac-

The Value of the Medically Integrated Pharmacy and the Oncology Care Team - continued

tive toxicity management, consistent patient education processes, financial navigation, and ongoing quality improvement activities that center the needs and experiences of each patient. By embedding pharmacy services directly within the oncology clinic, teams can respond more efficiently to clinical changes, address barriers to medication access, and maintain continuity throughout the treatment journey.[3]

For patients receiving therapies like darolutamide, the MIP model supports timely initiation, close monitoring of laboratory parameters, management of treatment-related adverse effects, and adherence counseling. The collaborative structure ensures that every member of the care team contributes to a unified approach that enhances safety, improves quality of life, and supports optimal outcomes.

TEAM INSIGHTS ON THE VALUE OF THE MEDICALLY INTEGRATED PHARMACY

Insights from care team members illustrate how the medically integrated pharmacy (MIP) model strengthens coordination, enhances safety, and improves the overall patient experience during darolutamide therapy.

Dr. Stinnett described the meaningful impact the MIP structure has on patient care within his practice. He shared that his team has "seen a notable improvement in compliance and general patient understanding of their treatment and disease process as a result of our integrated pharmacy." He emphasized the coordinated roles across the care team, noting the value of dedicated nurse managers who maintain regular communication with patients and relay concerns promptly. He also highlighted the pharmacy team's essential contributions, including securing financial assistance, ensuring timely refills, and screening for drug interactions in "an older population who often have polypharmacy concerns."

Brandon L. Keith, PharmD, DPLA, BCACP, Manager of Specialty and Clinical Pharmacy Services at GW Medicine, emphasized the importance of multidisciplinary teamwork in delivering well-rounded care. He noted, "It is important to have the perspectives of various team members. We all have different training and experience, and as pharmacists we are the medication experts." He also underscored the operational value of MIP structures, explaining that the specialty pharmacy team manages prior authorizations, billing, and patient assistance programs while maintaining direct communication with prescribers and patients. "All this communication can be tracked within the patient's EMR," he said, which supports efficiency and care continuity.

From the perspective of McDonald, close communication between pharmacy, nursing, and advanced practice providers is critical for maintaining patient safety. She shared that regular check-ins and collaborative adherence to safety guidelines ensure that patients are monitored proactively throughout their treatment course.

Jordyn Felix, CPhT a pharmacy technician at Utah Cancer Specialists, highlighted how the integrated approach enhances medication safety and reduces communication gaps. "The value of our team is definitely the comprehensive patient care," she said. "When we all work together, our model reduces communication gaps between the providers and the pharmacy while also improving medication safety for our patients."

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Jordyn Felix, CPhT.

TEAM ROLES IN MEDICALLY INTEGRATED PROSTATE CANCER CARE

The management of prostate cancer, including therapies such as darolutamide, relies heavily on the coordinated efforts of a medically integrated oncology team. Each member contributes unique expertise to ensure patients receive safe, timely, and comprehensive care. Through interviews with physicians, pharmacists, pharmacy technicians, nurses, and advanced practice providers, a consistent theme emerged: streamlined communication, shared responsibility, and integrated workflows lead to better patient experiences and improved treatment access. The following sections highlight the distinct and complementary roles within the medically integrated pharmacy model.

PHYSICIAN AND ADVANCED PRACTICE PROVIDERS

Physicians and advanced practice providers (APPs) play a central role in directing treatment decisions, assessing patient readiness for therapy, and managing symptoms throughout the course of care. Their clinical oversight ensures that therapies such as darolutamide are used appropriately and safely within the broader treatment landscape of prostate cancer.

At Utah Cancer Specialists, Dr. Stinnett provides comprehensive hematology and oncology care, treating a broad mix of patients with both malignant and benign conditions. Prostate cancer represents one of the most common diagnoses in his practice, second only to breast cancer. In addition to his clinical responsibilities, he dedicates a portion of his time to administrative duties, but his primary focus remains direct patient care.

Advanced Practice Providers (APPs) support treatment decisions, symptom management, and ongoing assessment of patients receiving therapies such as darolutamide. McDonald cares primarily for patients with prostate cancer, urothelial carcinoma, and testicular cancer. She noted that her work involves close collaboration with pharmacy and nursing to ensure patients start therapy safely, remain adherent, and receive timely monitoring.

PHARMACISTS

Pharmacists are the medication experts within the medically integrated pharmacy model and provide critical oversight for oral and IV anticancer treatments. Ruplin shared that he serves as “the medication expert for our entire medical oncology team in the GU clinic.” His responsibilities include reviewing antineoplastic orders, evaluating supportive medications, managing comorbid conditions such as hypertension, and conducting in-depth patient education on oral prostate cancer therapies.

McDonald emphasized the team’s reliance on pharmacists when patients begin therapies such as darolutamide. She shared that pharmacists “take a thorough look at their other medications and let us know if there are any red flags or things that should be addressed or adjusted.” Keith oversees a team of pharmacists, pharmacy technicians, and pre-certification staff. His role includes maintaining accreditation, managing relationships with payers and manufacturers, overseeing operational performance, and ensuring coordination “from the beginning when treatment is initiated to dispensing, monitoring, follow-up, and refills.”

At Texas Oncology, Astrid Slaughter, PharmD, PhD, BCSCP, BCOP ensures that every regimen aligns with guidelines and reviews both IV and oral therapies for safety and appropriateness. She noted that as nursing workload has increased, pharmacy is likely to take the lead in chemotherapy education because “we are geared toward patient education based on our training.”

Daniel Silva, PharmD, from the START Center, emphasized operational leadership in the outpatient medically integrated pharmacy. His responsibilities include maintaining workflow efficiency, resolving process challenges, supporting technicians and pharmacists, and ensuring patients receive timely access to oral oncology therapies.

NURSING

Nurses are essential to patient education, symptom monitoring, and day-to-day support throughout prostate cancer treatment. Rachel Bierlein, BSN, RN, a clinical nurse coordinator in the Genitourinary Oncology department at Fred Hutch, described nursing as “really patient education, symptom management, and supporting patients from their first visit and throughout their entire treatment journey.”

Because patients have direct access to the nursing line, they consistently reach the same team, which creates continuity and builds strong, trusting relationships. Nurses coordinate pre-education steps, follow-up plans, and ensure that patients are connected with financial services when cost concerns arise. Ruplin added that nurses play a critical educational role, noting that “I cannot do every single educational session, and my nurses help by doing the intravenous chemotherapy education.”

McDonald emphasized that nurses are “pivotal to making sure that patients

Team Roles In Medically Integrated Prostate Cancer Care - continued

are taking the drug as prescribed, following safety instructions, and coming in for follow-up about a month after they start darolutamide to repeat labs and check for unexpected toxicity."

PHARMACY TECHNICIANS

Pharmacy technicians support the operational backbone of the medically integrated pharmacy by coordinating benefits investigations, obtaining prior authorizations, securing financial assistance, and ensuring timely access to therapy. Felix works as both a technician and an oral patient advocate. She explained, "My primary responsibilities with darolutamide are to obtain the prior authorization, get co-pay assistance if it is needed, and begin the dispensing process to get the medication to the patient in a timely manner."

Felix highlighted the integrated value of the technician role, noting that "our model reduces communication gaps between providers and the pharmacy while improving medication safety." Technicians support adherence through reminder calls, follow-up outreach, and refill coordination. They also manage daily operational steps to ensure prescriptions are processed accurately and efficiently.

Jenn Shelley, CPhT, the lead billing coordinator at Fred Hutch, described the technician and billing role as essential due to the complexity of insurance processes. Her team manages prior authorizations "from start to finish," coordinates with required pharmacies, communicates cost and coverage back to the care team, and connects patients to assistance programs if copays are high. She added that technicians are ideal for this work because they understand how to navigate the "convoluted and muddy" requirements of insurance companies and answer questions in the appropriate way to move approvals forward.

> "My work centers on closely partnering with pharmacy and nursing to ensure patients start therapy safely and stay on track with follow-up."
>
> Nerina McDonald, PA-C

PQI PROCESS: IMPLEMENTING DAROLUTAMIDE IN PRACTICE

Across practices, teams described a streamlined and coordinated workflow that begins the moment a darolutamide order is placed. The NCODA PQI Process is a guide to safe initiation, dosing, and monitoring. Once a provider enters the order, it is routed simultaneously to the pharmacist and the billing or authorization team.

Pharmacists perform a detailed clinical review that includes verifying the correct dose and quantity, evaluating for drug interactions, confirming that the indication aligns with approved use, and ensuring the patient is receiving concurrent androgen deprivation therapy when required. As part of this process, pharmacists also check for appropriate timing if darolutamide will be given with docetaxel, ensuring that docetaxel is initiated within six weeks of starting therapy. They confirm the appropriate dose of darolutamide 600 mg (two 300-mg tablets) taken twice daily with food. Dose adjustments are also evaluated when needed, including 300 mg twice daily for patients with severe renal impairment (eGFR 15–29 mL/min) or moderate hepatic impairment (Child-Pugh B).

Teams emphasized that the first fill often requires additional patient communication, as many individuals are unfamiliar with specialty medication workflows. Practice staff work closely with patients to explain what to expect. Pharmacists or clinical team members begin education early to reinforce correct dose administration, food requirements, and what to monitor for at home. As Keith explained, setting expectations at the outset helps patients

PQI Process: Implementing Darolutamide in Practice - continued

understand why therapy cannot always be started the same day and prepares them for the steps that follow.

Once authorization steps and clinical review are complete, the prescription moves either to the internal medically integrated pharmacy or, when required by insurance, to an external pharmacy for dispensing. Pharmacists then contact patients directly or meet with them in clinic to conduct comprehensive education prior to the first dose. Ruplin shared that after this visit, the treatment plan is activated and coordinated follow-up begins immediately. Order sets in the electronic medical record pre-load required labs such as CBC with differential, CMP, PSA, and testosterone, which are obtained at baseline and monthly thereafter. These standardized orders allow the team to maintain consistent monitoring and ensure patients receive timely evaluations to assess both efficacy and tolerability.

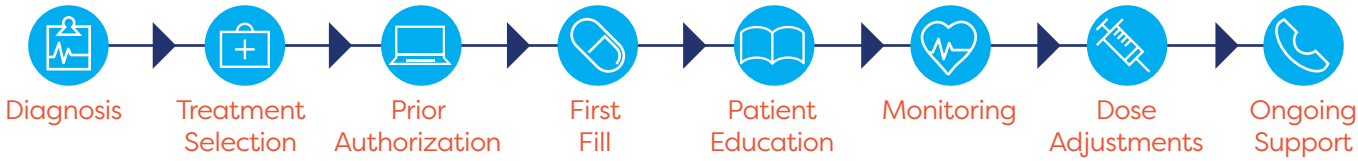
At Texas Oncology, Slaughter shared that all patients on active treatment undergo routine laboratory monitoring that includes a CBC and metabolic panel. Labs are drawn either the same day as treatment or a few days beforehand, allowing the pharmacy team to review results quickly and identify toxicities. Any notable changes prompt immediate communication to the treating physician to determine management strategies.

Nursing teams reported similar approaches. At Fred Hutch, Bierlein explained that patients are typically seen monthly for the first three months, with PSA levels, kidney and liver function, and adherence assessed at each visit. Nurses also provide follow-up phone calls for individuals who need closer monitoring, reinforcing education and ensuring that prescriptions are dispensed successfully from the contracted pharmacy.

McDonald noted the importance of flexible visit structures to meet patients' needs. When appropriate, telehealth check-ins are used to confirm that patients are tolerating therapy and are not experiencing new or unexpected toxicities. Once stability is established, visits may be spaced out, but patients are encouraged to contact the clinical team promptly if any concerning symptoms arise.

Practices that operate under pharmacy accreditation described additional structure in their workflow, including formalized care plan reviews after the first dispense. Silva explained that accreditation-driven processes reinforce timely communication, consistent documentation, and coordinated follow-up with providers. These steps help ensure that patients can begin therapy promptly and continue treatment safely. Clinical teams then maintain regular communication with the patient throughout therapy, reviewing labs, assessing for adverse events, and making dose adjustments based on PQI guidance. This integrated approach allows practices to support patients from the initial order through ongoing monitoring in a coordinated and efficient manner.

DAROLUTAMIDE CARE PATHWAY



ADVERSE EVENT MANAGEMENT: A PROACTIVE, TEAM-BASED APPROACH

Across practices, clinicians emphasized that early detection, clear communication, and patient-centered follow-up are essential to managing toxicities related to darolutamide and its combination regimens. While many adverse events stem from the underlying ADT, teams consistently highlighted the importance of distinguishing

Adverse Event Management: A Proactive, Team-Based Approach - continued

between symptoms associated with darolutamide, ADT, and cytotoxic chemotherapy when applicable.

Slaughter explained that their workflow is designed to catch serious concerns as early as possible: "Every patient on active treatment sees a mid-level provider before they get treatment, if we dispense an oral medication as part of the treatment." Routine monitoring of CBC and metabolic panels allows the team to promptly identify cytopenias or organ function changes that may require intervention. If a patient's ANC drops below 1.5, "we would alert the physician and say, do we want to at least dose reduce?" she noted.

Clinicians also reported that darolutamide itself tends to be well tolerated, with adverse events often overlapping with the known effects of hormonal therapy. Ruplin described it this way: "I don't often see patients developing additional toxicities as a result of starting darolutamide other than those they may already be experiencing from androgen deprivation therapy." Even so, he acknowledged that some patients experience additional fatigue and occasional dermatologic symptoms such as rash.

Fatigue emerged as the most common symptom across practices. Slaughter and Silva see it regularly, and McDonald agreed that it is among the most frequent patient complaints. For this reason, supportive care strategies play a central role. Teams routinely recommend increased physical activity, referral to physical therapy, and structured lifestyle adjustments. As McDonald explained, "There are a lot of different things that we recommend... increasing exercise, engaging in PT, and other ways to overcome some of that fatigue."

While rare, liver function abnormalities are another important consideration. Ruplin noted that these changes may occur, and McDonald added that "we will sometimes see patients that have transaminitis or abnormal liver enzymes." When this happens, practices typically hold therapy, monitor values closely, and resume darolutamide at a lower dose once liver enzymes normalize.

Some patients also report worsening vasomotor symptoms. According to McDonald, "With darolutamide, sometimes patients can see an increase in hot flashes," which are managed through lifestyle strategies or pharmacologic options, depending on severity.

Distinguishing toxicities becomes especially important when darolutamide is used alongside docetaxel. Ruplin emphasized that it is generally straightforward due to the differences between hormonal therapy and cytotoxic chemotherapy: neutropenia and alopecia clearly point to docetaxel, whereas hormonal therapies are more often associated with metabolic changes, mood and cognitive effects, and vasomotor symptoms. He also explained that growth factor support and antiemetics are not routinely required with darolutamide alone but become relevant when docetaxel is part of the regimen. Treatment decisions rely on clinical judgment, guideline-driven protocols, and individualized assessment, "treating the patient as an individual is always the first approach," he said.

Finally, teams remain vigilant for rare but important risks such as seizures and ischemic events. Ruplin highlighted that darolutamide's limited penetration across the blood-brain barrier significantly reduces seizure risk, and cardio-oncology collaboration helps identify patients with underlying cardiovascular concerns before therapy begins. Together, these insights reflect a cohesive care model in which adverse event management is not only proactive but thoughtfully tailored to each patient, leveraging multidisciplinary expertise to maintain safety and quality of life throughout treatment.

PQI Clinical Pearls

- **Optimize cardiovascular risk factor management - hypertension, diabetes, dyslipidemia**
- **Use effective contraception during treatment and for 1 week post last dose of darolutamide**
- **Avoid using darolutamide with a combined P-gp and strong or moderate CYP3A4 inhibitor/inducer**
    - **o If combination is necessary, monitor patient more frequently**
- **Review prescribing information of the BCRP, OATP1B3, OATP 1B1 substrates when used concomitantly with darolutamide**

PATIENT EDUCATION AND REDUCING BARRIERS TO CARE

Patient education for darolutamide is most effective when it is consistent, individualized, and supported by a coordinated team approach. Practices emphasized that clear communication at the start of therapy helps patients understand their treatment plan and reduces confusion as they transition between clinic visits, pharmacy services, and home administration.

Language and health literacy remain key equity considerations. Keith explained that language barriers can create real obstacles for starting and maintaining therapy. “We do have certified language interpreters here, which is helpful. They can be present during the clinic visit or accompany the patient to the pharmacy.” He added that patients with limited English proficiency are at greater risk for nonadherence, so having in-person interpreter support helps ensure that no patient begins therapy without a full understanding of how and when to take their medication.

For patients who would benefit from greater visual or verbal reinforcement, teams supplement verbal counseling with structured education tools. Slaughter noted that her team “utilizes the NCODA Patient Education Sheets because they list everything very clearly.” She also introduces the pharmacist as a direct patient advocate. “Patients get our phone number and know they can call us. If they need support after hours, our answering service routes them to a pharmacist.”

The Patient Education Sheets serve as an anchor for the education session. Silva described the workflow: “A quick explanation of the drug, then bullet points on how to take the medication, then a flow into whether there are any food contraindications. It covers what to expect, what to watch out for, and key side effects.” His team reviews each major point with the patient and explains why ongoing lab monitoring is needed, such as checking platelet counts or liver function.

Ruplin emphasized the value of the structured handouts in helping patients absorb complex information. “I do love to use the Patient Education Sheets. When I walk patients through treatment, I start with the simple pharmacy items: how do you take your medicine, how do you store it, and what type of treatment is this. Is it indefinite or does it have a defined endpoint.” He also distinguishes monitoring expectations based on whether the patient is receiving darolutamide alone or in combination with docetaxel. For example, a patient starting darolutamide for nonmetastatic castration resistant disease may continue therapy until progression or intolerance, while a patient receiving combination therapy may complete six cycles of docetaxel and then continue darolutamide alone. “I like to set a clear global picture of what their treatment looks like,” he said.

Bierlein reinforced this approach, describing her team’s process from authorization to follow-up. Nurses track approvals and “once we have an approval, we reach out to schedule that initial education session.” These sessions cover dosing, safety considerations, and drug interactions. Teach back is used to confirm understanding. Her team then performs a follow-up call one week later to assess early tolerance and identify barriers such as financial concerns or delays in receiving medication from the dispensing pharmacy. Patients with low health literacy or limited English proficiency are offered in person appointments so the team can observe body language and ensure comprehension.

Keith described their welcome call program as another way to overcome disparities. “Hi, my name is Brandon. I want to talk to you about our specialty pharmacy services.” During these calls, technicians share patient education links through the patient portal and provide printed packets when needed. This early outreach ensures that patients understand what to expect before therapy begins. Slaughter highlighted how education is coordinated across services, so patients understand the full treatment landscape. For newly approved therapies, her team ensures patients know if another medication or injection will be required. “Coordination of these services is key,” she explained. “Patients need to understand what the treatment looks like. It is not just coming to the clinic for a shot.”

Dr. Stinnett underscored how this team-based education supports patients who may feel overwhelmed by a new diagnosis. He shared that patients “tend to need a few sessions to feel comfortable with any treatment for advanced cancer,” and that recognizing the presence of a full support team is reassuring. His counseling focuses on expected side effects, the low risk of serious cardiovascular events or seizures, and common concerns such as constipation, rash, decreased appetite, or weight gain with reduced activity.

Taken together, these approaches reflect how patient education within a medically integrated team can directly reduce disparities. By combining written resources, interpreter support, coordinated follow-up, and detailed coun-

Patient Education and Reducing Barriers to Care - continued

seling, practices help ensure that every patient has equitable access to clear, comprehensive information and the tools needed for safe and successful treatment.

FINANCIAL NAVIGATION AND RAPID ACCESS TO THERAPY

Financial navigation plays a central role in ensuring timely access to darolutamide, particularly as payer expectations and coverage criteria continue to evolve. Teams across institutions described a highly coordinated, detail driven workflow that reduces delays and supports patients through financial, insurance, and logistical barriers.

Following the expanded indication for darolutamide, many practices saw immediate changes in payer behavior. Shelley shared that denials were previously common when patients were prescribed darolutamide without docetaxel. “Since that has changed, we are seeing fewer denials come through, which is really great.” Her team manages prior authorizations from start to finish, including coordinating peer to peer reviews, drafting letters of medical necessity, and pushing insurers to expedite cases. She described their approach as “following it through the insurance company and making sure it gets fast tracked,” because these administrative processes directly affect how quickly patients can begin therapy.

Pharmacy teams also emphasized the importance of structured internal workflows. Keith explained that because their pharmacy and providers operate within the same health system, prescriptions are visible in real time, which allows the financial team to immediately begin processing authorizations. He noted that technicians track every active case through spreadsheets or written reminders and follow-up consistently until a determination is made. “We have an internal expectation that all authorizations should be acted on within 48 to 72 business hours,” he explained. This service goal supports rapid turnaround and prevents avoidable treatment delays.

Cross-trained specialty technicians are essential to navigating the financial landscape. Keith noted that his team intentionally assigns the same technician to oncology cases so that patients, providers, and pharmacists have a central point of contact. “She knows like the back of her hand what the available programs are,” including commercial co-pay cards, Medicare Part D options, PAP applications, and free drug programs. His team is also able to coordinate these applications on behalf of patients once permission is obtained.

Other practices described similar structures. Slaughter noted that their clinic benefits from a dedicated team for prior authorizations and patient assistance that works in parallel with dispensing services. This structure is especially important when insurance mandates that a medication be filled externally. “We can make sure the patient has all the financial resources available,” she said.

Pharmacy technicians also shared strategies for overcoming prolonged authorization timelines. Felix noted that urgent authorizations can still take seven to ten days despite the urgency of oncology care. To prevent treatment delays, she often relies on manufacturer samples or voucher programs. Challenges such as insurers blocking CoverMyMeds submissions require alternate routes like phone or fax, although these are not always accepted. Despite these barriers, Felix works closely with patients to minimize financial stress. She assists with enrollment in co-pay programs and updates billing profiles to ensure cards apply correctly. Having manufacturer support “is major in keeping my patients on therapy and making sure they have ease of mind financially through their cancer journey.”

Shelley echoed that co-pay costs and insurance authorization timelines remain the two most significant hurdles. Her team uses both external manufacturer programs and internal health system funds to reduce patient costs. For every patient, a dedicated financial coordinator ensures that applications are completed correctly to avoid delays. “With our teams both aligned in their focus on a certain task, it really does help streamline things,” she said.

Geographic barriers are also addressed through proactive pharmacy support.

Financial Navigation and Rapid Access to Therapy - continued

Keith described free delivery services that allow patients to receive medication quickly even if they cannot travel to the clinic. "We can sometimes deliver same day or next day if the medication is in hand," which is especially valuable for oncology patients who require fast initiation of therapy.

Together, these experiences highlight the critical role of financially focused pharmacy personnel in the medically integrated model. Their ability to navigate complex payer requirements, coordinate rapid access programs, and provide individualized financial counseling ensures that patients begin therapy as quickly and affordably as possible.

"Having manufacturer assistance in the background is major in keeping my patients on therapy."

Jordyn Felix, CPhT

BARRIERS & SOLUTIONS TO DAROLUTAMIDE ACCESS AND EDUCATION

01	Insurance Delays	**Barrier:** PA bottlenecks, denials, slow insurer review **Solution:** Fast-track PA teams, daily follow-up, peer-to-peer support, manufacturer vouchers
02	High Out-of-Pocket Costs	**Barrier:** Brand-only cost burden **Solution:** Co-pay cards, PAP/free drug programs, internal financial assistance
03	Language & Literacy Challenges	**Barrier:** Understanding treatment instructions **Solution:** On-site interpreters, NCODA Patient Education Sheets, in-person teach-back
04	Transportation & Access	**Barrier:** Patients unable to come to clinic/pharmacy **Solution:** Free delivery (same- or next-day), telephonic education and support
05	Complex Treatment Instructions	**Barrier:** Remembering how to take, monitor, and manage therapy **Solution:** Structured Patient Education Sheets, step-by-step counseling, 1-week follow-up call
06	Distinguishing Toxicities	**Barrier:** Differentiating ADT, darolutamide, and docetaxel side effects **Solution:** Clear symptom explanations and supportive care guidance
07	Workflow Coordination	**Barrier:** Multiple teams involved in patient care **Solution:** Integrated EMR workflow, cross-trained technicians, standardized order sets

CONCLUSION

Across practices, teams emphasized that darolutamide has become a reliable, well-tolerated option that integrates smoothly into medically integrated pharmacy workflows. This streamlined care model supports timely initiation, proactive monitoring, and individualized patient education, all of which contribute to improved adherence and patient confidence throughout therapy.

Emerging evidence also reinforces the broader public health value of darolutamide. A recent distributional cost-effectiveness analysis evaluating darolutamide plus androgen deprivation therapy for nonmetastatic castration resistant prostate cancer found that this combination offers greater quality-adjusted life-years than ADT alone.[4] The study concluded that the largest health gains are expected among non-Hispanic Black patients, whose higher incidence of nmCRPC means that the positive inequality impact of darolutamide may help reduce population-level disparities in prostate cancer outcomes.[4] These findings highlight an important alignment between high quality clinical care and meaningful progress toward health equity.

Positive Quality Interventions further strengthen this impact by giving oncology teams a trusted, concise resource to guide safe and efficient implementation. Ruplin noted that the darolutamide PQI "is a nice simple clean reference" for a therapy that is straightforward to use. He explained that traditional drug information sources are often overwhelming, while the PQI delivers exactly what clinicians need to start and monitor treatment successfully. Felix agreed, sharing that "NCODA's PQI resource is an absolute integral guide to starting a patient on the medication" and helps ensure the fastest possible path to therapy access. From the APP perspective, McDonald emphasized that pooled experience within a PQI allows teams to learn from each other and apply real world insights that improve patient safety and consistency of care.

Together, darolutamide's favorable clinical profile, its demonstrated potential to reduce inequities in prostate cancer outcomes, and the structured support provided by medically integrated teams and PQIs represent a unified approach to patient centered prostate cancer care. This combination of evidence-based treatment, operational excellence, and multidisciplinary collaboration positions oncology practices to deliver high quality, equitable care for every patient starting therapy with darolutamide.

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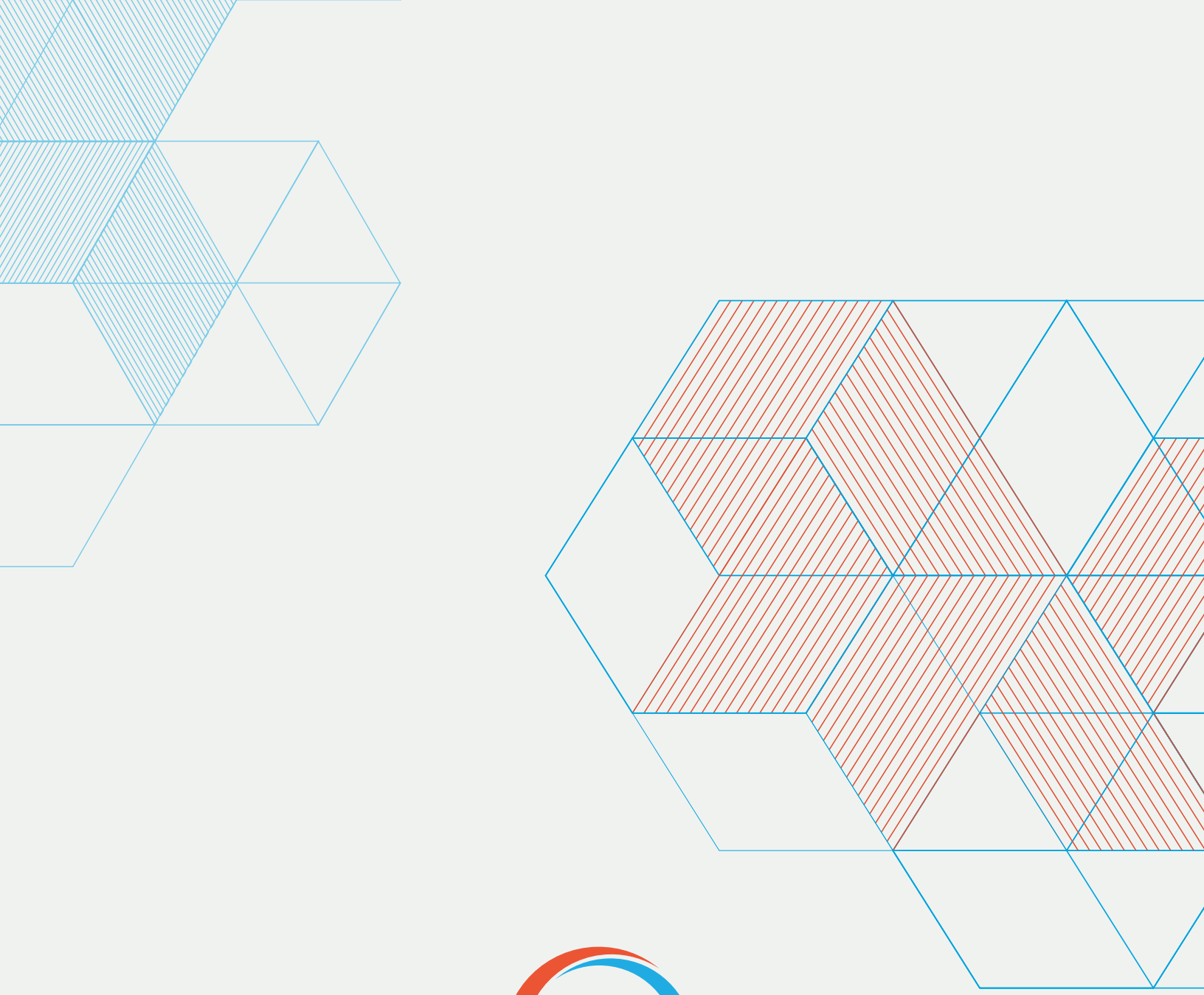

Practice panelist's comments reflect their experiences and opinions and should not be used as a substitute for medical judgment.

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