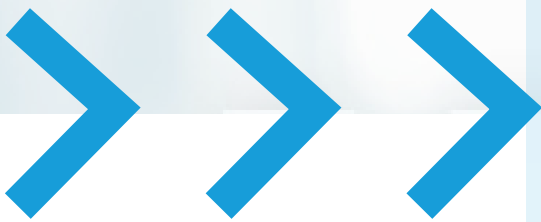


PQI IN ACTION



**DAROLUTAMIDE (NUBEQA®) IN
COMBINATION WITH DOCETAXEL
(TAXOTERE®) FOR METASTATIC HORMONE
SENSITIVE PROSTATE CANCER PQI**



**NCODA'S POSITIVE QUALITY
INTERVENTION IN ACTION**

INTRODUCTION

In an effort to promote higher quality patient care NCODA created the NCODA Positive Quality Intervention (PQI) as a peer-reviewed clinical guidance resource for healthcare providers. By providing Quality Standards and effective practices around a specific aspect of cancer care, PQIs equip the entire multidisciplinary care team with a sophisticated yet concise resource for managing patients receiving oral or IV oncolytics. This PQI in Action is a follow up to the **Darolutamide (NUBEQA®) in Combination with Docetaxel (TAXOTERE®) for Metastatic Hormone Sensitive Prostate Cancer PQI** and explores how the medically integrated teams at Illinois CancerCare and Arizona Blood and Cancer Specialists incorporate the information found in the PQIs as part of their daily workflow. This article will discuss how utilizing the **Darolutamide (NUBEQA®) in Combination with Docetaxel (TAXOTERE®) for Metastatic Hormone Sensitive Prostate Cancer PQI** elevates patient care.

Illinois CancerCare is one of the largest private oncology practices in the nation. With 14 clinics and a team of 500+ healthcare and administrative professionals, the residents of central and western Illinois have easy access to state-of-the-art cancer treatments right in their own hometown. Illinois CancerCare aims to provide comprehensive, compassionate care while staying on the leading edge of breakthrough research and medications. Illinois CancerCare's commitment to high quality research is evidenced by their numerous accolades including recognition by the American Society of Clinical Oncology as one of the top 10 community research centers in the nation.

Arizona Blood and Cancer Specialists is a Tucson-based oncology practice committed to compassionate support and clinical excellence. In addition to providing the most advanced, clinically proven treatments, Arizona Blood and Cancer Specialists prioritize providing personalized care and education to patients. This ensures treatments are as individual as the patients themselves. Arizona Blood and Cancer Specialists believes that their dedication to improving their patient's experience and outcomes are what sets them apart. They are a partner of OneOncology, a network of oncology practices that utilizes data-driven and technology-powered resources to enhance patient-centered care.

THE PARTICIPANTS

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MID, THE PQI, AND DAROLUTAMIDE IN COMBINATION WITH DOCETAXEL: AN EVOLVING STANDARD OF CARE FOR METASTATIC, HORMONE-SENSITIVE PROSTATE CANCER

Prostate cancer is the second most common cancer among men in the United States.¹ This cancer is fueled by male hormones called androgens, which stimulate prostate cancer cells to grow.² Darolutamide (NUBEQA®) is an androgen receptor inhibitor that decreases prostate cancer cell growth.³ It was originally approved in 2019 for the treatment of non-metastatic castration-resistant prostate cancer.⁴

Castration-sensitive prostate cancer (also known as hormone-sensitive prostate cancer) means the cancer is being controlled by testosterone levels that are at or below what would be expected if the testicles were surgically removed. Castration can be achieved either surgically or medically with androgen deprivation therapy.² Castration resistance is defined as progression of disease despite castrate levels of testosterone (< 50 ng/mL).⁵

Historically, treatment of metastatic hormone-sensitive prostate cancer included the addition of the microtubule inhibitor docetaxel or an androgen-receptor pathway inhibitor to androgen deprivation therapy (ADT). Androgen-receptor pathway inhibitors include darolutamide, abiraterone, apalutamide, and enzalutamide.⁶ Combining docetaxel or an androgen-receptor pathway inhibitor to ADT has been proven to be more effective than ADT alone.⁷⁻¹² However, phase 3 trials that combine both androgen-receptor pathway inhibitors and docetaxel with ADT have been mixed.^{12,13}

In the phase 3 ARASENS trial, darolutamide was studied in combination with both docetaxel and ADT in patients with metastatic, hormone-sensitive prostate cancer. The primary outcome of overall survival at 4 years was 62.7% (95% CI, 58.7-66.7) in the darolutamide group and 50.4% (95% CI, 46.3-54.6) in the placebo group. The risk of death was 32.5% lower in the darolutamide group compared to the placebo group.¹⁴ Darolutamide is structurally distinct from other medications in its class with lower blood-brain-barrier penetration, resulting in decreased neurological side effects including seizures.¹⁵ In the ARASENS trial, adding darolutamide to docetaxel and ADT did not significantly increase toxicity.¹⁴ Darolutamide in combination with docetaxel and ADT is now FDA-approved and a category 1 NCCN preferred regi-



Illinois CancerCare takes expert care of their patients.

men for metastatic, hormone-sensitive prostate cancer.⁶

Dr. Benjamin Schwartz, MD, medical oncologist with Arizona Blood and Cancer Specialists says that he typically uses darolutamide in combination with docetaxel in a younger or more fit patient population that can tolerate more aggressive treatment. “We’ve had good results and patients have tolerated it well.”

Darolutamide can be dispensed by the Medically Integrated Team, and thus offers patients more comprehensive care. NCODA defines Medically Integrated Dispensing (MID) as a dispensing pharmacy within an oncology center of excellence that promotes a patient-centered, multidisciplinary team approach. The MID is an outcome-based collaborative and comprehensive model that involves oncology healthcare professionals and other stakeholders who focus on the continuity of coordinated, quality care and therapies for cancer patients.¹⁶ The MID model can improve management of patients on therapies like darolutamide in several ways including improved communication issues, measuring adherence, managing regimen changes, quicker therapy initiation, increased patient satisfaction, financial assistance, cost avoidance, and producing less waste.¹⁷

Dr. Kimberly Ku, MD, medical oncologist at Illinois Cancer-

Care speaks to the value of having pharmacy integrated within her practice. “It really is so hard to do anything without a team, and I feel like I’m only as good as my team. And the pharmacy plays such a huge role because I need to be able to have people who can help me with double checking, being safe, making sure that I’m thinking about more than just what I’m trained to do. But there are also so many different aspects of medicine that are important for what a patient needs that I need to have all those dimensions and perspectives. So, I think pharmacy is a huge component, just as any of the team members are for excellent patient care.”

NCODA offers multiple tools to aid the MID practice in managing oncolytics. This toolbox contains a Patient Survey that is practice-customizable, a Cost Avoidance and Waste Tracker tool, a Financial Assistance database, Treatment Support Kits, Oral Chemotherapy Education sheets, and of course the Positive Quality Intervention clinical resource documents.

“IT REALLY IS SO HARD TO DO ANYTHING WITHOUT A TEAM, AND I FEEL LIKE I’M ONLY AS GOOD AS MY TEAM. AND THE PHARMACY PLAYS SUCH A HUGE ROLE BECAUSE I NEED TO BE ABLE TO HAVE PEOPLE WHO CAN HELP ME WITH DOUBLE CHECKING, BEING SAFE, MAKING SURE THAT I’M THINKING ABOUT MORE THAN JUST WHAT I’M TRAINED TO DO. SO, I THINK PHARMACY IS A HUGE COMPONENT, JUST AS ANY OF THE TEAM MEMBERS ARE FOR EXCELLENT PATIENT CARE.”

Dr. Kimberly Ku, MD, Medical Oncologist

THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

Stephanie Parker, PharmD, retail pharmacy manager at Illinois Cancer Care comments on the value of the PQI in training new staff. “As we’ve expanded our team of pharmacists, this is usually one of the first resources that I put in front of a non-oncology trained pharmacist. As we’re welcoming them into the oncology world, this is a great way to have a snippet of the guidelines. You’ve got the clinical information as to when this is recommended, what line of therapy, there is high level information about the clinical pearls, and what dose adjustments are needed.”

[CLICK HERE TO VIEW DAROLUTAMIDE \(NUBEQA\) IN COMBINATION WITH DOCETAXEL \(TAXOTERE\) FOR METASTATIC HORMONE SENSITIVE PROSTATE CANCER PQI](#)

This article will explore the benefits of PQI utilization as a core standard of the MID and how adoption can benefit any practice. Illinois CancerCare and Arizona Blood and Cancer Specialists each found successful ways to incorporate the PQI clinical resource. Both practices position their Medically Integrated Teams in a way to ensure appropriate treatment, increase compliance, and maximize clinical outcomes. We will explore their practice settings, how implementing

the **Darolutamide (NUBEQA®) in Combination with Docetaxel (TAXOTERE®) for Metastatic Hormone Sensitive Prostate Cancer PQI** benefits their staff and patients, and how they advance patient care on a daily basis.

Both physicians and pharmacists at Illinois CancerCare love how the PQIs are concise and to-the-point. Kirsten Sutton, PharmD, BCOP, clinical pharmacy manager says, “I think it’s a to-the-point, quick reference. It’s nice that it’s only 2 pages. It’s pretty brief to go through and read, especially if we have a pharmacist who is newer or not very familiar with the combination therapy, if they typically work more with the orals, and they aren’t familiar with the combination. Having that brief background is really nice.”

Dr. Ku mentions that the PQI could make her more efficient when she sees multiple patients per day on different therapies. “It spells things out in a way that I, as a generalist, find really helpful, just carrying around in my back pocket when I’m talking to patients. It’s kind of like a little cheat sheet even for me, if I have to see 25 patients in a day and they all have different regimens and I’m counseling them. I like that it is very succinct.”

MEDICALLY INTEGRATED DISPENSING: ELEVATING CARE

As cancer treatment continually grows in complexity containing IV, oral and combination regimens, MID continues to offer an invaluable option for patient care. The MID and multidisciplinary staff has unparalleled access to patient information and means of direct communication with other members of the team. The pharmacy members of the team also have direct access to communication with patients and can easily report information back to the providers. This model greatly reduces fragmentation of care.

Both Illinois CancerCare and Arizona Blood and Cancer Specialists value MID as an opportunity to improve interdisciplinary collaboration. Emily Kaufmann, CPhT, retail financial counselor at Illinois CancerCare says, “I think the patients and staff really benefit by having so many different types of knowledge and training in one area.” Mara Greenwell, RN, nurse manager at Arizona Blood and Cancer Specialists agrees by saying “I think it's very important to have all the providers and staff on board and that we all work together and everybody is available.”

Medically integrated dispensing also improves patient care by increasing transparency related to patient compliance and insurance/delivery issues and also increasing convenience. Parker says, “From a staff standpoint, it helps with the care

of the patient. When you have to defer an oral prescription outside, it's so easily lost track of. If there are any delays that are upholding treatment, you don't necessarily know that until the patient calls you. Whereas we have that complete transparency when we keep it in house. On the flip side we ultimately believe that it allows the patient to receive better care. Definitely a convenience factor, having the pharmacy on the oral side integrated with the doctor's office provides great benefit in and of itself.”

“WE HAVE COMPLETE TRANSPARENCY WHEN WE KEEP [THE ORAL PRESCRIPTION] IN HOUSE. WE ULTIMATELY BELIEVE THAT IT ALLOWS THE PATIENT TO RECEIVE BETTER CARE. DEFINITELY A CONVENIENCE FACTOR, HAVING THE PHARMACY ON THE ORAL SIDE INTEGRATED WITH THE DOCTOR'S OFFICE PROVIDES GREAT BENEFIT IN AND OF ITSELF.”

Stephanie Parker, PharmD,
Retail Pharmacy Manager

PUTTING THE DAROLUTAMIDE (NUBEQA®) IN COMBINATION WITH DOCETAXEL (TAXOTERE®) FOR METASTATIC HORMONE SENSITIVE PROSTATE CANCER PQI INTO ACTION

The PQI is a peer-reviewed clinical guidance document that provides Quality Standards and effective practices around a specific aspect of cancer care. The Medically Integrated Pharmacy team is in a unique position to ensure appropriate treatment, increase compliance, and maximize clinical outcomes. Positive Quality Interventions (PQIs), an NCODA Quality Standard, are designed to operationalize and standardize those practices to achieve these positive clinical outcomes.

The **Darolutamide (NUBEQA®) in Combination with Docetaxel (TAXOTERE®) for Metastatic Hormone Sensitive Prostate Cancer PQI** is written in sections, beginning with a Description and ending with Patient-Centered Activities and References.

Following the description, the background section gives pertinent historical data and information, clinical trial experience, and the main focus of the intervention. Regarding darolutamide, the background discusses side effect differen-

ces from other medications, indication, and published data leading to approval. The background also discusses appropriate timing regarding initiation of ADT and docetaxel and the importance of distinguishing between darolutamide and docetaxel side effects. Again, it discusses the ARASENS trial, specifically darolutamide's approval for use in metastatic, hormone-sensitive prostate cancer in combination with both docetaxel and ADT.¹⁸

Schwartz finds that the level of information in the PQI is valuable for both patients and providers. "It's nice to have this for patients, physicians, and pharmacists, because it allows them to look back and have the data in a concise, easy way to look at it and get to the points and the highlights. Patients are very educated these days, they have a lot of online resources, so they ask a lot of questions and they have access to a lot of information. So, I think it's important to have these things out there that they can read and ask questions about and have it for us as well."

"PATIENTS ARE VERY EDUCATED THESE DAYS, THEY HAVE A LOT OF ONLINE RESOURCES, SO THEY ASK A LOT OF QUESTIONS AND THEY HAVE ACCESS TO A LOT OF INFORMATION. SO, I THINK IT'S IMPORTANT TO HAVE THESE THINGS OUT THERE THAT THEY CAN READ AND ASK QUESTIONS ABOUT AND HAVE IT FOR US AS WELL."

Benjamin Schwartz, MD, Medical Oncologist

THE PQI PROCESS: A TEAM EFFORT

The next section of the **Darolutamide (NUBEQA®) in Combination with Docetaxel (TAXOTERE®) for Metastatic Hormone Sensitive Prostate Cancer PQI** is the PQI Process. This section lays out the intervention in step by step points, contains clinician directed guidance, and critical clinical criteria that can benefit the entire team.

Carol Hemersbach, CPhT, BSHCA, IOD supervisor at Arizona Blood and Cancer Specialists looks at the PQI as a resource that caters to all members of the practice and ultimately improve care for patients. "I think having the information available and having the different processes in the PQI are beneficial to everybody because they're made for everybody in the practice. Anybody can read them, take what they can from it, and learn from it to make the system better for the patient."

The first step of the **Darolutamide (NUBEQA®) in Combination with Docetaxel (TAXOTERE®) for Metastatic Hormone Sensitive Prostate Cancer PQI** includes guidance on when to start ADT in relation to darolutamide and docetaxel. For both darolutamide and docetaxel, the PQI process continues with when to start both darolutamide and docetaxel, dosing of each medication, necessary dose modifications for renal and hepatic impairment, and dose modifications for



An Arizona Blood and Cancer Specialists staff member prepares medication for a patient.

toxicity. The PQI also includes clinical pearls for both darolutamide and docetaxel, including drug interaction considerations, clinical risk factor management, and appropriate docetaxel infusion.

PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

The Patient-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. The **Darolutamide (NUBEQA®)** in Combination with **Docetaxel (TAXOTERE®)** for Metastatic Hormone Sensitive Prostate Cancer PQI Patient Centered Activities suggests providing the patient with an Oral Chemotherapy Education (OCE) sheet and a docetaxel Intravenous Cancer Treatment Education Sheet. OCE sheets and Intravenous Cancer Treatment Education Sheets are NCO-DA-led initiatives that provide information about oral and IV chemotherapy drugs and their side effects to both cancer patients and caregivers.

[CLICK HERE TO VIEW
DAROLUTAMIDE OCE SHEET](#)

[CLICK HERE TO VIEW
DOCETAXEL IVE SHEET](#)



Illinois CancerCare MID staff help provide positive outcomes for patients.

In 2019 the Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards were published to provide standards for medically integrated dispensing of oral anticancer drugs and supportive care medications.¹⁹ Standard 1.2 of the ASCO/NCODA Standards reads:

Prior to initiation of an oral anticancer drug, a formalized patient education session should occur with an experienced clinical educator such as a nurse, physician, pharmacist, nurse practitioner, or physician assistant. The discussion should include drug name (generic and brand), drug dose, schedule, potential adverse effects and how to properly manage them, fertility (where applicable), treatment goal, duration of therapy, and financial and affordability considerations.¹⁹

Both Illinois CancerCare and Arizona Blood and Cancer Specialists ensure that their patients are fully educated and comfortable with their treatment plan prior to starting. Their differing workflows illustrate that patient education isn't a one size fits all process.

At Illinois CancerCare, the physicians provide a high-level overview of treatment plans and side effects at initial visits and nurse practitioners provide more in-depth counseling to ensure that patients get consistent education. Parker says, "As part of our accreditation, we have to provide documented, thorough counseling. We often refer to NCODA's OCE sheets. We really like those in the way that they are broken out in a simplistic 'yes you can get a lot of that information in the PI' but it's kind of wordy and you have to hunt through it. So, we like those. And sometimes they are helpful for patients to have those as a takeaway as well. And once medication is dispensed, we are really the first

opportunity to call back with questions. In a patient education/adverse event screening and mitigation step as well."

At Arizona Blood and Cancer Specialists, the physicians do a large portion of darolutamide counseling, but they bring in pharmacists as a teaching resource. Schwartz says, "Education is huge too. You are putting a lot of trust in the patient and caregivers when you put them on oral medications, relying on them to take it at home without monitoring when you are on IV or SC, you monitor your treatment a little more closely because we are giving it. So, we really try to educate the patients, with me the doctor but it also involves the pharmacy technicians. A lot of the time, I'll bring the pharmacy technician in with me right there in clinic as I talk to the patient about the medication, risks, side effects, benefits, toxicity, have them there to clarify and answer any questions on how they are going to get the medication, simple things, how much is it going to cost. A lot of the pharmacy technician's information and help is really great to have.

The Patient-Centered Activities section also discusses important side effects to watch out for, how to appropriately manage them, when to call the clinic, and appropriate contraceptive measures to take when on this regimen. This section also discusses the importance of steroid use steroids for prevention of fluid retention and reactions related to docetaxel.

FINANCIAL ASSISTANCE: A BENEFIT OF MID AND THE MULTIDISCIPLINARY TEAM

In addition to close follow up and detailed education, MID renders the practice able to provide excellent customer service, unmatched patient care, and help with finding funding so the patient can afford to take the medication.

Illinois CancerCare utilizes dedicated retail financial counselors to make the insurance approval and financial assistance process much smoother for patients. Sherri Haley, CPhT, Retail Financial Counselor explains that having a MID increases efficiency for prior authorizations (PAs) and financial assistance approval. “We can see when it needs a PA or copay assistance immediately. It makes everything go quicker. I’ve had a PA and copay assistance be done in one day. If you are dealing with a mail order pharmacy, we have to wait for them and it takes them 24-48 hours to acknowledge that they got something. Our prescriptions are done the same day, every day. It’s not like waiting and then they have to go through so many different departments and you are waiting 24 hours for each one of them. That’s a huge difference and patients are going without their medicine that whole time.”

Kaufmann also discusses the challenges in coordinating approvals of regimens that require both oral and IV medications. “We have a team for our IV medical side [approvals], and our team that handles oral retail. The two teams would complete their authorizations separately, usually. It depends on if they are part of one of the third-party applications that we must use for some of the insurances. Nine times out of ten, we have a different workflow and agenda. And towards

the end, if both medications need assistance with their copays, they usually tag team at some point and obtain grants and correlate with each other to see how much money is going to be used out of that. So, towards the end of the process it does end up coming together, but we do keep it separate when it comes to the authorization and looking into things first.”

Communication is key in making sure that both docetaxel and darolutamide are approved in a timely manner. Sutton says, “It’s just a lot of communication, being a part of the same office, being a multidisciplinary team, you know that communication goes both sides. The nursing team and the pharmacists work together to make sure that all of the appropriate financial approvals are in and that the oral drug can be coordinated to fill when the patient needs to start and the IV therapy is scheduled to start at the same time.”

“WE CAN SEE WHEN IT NEEDS A PA OR COPAY ASSISTANCE IMMEDIATELY. IT MAKES EVERYTHING GO QUICKER. I’VE HAD A PA AND COPAY ASSISTANCE BE DONE IN ONE DAY.”

Sherri Haley, CPhT,
Retail Financial Counselor

CONCLUSION: NCODA, THE MID AND PQI: OPTIMIZING PATIENT OUTCOMES

All team members agree that the MID model and the PQI Clinical Resource are valuable to the team and to patients. Every day the MID team can make a difference in the life of patients.

“We have a lot of resources available to them that the specialty pharmacies probably know about it, but probably will not provide to our patients. And I think we are able to better

track their medication and make sure they're compliant, make those phone calls to them to see how they're doing, and answer any questions that arise. We have that relationship with our patients versus going to the specialty pharmacies. That is our customer service.” Mara Greenwell, RN, Nurse Manager

The team can continually learn something new or can begin

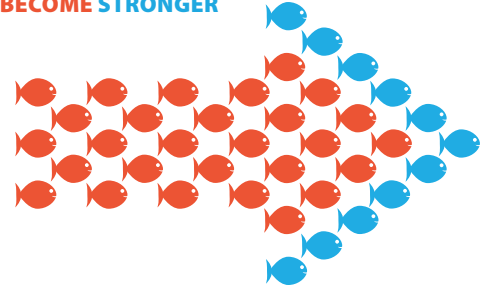
a process that optimizes care. The PQI fosters this through appropriate patient identification, selection, increased speed to therapy, reduced cost, and hospitalization and by improving adherence techniques for the patient and their Medically Integrated Teams.

“That personalized touch on the prescription, I think is a real benefit for the patient. Not only that, but especially if we can fill it. It helps the patient with keeping them on track with their medicine. I think the adherence is better. The MID provides a white glove service to our patients ensuring that they receive the appropriate care whether we are filling the prescription or not. We take pride in knowing our patients are taken care of throughout their journey.” Carol Hemersbach, CPhT, BSHCA, IOD Supervisor

Darolutamide gives patients with metastatic hormone-sensitive prostate cancer a new preferred treatment option. The PQI provides the MID program with an easy to use, compact clinical resource guide when discovering the right patient and dispensing darolutamide. It helps the team ensure they are

providing patients with the tools and education to improve clinical outcomes. Pairing Medically Integrated Dispensing with the Darolutamide (NUBEQA®) in Combination with Docetaxel (TAXOTERE®) for Metastatic Hormone Sensitive Prostate Cancer PQI meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.

**WORKING TOGETHER,
WE BECOME STRONGER**



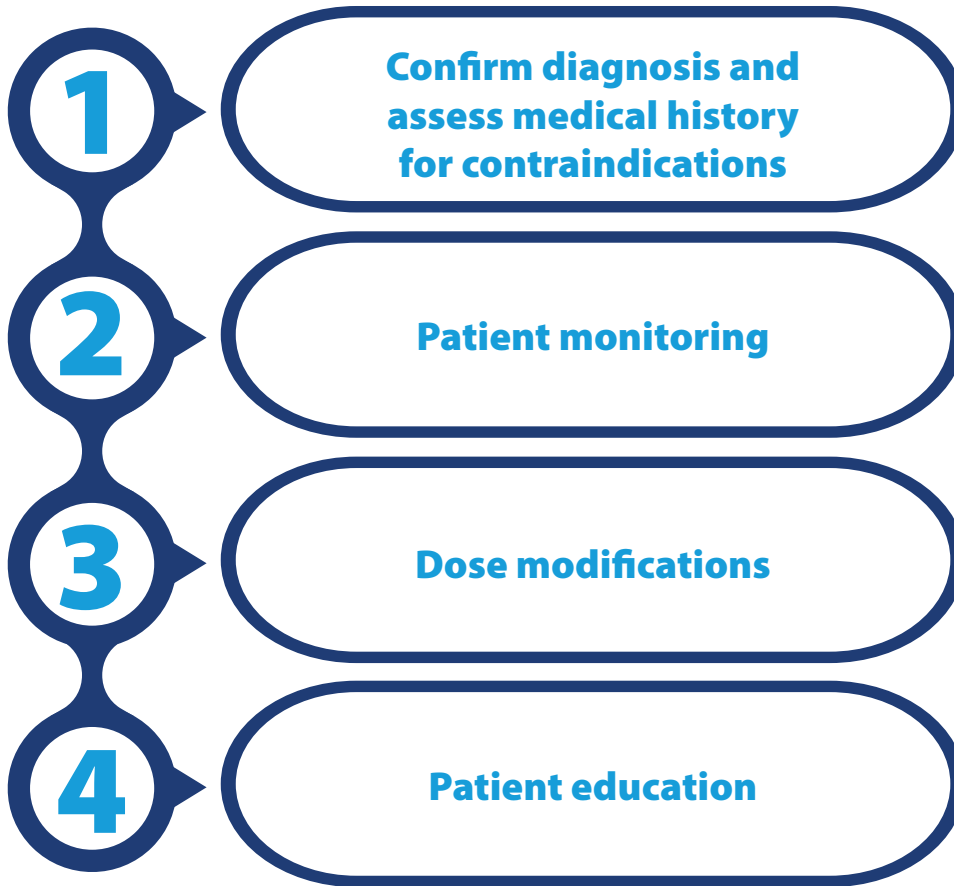
Helpful Online Resources

- [NCODA Website](#)
- [Positive Quality Interventions](#)
- [Darolutamide \(NUBEQA®\) in Combination with Docetaxel \(TAXOTERE®\) for Metastatic Hormone Sensitive Prostate Cancer PQI](#)
- [NCODA OCE Sheets](#)

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PQI PRINCIPLES:

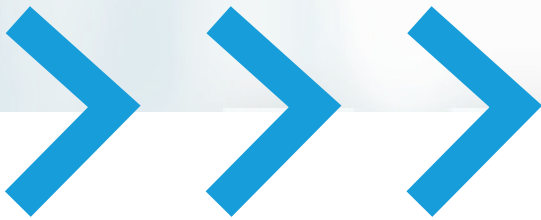


ON THE COVER:

- Medically Integrated Dispensing staff at Illinois CancerCare provides excellent patient care.

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

Important notice: NCODA has developed this Positive Quality Intervention in Action platform. This platform represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and 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 discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.



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