

PQI IN ACTION



**DAROLUTAMIDE (NUBEQA®) IN
THE TREATMENT OF NON-METASTATIC
CASTRATION RESISTANT 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 document 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 the Treatment of Non-Metastatic Castration Resistant Prostate Cancer PQI** and explores how the medically integrated teams at Chesapeake Urology, a member of the United Urology Group and The Urology Group incorporate PQI's as part of their daily workflow. It will discuss how utilizing the **Darolutamide (NUBEQA®) In the Treatment of Non-Metastatic Castration Resistant Prostate Cancer PQI** elevates patient care.

Chesapeake Urology, a member of the United Urology Group, is the largest urology practice in Maryland and the Mid-Atlantic region, providing a comprehensive array of urologic services to patients. Chesapeake Urology operates 24 medical offices and 18 AAAHC-certified ambulatory surgery centers in Anne Arundel, Baltimore, Harford, Howard, Carroll, Montgomery, Prince George's, Wicomico, Worcester, MD counties, Baltimore City, and Sussex County, DE, and has a staff of more than 900 including 90 physicians, 84 of whom are urologists. United Urology Group, formed in August 2016, is a management services organization that has created a national network of urology affiliates which provide the highest quality, most fully-integrated urology care available to patients.

The Urology Group, an affiliate of Solaris Health, is one of the largest single specialty groups of urologists in the United States. Their group consists of more than 34 board-certified urologists with 11 locations in Ohio, Kentucky, and Indiana, and a state-of-the-art outpatient surgery center located in Ohio. Together, they offer their patients a comprehensive team of urologic healthcare providers – Greater Cincinnati's and Northern Kentucky's premier healthcare resource in this specialty. Their unique model immediately transitions a prostate cancer patient to a specialised team that works only with prostate cancer. According to Gary Kirsh, MD with The Urology Group "they all fit together very well because of the fundamental premise of the model." He goes on to state that each provider is, "trained, committed, and an expert in prostate cancer."

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THE PARTICIPANTS

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Advanced Prostate Cancer
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The Urology Group Cincinnati, OH



Gary Kirsh, MD
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Group



Melissa Ruter, PharmD
Pharmacist



Angela Hunter, BSN, RN
Manager of Navigation

PROSTATE CANCER THERAPY AND THE MID: BENEFICIAL FOR PATIENTS AND PRACTICES

Prostate cancer is the second most common cancer among men in the United States, following only non-melanoma skin cancer.¹ It is also one of the leading causes of death in men of any race.¹ When a patient's prostate cancer recurs after primary treatment, androgen deprivation therapy becomes part of the standard of care. However, even with androgen deprivation treatment, many of these men will still have disease progression. For those patients classified as having non-metastatic castration-resistant prostate cancer (nmCRPC), delaying the development of metastases is a key therapeutic goal.² NUBEQA® (darolutamide) is a next-generation androgen receptor antagonist approved in 2019 for the treatment of nmCRPC.³ Urologists are in a unique position to treat these patients as they often are seeing the patient from their initial diagnosis and treatment of prostate cancer. Both Chesapeake Urology and The Urology Group manage patients taking darolutamide through the Medically Integrated Dispensaries (MID).

NCODA defines Medically Integrated Dispensing (MID) as a dispensing pharmacy within an oncology center of excellence, including urology centers, that promotes a patient-centered, multidisciplinary team approach. The MID is an outcome-based collaborative and comprehensive model that involves oncology health care professionals and other stakeholders who focus on the continuity of coordinated, quality

care and therapies for cancer patients.⁴ The MID model can improve management of patients on therapies like darolutamide in several ways including improved communication issues, measuring adherence, managing regimen changes, speed to initiation, increased patient satisfaction, financial assistance, cost avoidance and producing less waste.⁵ 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, a Financial Assistance database, Treatment Support Kits, Oral Chemotherapy Education sheets, and of course the Positive Quality Intervention clinical resource. Gary Kirsh, MD from The Urology Group shares, "I really recommend the integration of all services under one roof for patient care."

"I REALLY RECOMMEND THE INTEGRATION OF ALL SERVICES UNDER ONE ROOF FOR PATIENT CARE."

Gary Kirsh, MD

THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

As cancer treatment continually grows in complexity containing injectable, oral, and combination regimens, the MID continues to offer an instrumental option for patient care. This article will explore the benefits of PQI utilization as a core standard of the MID and how adoption can benefit any practice.

Chesapeake Urology's urologist Benjamin Lowentritt, MD shares that "we have spent a lot of time developing our best practices. So, having these kinds of tools, like the PQIs, is really helpful. Especially as new drugs or new indications come out; being able to just go to it is very helpful." He

"HAVING THESE KINDS OF TOOLS, LIKE THE PQIs, IS REALLY HELPFUL."

Benjamin Lowentritt, MD

goes on to say, "from a provider standpoint, to have a resource that's just a quick reminder, that hits the high points, helps to identify the patient appropriately, point out what are those special considerations that I need to know, that's

really, really helpful. It provides a kind of checklist for our dispensing team, as well.”

The Urology Group and Chesapeake Urology have both found successful ways to incorporate the PQI clinical resource tool. Each practice positions their Medically Integrated Teams in a way to ensure appropriate treatment, increase compliance, and maximize clinical outcomes. We will take a look specifically at their MID settings, how im-

plementing the **PQI Darolutamide (NUBEQA®) In the Treatment of Non-Metastatic Castration Resistant Prostate Cancer** benefits their staff and patients, and how they advance patient care on a daily basis.

SCAN THE QR CODE
TO VIEW THIS PQI



MEDICALLY INTEGRATED DISPENSING: ELEVATING CARE



A pharmacy technician at The Urology Group provides a prescription to a patient.

The MID staff has unparalleled access to patient information and means of direct communication with other members of the multidisciplinary team, making the MID staff indispensable. The MID team also has direct access to communication with patients and can easily report information back to the clinic staff. This model greatly reduces fragmentation of care. For example, Maria Webster with Chesapeake Urology focuses on patient identification and patient communication. She states, “every one of the patients has my cell phone number. If a patient has any issues, they may reach out to me. I’ll then reach out to the appropriate person and we navigate them through the continuum of care. We hold their hands until we can no longer hold their hands. That is how I live my life; every day with these patients. It’s a 24/7 job! Actually, I don’t even consider it a job; it’s an honor.”

**“I DON’T EVEN CONSIDER IT A JOB;
IT’S AN HONOR.”**

Maria Webster

The dedication of the MID is unparalleled. Maintaining a good relationship with great communication between the patient and the medically integrated team is important to adherence.⁹ This is a perfect example of how the MID is continually elevating care. The maintenance of open communication can help patients feel like they can be honest with their team about side effects, compliance, etc. This in turn allows the team to be able

**“THE GOAL IS TO BE AS INVOLVED AS
YOU CAN BE IN THE PATIENT CARE
PROCESS.”**

Melissa Ruter, PharmD

to better support the patient and improve outcome. Melissa Ruter, PharmD from The Urology Group echoes Maria’s comments stating, “the goal is to be as involved as you can be in the patient care process.”

QUALITY STANDARDS: POSITIVE QUALITY INTERVENTION

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. Natasha Brewer, CPhT of Chesapeake Urology was tasked with standardizing operations and implementing policies and procedures to ensure appropriate treatment, increase compliance, and maximize clinical outcomes at her practice. All the while upholding the practice vision of, “a superior experience.” She states that, “the PQI essentially is a great check and reinforces what we currently do.” Melissa Ruter, PharmD of The Urology Group also says that her practice uses the PQI to, “make sure we check all of our boxes” and that they have “taken a lot from the PQI.”

✓ **VERIFY APPROPRIATE DIAGNOSIS AND DOSE**

✓ **CHECK FOR DRUG INTERACTIONS**

✓ **EDUCATION**

✓ **MONITOR FOR LABS**

✓ **COMMUNICATION AND FOLLOW UP**

PUTTING THE DAROLUTAMIDE PQI INTO ACTION

The **Darolutamide In the Treatment of Non-Metastatic Castration Resistant Prostate Cancer** PQI is written beginning with a description of what the PQI will cover followed by a background section which gives the reader pertinent information regarding trail data and other helpful information for member of the medically integrated team.¹⁰ Regarding darolutamide, the document discusses that the drug was given a category 1 recommendation by NCCN for patients with nmCRPC and a prostate specific antigen doubling time (PSADT) of ≤ 10 months based on the results of the phase 3 ARAMIS trial.⁶ This trial demonstrated that darolutamide 600mg twice daily improved median metastasis-free survival versus placebo in this patient population.² Angela Hunter, BSN, RN of The

Urology Group appreciates the quick summary of the studies and states, “the PQI has the study right there for us. The PQI is a good reference for me to quickly look at when I’m talking to the patient, because a lot of patients are more internet savvy and I find them asking more questions about what the studies show.”

Dr. Lowentritt goes into the specifics and importance of patient identification, “the big issue with NUBEQA® currently is its indication is very specific and this is probably the smallest subset of patients within our overall prostate cancer population. In order to be a candidate for NUBEQA® you need to have no evidence of metastases, yet have evidence of castrate resistant disease, which that in and of itself is a fairly small group of patients... It is a subset of a subset and these are very specific patients, but the benefit is so dramatic that you really want to look for them.”

**“THE PQI IS A GOOD REFERENCE FOR
ME TO QUICKLY LOOK AT WHEN I’M
TALKING TO THE PATIENT.”**

Angela Hunter, BSN, RN


NUBEQA®
(darolutamide) 300 mg
tablets

THE PQI PROCESS: A TEAM EFFORT

Following, is the PQI process section of the Darolutamide PQI.¹⁰ This section of the document gives readers a step by step process to follow. This section lays out the intervention, contains clinician directed guidance, and critical clinical criteria that potentially could be missed or overlooked if not delivered in the PQI. This section is where the MID should begin upon receipt of an order for darolutamide.

At The Urology Group, the practice has a collaborative process to ensure that the patient is getting the best care possible. Following the PQI process, Melissa Ruter, PharmD verifies the diagnosis of nmCRPC, the appropriate dosing, and screens for drug interactions.¹⁰ She not only collaborates with physicians in the practice, but also outside of the practice to make sure that all people involved with the patient's care are up to date and on the same page.

Lori Rossi, CPhT of Chesapeake Urology explains how having the MID and implementing the PQI improves care. "Having the MID onsite and being able to see the doctors and patients face to face, allows MID staff members to build

relationships with patients and doctors, allowing the patients to be more comfortable with the people dispensing their medications, and maybe a little more at ease regarding their illness. We build relationships with these patients, and they trust us with their medications." Lori goes on to explain how the ease of communication between the medically integrated team keeps physicians in tune with the patients care throughout the process.

The last section of the darolutamide PQI Process section gives the team information on the DUDE Access Services Patient Service Request form that can help patients receive a complimentary trial while waiting on prior authorization from insurance and assessing for tolerability. The Co-pay Assistance section gives the link for co-pay assistance for patients with private insurance (<https://www.nubeqacopay-program.com>). Both practices have extensive experience with the DUDE Access program, but still touch base with patients to keep the continuity of care in place.

PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

The Patient-Centered Activities section follows the PQI Process and gives specific patient-centered guidance for the team. The first point of the darolutamide PQI Patient-Centered activities is to ensure the patient is receiving a concomitant gonadotropin releasing hormone (GnRH) antagonist. Melissa Ruter, PharmD of The Urology Group touches on the complexity of the darolutamide regimen and this specific point, "we need to make sure that they know they are not going off of their shots (GnRH antagonist) because that is something patients assume. That they are starting a new medicine and that the other one wasn't working so they're stopping it." She goes on to suggest the darolutamide PQI provides a valuable double check to ensure patients continue their GnRH injections.

The next point on the darolutamide patient-centered activities section is reviewing potential side effects with patients. Ac-

**"WE GO OVER THE MEDICATION
WITH THE PATIENT FROM TOP
TO BOTTOM."**

Angela Hunter, RN

According to publication, darolutamide has a distinct structure that offers a potential for less severe toxic effects because of its low penetration of the blood-brain barrier and low binding affinity for γ -aminobutyric acid type A receptors.² According to the ARAMIS trial, safety data indicated no clinically relevant difference between darolutamide and placebo in the incidence of adverse events that occurred during the treatment

period, including falls, fractures, seizures, cognitive disorders, and hypertension.² The most common adverse events include fatigue, decreased neutrophil count, elevated liver function tests, pain in extremities and rash.⁷

Much of the important educational information for patients can be found in the NCODA-led Oral Chemotherapy Education (OCE) sheets. Both participating practices take patient education very seriously and have it as a foundational element of their oral oncolytic programs. 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.⁸ 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's 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.⁸



The Urology Group in Cincinnati, OH.

contact me if they have any questions. They've always got the information they need and the contact information handy. I find that the oral chemo education sheets are a little bit more refined to the need-to-know basics for the patient."

Monitoring for toxicities is also imperative. Veronica Young, RN, OCN from Chesapeake Urology is a nurse navigator. The role of the navigator has been a valuable role in the Chesapeake Urology system. These passionate individuals have not only helped with education and logistics, but play an integral role in patient follow up. Veronica touched on her role, "of course compliance is always an issue. It could be from forgetting to refill, or refilling the medication when they have already run out, or they are having side effects." Instead of finding out weeks after the fact, by calling, Veronica is able to bridge the communication between the patient and the provider. Veronica states, "I am able to review with Dr. Lowentritt any issues that the patient may be having." Natasha Brewer, CPhT also with Chesapeake Urology has taught the pharmacy staff to ask probing questions to follow up on side effects. These "probing questions," as she calls them, help to identify any issues the patient may be having with the medication. Because their team has developed such a good relationship with each patient, they feel more comfortable talking about uncomfortable side effects. Natasha states, "I personally love having that relationship with these patients. It certainly does hit hard when we lose someone, because you really do learn about these patients and their families and you are a part of their lives and they are part of yours."

"YOU ARE A PART OF THE PATIENTS' LIVES AND THEY ARE PART OF YOURS."

Natasha Brewer, CPhT

At The Urology Group, the patient gets education from many different people. Both Melissa Ruter, PharmD and Angela Hunter, RN tackle the education of patient. Melissa is able to catch patients at the first fill. Angela and her team of nurse navigators follow up after everything is in place. Angela states, "we go over the medication with the patient from top to bottom: how it's taken, side effects/what to look for, blood work, how to store the medication." Melissa shares that the customizability of the OCE sheets are of great value to her; "I add my contact information at the end, so that they can

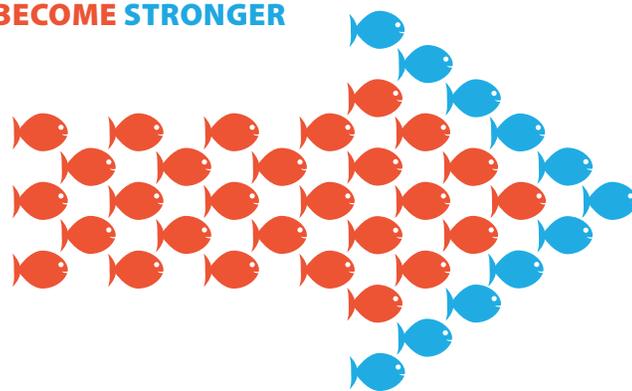
CONCLUSION: NCODA, THE MID, AND PQI: OPTIMIZING PATIENT OUTCOMES

All team members agree that the MID model and the PQI Clinical Resource are valuable to the team and to patients. It has been shown time and time again that fragmented care can lead to increased spending, but more troubling, worse clinical outcomes for the patient.¹¹ Both Chesapeake Urology and The Urology Group have made it their mission to combat fragmented care on a number of fronts. A consistent theme across both practices is the dedication and passion for patients.

Every day the MID team has the opportunity to make a difference in the life of patients. Every day the team can learn something new or can begin a process that optimizes care. The PQI fosters this through the identification of the appropriate patient, accurate selection, increased speed to therapy, reduced cost, and by improving adherence techniques for the patient. Darolutamide gives a specific population of non-metastatic prostate cancer patients another treatment option to help improve metastasis-free survival and overall survival through a novel agent.¹² The PQI gives the MID program an easy to use, succinct clinical resource guide for identifica-

tion of the right patient and best practices for the treatment of a darolutamide patient. 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 PQI meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.

**WORKING TOGETHER,
WE BECOME STRONGER**



REFERENCES

- Centers for Disease Control and Prevention. Prostate Cancer Statistics. <https://www.cdc.gov/cancer/prostate/statistics/index.htm>. Accessed February 2021.
- Fizazi K, Shore N, Tammela TL, et al. "Darolutamide in Non-metastatic, Castrate-Resistant Prostate Cancer." *N Eng J Med*. 2019; 380:1235-1246.
- Bastos DA, Antonarakis ES. Darolutamide for castration-resistant prostate cancer. *Onco Targets Ther*. 2019; 12: 8769 – 8777.
- NCODA. NCODA Announces the defining of the Medically Integrated Dispensing Pharmacy. <https://www.ncoda.org/medically-integrated-dispensing-pharmacy/>. February 2021.
- Wimbiscus, Bill. "Medically Integrated Dispensing: An Alternative to How Oral Drugs Get Dispensed." *Am J Manag Care*. March 14, 2019. <https://www.ajmc.com/view/medically-integrated-dispensing-an-alternative-to-how-oral-drugs-get-dispensed>. Accessed February 2021.
- National Comprehensive Cancer Network. Prostate cancer. NCCN Clinical Practice Guidelines in Oncology. Version 2.2021 – February 17, 2021. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 2021.
- NUBEQA® (darolutamide) [prescribing information]. Whippany, NJ; Bayer HealthCare Pharmaceuticals Inc: 2019 (Revised 1/2021).
- Dillmon MS, Kennedy EB, Anderson MK, et al. "Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards." *J Clin Onco*. 2019;38(6):633-644.
- McCue DA, Lohr LK, Pick AM. Improving Adherence to Oral Cancer Therapy in Clinical Practice. *Pharmacotherapy*. 2014;34(5):481-494.
- Phillips. Positive Quality Intervention: Darolutamide In the Treatment of Non-Metastatic Castration Resistant Prostate Cancer. NCODA. <https://www.ncoda.org/darolutamide-in-nmcrpc/>. Accessed February 2021.
- Skolarus TA, Zhang Y, Hollenback BK. Understanding Fragmentation of Prostate Cancer Survivorship Care Implications for Cost and Quality. *Cancer*. 2012; 118(11) 2837-2845.
- Fizazi K, Shore N, Tammela TL, et al. "Nonmetastatic, Castrate-Resistant Prostate Cancer and Survival with Darolutamide." *N Eng J Med*. 2020; 383:1040-1049.

PQI PRINCIPLES:

1

Identify eligible nmCRPC patients as potential candidates for darolutamide

2

Dose adjustments when necessary

3

Screen for drug interactions

4

Patient education



Helpful Online Resources



NCODA Website



Positive Quality Interventions



Oral Chemotherapy Education Sheets



Darolutamide (Nubeqa®) in the Treatment of Non-Metastatic Castration Resistant Prostate Cancer PQI

ON THE COVER:

- Dr. Lowentritt consults with a patient.

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

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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