

PQI IN ACTION

NCODA's POSITIVE QUALITY INTERVENTION IN ACTION >>>>



DAROLUTAMIDE IN THE TREATMENT OF NON-METASTATIC CASTRATION RESISTANT PROSTATE CANCER (NMCRPC)



PASSION FOR PATIENTS
ncoda.org

INTRODUCTION

In an effort to promote higher quality patient care the 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 oncology. This *PQI in Action* is a follow up to the Nubeqa (darolutamide) PQI and explores how the medically integrated teams at Florida Cancer Specialists and Regional Cancer Care Associates - Central Jersey Division incorporate PQI's as part of their daily workflow. It will discuss how utilizing the **Darolutamide in the treatment of non-metastatic castration resistant prostate cancer (nmCRPC)** PQI elevates patient care.

Florida Cancer Specialists and Research Institute (FCS) is the one of the largest independent medical oncology/hematology practices in the United States with over 250 physicians and 220 nurse practitioners and physician assistants. They provide oncology care in the community setting at almost 100 locations. Rx To Go is the in-house pharmacy for FCS and provides convenient dispensing and delivery of oral oncology medications to FCS patients. Rx To Go is staffed by qualified pharmacists and trained support personnel and assists their patients in achieving optimal clinical outcomes while effectively managing the cost of therapies.

Regional Cancer Care Associates - Central Jersey Division (RCCA-CJ) is located in New Jersey and has 25 medical oncologists and 11 radiation oncologists. They have six medical oncology locations and six radiation oncology locations. RCCA-CJ offers the most advanced treatments, including immunotherapy and targeted therapy. Their MID pharmacy, RCCA Pharmacy, collaborates with practice physicians, insurers and other healthcare providers in order to achieve the best possible outcomes for patients utilizing their pharmacy services.

THE PARTICIPANTS

Florida Cancer Specialists and Research Institute **Ft. Myers, FL**



Vijay Patel, MD
Hematologist-Oncologist



Kelly Jo Henson, PA
Physician Assistant



Katherine Hogan, RPh
Director of Pharmacy, P.I.C.
Rx To Go, LLC



Natasha Khrystolubova, RPh, BPharm, BCOP
Associate Director of Pharmacy Clinical Services
Rx To Go, LLC



Rebecca Garland, RPhT
Pharmacy Adherence Manager
Rx To Go, LLC

Regional Cancer Care Associates, Central Jersey Division **East Brunswick, NJ**



Ellen Ronnen, MD
Hematologist-Oncologist



Eileen Peng, PharmD
Practice Administrator and Pharmacy Manager



Shivangi Patel, BSN, RN
Triage Nurse



Claudia Sarmiento, CPhT
Pharmacy Technician

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

Prostate cancer is the second most common cancer in 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. Even with receiving this androgen-deprivation therapy, many of these patients will 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 Both RCCA-CJ and FCS manage patient taking darolutamide through the Medically Integrated Dispensing (MID) model.

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 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 therapy, 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



An FCS pharmacy technician prepares a Nubeqa prescription.

Avoidance and Waste Tracker, a Financial Assistance database, Treatment Support Kits, Oral Chemotherapy Education sheets, and of course the Positive Quality Intervention clinical resource. RCCA-CJ Practice Administrator and Pharmacy Manager Eileen Peng shares the biggest value of MID is that “we have access to the physicians, access to the healthcare workers and we have access to the patient so we are actually able to monitor their treatment with the potential toxicity and everything.” She goes on to say that with this monitoring “we are able to improve clinical outcomes while saving the healthcare system a lot of cost and waste.”

**“WE ARE ABLE TO IMPROVE
CLINICAL OUTCOMES WHILE
SAVING THE HEALTHCARE SYSTEM
A LOT OF COST AND WASTE.”**

Eileen Peng, PharmD

THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

**THE PQI IS “AN ADDED LAYER OF
SAFE-GUARDING. IT GOES OVER THE
DOSE, IT GOES OVER LABS, DRUG IN-
TERACTIONS, LOOKING FOR ANY SIDE
EFFECTS AND TALKING ABOUT WHAT IS
IMPORTANT TO THE PATIENTS.”**

Ellen Ronnen, MD

RCCA-CJ medical oncologist Dr. Ellen Ronnen shares that to her the PQI (www.ncoda.org/darolutamide-in-nmcrpc/) “is an added layer of safe-guarding. It goes over the dose, labs, drug interactions, looking for any side effects and talking about what is important to the patients.” FCS Medical Oncologist Dr.

Vijay Patel expresses that he finds the PQI to be “a phenomenal document” that is “really well written.” He adds that it can be “pretty convenient for physicians. It’s a good document to have in that it actually double checks certain things, two eyes are better than one.”

This article will explore the benefits of PQI utilization as a core standard of the MID and how adoption can benefit any practice. RCCA-CJ and FCS 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 implementing the PQI darolutamide in the treatment of non-metastatic castration resistant prostate cancer (nmCRPC) benefits their staff and patients, and how they advance patient care on a daily basis.

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 Medically Integrated Team has unparalleled access to patient information and means of direct communication with other members of the multidisciplinary team. FCS Physician Assistant Kelly Jo Henson says that it is easier to communicate with her MID pharmacy Rx To Go than outside pharmacies. She adds that Rx To Go always alerts her of any patient issues and provides a great system of “checks and balances.” Dr. Vijay Patel agrees and elaborates, “a lot of people are looking at the same charts along with you, and not just the providers, the pharmacists and so forth.” He continues and says the FCS MID “is an amazing system. It’s quick, it’s easy. It’s easy communication between my staff members.”

**“THE MINUTE THE DOCTOR REQUESTS
THE MEDICATION WE START ROLLING
AND WE AIM TO GET ALL OF OUR
PATIENTS THEIR MEDICATIONS AS
SOON AS POSSIBLE.”**

Claudia Sarmiento, CPhT

RCCA-CJ Triage Nurse Shivangi Patel explains that MID is more convenient for patients because they can get everything treatment related taken care of in one place. She says that when medications must be filled outside of this model she often sees “delays in therapy.” RCCA pharmacy technician Claudia Sarmiento shares that MID “is beneficial, very much so,” because the MID staff has “some type of connection” with the patients. She adds the MID pharmacy is providing the medication “in a faster time frame” since they have dedicated staff who complete prior authorizations and verification of benefits more efficiently than outside mail order pharmacies. “The minute the doctor requests the medication we start rolling and we aim to get all of our patients their medications as soon as possible.”



An automated system that FCS uses to improve prescription filling efficiency.

POSITIVE QUALITY INTERVENTIONS: QUALITY STANDARDS IN CANCER CARE

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. Dr. Ronnen states “I think standards and gold standards are really important when you are dealing with chemotherapy, hormonal therapy, or immunotherapy.” She adds, “and especially for oral drugs, the issue becomes the patients are not in the office as much.” Her practice is QOPI (Quality Oncology Practice Initiative) certified and she has worked extensively with Peng on various pharmacy projects including QOPI requirements surrounding oral oncolytics and many others. Regarding the PQI and standardization she says, “you need to have policies that standardize how you are administering oral and IV therapies and these documents are really helpful for individual drugs because there is a void in that space.”

FCS Associate Director of Pharmacy Clinical Services Natasha Khrystolubova, RPh, BPharm, BCOP helps design and implement clinical processes in her MID pharmacy. She comments that the darolutamide PQI is a valuable resource

for practices with MID because “it’s wonderful that the whole process is well written out, what to watch for when the electronic order comes in. It’s very clear what to look for right from the start. You look for diagnosis, you look for the dose. It very clearly says you look at the renal function, you look at the liver function, you look at baseline labs and the drug interactions. So, all of this is really great.” Peng agrees and adds, “for me it is easier to have everything in one place where I can get all of the talking points. When we look at the manufacturer’s prescribing information, we still have to figure out what is important and what is relevant.”

**“YOU NEED TO HAVE POLICIES THAT
STANDARDIZE HOW YOU ARE ADMINISTERING
ORAL AND IV THERAPIES AND THESE DOCUMENTS
ARE REALLY HELPFUL FOR INDIVIDUAL DRUGS
BECAUSE THERE IS A VOID IN THAT SPACE.”**

Ellen Ronnen, MD

PUTTING THE DAROLUTAMIDE PQI INTO ACTION

The darolutamide in the treatment of non-metastatic castration resistant prostate cancer PQI is written in sections beginning with a description (summary) and ending with supplemental information 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, it 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 Khrystolubova comments, “this is a really important space in prostate cancer because this is non-metastatic so you are trying to prevent metastatic disease.” She goes on, “that is why it is important that we find this category of patients, identify them early and put them on the appropriate therapy.”



Dr. Ronnen discusses her general procedure for determining if a patient is a candidate for a drug and explains, “we do a history of disease in terms of disease treatment and standards of care.” She then looks at available treatment options and states “a big part of the discussion is the status of the patient and the side effects they might experience.” Dr. Vijay Patel comments that the urologists in his area are very savvy and work with him when they feel a patient is in need of an Axumin PET scan because FCS has this scanning capability. He says the rising PSA is usually an indication that patients may need to start on some type of therapy.

“IT IS IMPORTANT THAT WE FIND THIS CATEGORY OF PATIENTS, IDENTIFY THEM EARLY AND PUT THEM ON THE APPROPRIATE THERAPY.”

Natasha Khrystolubova, RPh, BCOP

THE PQI PROCESS: A TEAM EFFORT

The next section of the darolutamide 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 has the potential to 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.

Both practice participants build oral care plans into their EMR systems as another method of ensuring all crucial elements are part of the process. A pharmacy and clinic shared EMR system as well as pharmacist guidance in creating the oral care plans is another benefit to patient care that sets the MID apart. When an oral therapy like darolutamide comes to market, Peng assists in building this care plan in her practice

and includes lab schedules, side effects and more. Regarding care plans, she states “We always consult the PQI as a guide. If we have questions, we always go back to the PQI as our reference.” She elaborates that when they give providers and staff a printed paper or even a website, “there is no guarantee that they will remember to log on, so we try to incorporate the PQI into the care plan.”

FCS also uses their EMR system for new oral starts. Dr. Vijay Patel appreciates the flow sheet in his EMR. He can simply “click in this flow sheet and it already has the algorithms in there” concerning scans, labs, etc. Khrystolubova discusses working with the FCS team to build the regimens and says it is part of “integrated clinical services within the FCS practice.” She explains that the pharmacy team talks to integrated

services about what to address in the regimen including side effects and important points that require emphasis. She says each regimen is in EMR and when the physician selects the regimen it creates the flow sheet that Dr. Patel uses and “will provide warnings and precautions” when warranted.

“WE ALWAYS CONSULT THE PQI AS A GUIDE. IF WE HAVE QUESTIONS, WE ALWAYS GO BACK TO THE PQI AS OUR REFERENCE.”

Eileen Peng, PharmD

The darolutamide PQI process walks the team through various clinical steps in filling the prescription beginning with verifying a diagnosis of nmCRPC, ensuring an appropriate dose, verifying labs, and screening for clinically relevant drug interactions. At FCS, the pharmacists follow these steps. Khrystolubova explains that when the MID pharmacy receives the prescription, “first we need to look at the disease state. We want to make sure this is the correct diagnosis, non-metastatic castrate-resistant prostate cancer.” She goes

on, “we want to make sure that the dose is checked, we will look at the eGFR and creatinine clearance. We will look for hepatic impairment, we look at the baseline testosterone. We check everything and we check the physician’s notes, that is why it is so crucially important for us that we have this EMR.” Peng comments that her MID pharmacy screens for drug interactions with darolutamide. She says, “we have the medication profile for every patient, we follow the medication reconciliation in EMR for every patient and update it in the dispensing system and screen for interactions.” Henson finds the “double check” by the pharmacy of “interactions, side effects, and dosing” to be one of the biggest values of the MID platform. Shivangi Patel feels the “PQI process really standardizes things” and finds information on dose modifications to be one of the most useful parts of the darolutamide PQI.

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 2-month free 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.nubeqacopayprogram.com>) Sarmiento appreciates this section of the PQI and shares, “I think co-pay assistance is always, always a big thing for patients and very important.”

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 first point of the darolutamide PQI Patient Centered activities is to ensure the patient is receiving a concomitant gonadotropin releasing hormone (GnRH) antagonist. Peng explains that RCCA-CJ ensures all supplemental medications are in the care plan, “so when a physician initiates Nubeqa they will follow the care plan and write any orders for medications to go with Nubeqa. Everything initiates with the care plan.” This section of the PQI continues with guidance to ensure patients are educated on taking darolutamide twice daily after a meal, swallowing the tablets whole, and storing in the original container. Where darolutamide is concerned, Peng mentions her MID pharmacy “always asks our patients to store the medication in the original container, we do not take it out of the original package.”

The next point on the darolutamide patient centered activities section is reviewing potential side effects with patients. 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 Khrystolubova comments that she has heard from various physicians that darolutamide is well tolerated “because it doesn’t hit the CNS, so it doesn’t have penetration into the CNS, so we can avoid a lot of those cognitive side

PATIENT CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS CONTINUED

effects with this drug.” She believes this is important because “a lot of these patients are younger and are still working and very active and they have families and they just want to have a good quality of life.” She continues and explains that according to the most prominent darolutamide publications, the side effects are “very comparable to placebo.”

Dr. Vijay Patel shares, “I always go over side effects, that is definitely the most important thing, because if a patient is prepared for a side effect, they know exactly what to do and we can keep these patients on these medications longer.” He continues “if they know what to expect they are better prepared; they are better at preventing their own side effects.” He says they also tell patients to swallow the pills, “for example Nubeqa cannot be crushed. We educate them on twice daily after meals.” He feels making sure the patient understands the correct dosing schedule is of utmost importance. He also comments on the need for patients to let the physician know when they stop taking a medication and that he educates patients on the need to let the office know if they do decide to stop for any reason, “we need to know how long you have been on medications and so forth.”

The darolutamide Patient Centered Activities section also includes points about counseling patients regarding risk of embryo-fetal toxicity and monitoring for toxicities warranting dose adjustments. Much of the important educational information for patients can be found in the NCODA-led Oral Chemotherapy Education (OCE) sheets. (www.oralchemoedsheets.com/) 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 physicians 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

RCCA builds the educational information into their care plan, and then Advanced Practice Providers complete the “chemo teach” with the patients. Peng shares that during the teach the providers rely heavily on the care plan and says it a “standard way for pharmacy to communicate with providers and guide them in what needs to be talked about.” Peng adds that when educating patients on starting darolutamide, her practice lets the patient know to “make sure they reach out to us when they experience anything unusual and they need to keep their lab appointments because it is important for us to follow their blood counts, liver function, and renal function. Also, if they start any new medication, they need to let us know because there might be a drug interaction.” Sarmiento comments, “the Patient Centered Activities section gives me written information that the patient needs because sometimes they forget or just get overwhelmed with information.” This is why both practices also see the importance in following up with patients.

**“THE PATIENT CENTERED
ACTIVITIES SECTION GIVES ME
WRITTEN INFORMATION THAT
THE PATIENT NEEDS BECAUSE
SOMETIMES THEY FORGET OR
JUST GET OVERWHELMED WITH
INFORMATION.”**

Claudia Sarmiento, CPhT

ADHERENCE AND FOLLOW UP: KEEPING PATIENTS ON THERAPY

Khrystolubova says the FCS MID pharmacy Rx To Go has a focus on adherence and their goal is for patients to stay on therapy. She explains, “this has been our focus since 2013 when we implemented the adherence program within our practice.” She continues, “we are going to call either weekly or bi-weekly depending on when the side effects may start and we just want to make sure we reinforce the supportive care for the side effects.” She says a lot of the drug education and side effect support “needs to be reinforced and followed up.” Her MID pharmacy builds elements into their own patient management system called ORCA and tries to prevent and manage potential therapy issues from the front-end. She comments, “we don’t wait, we are very proactive.”

One proactive measure that Rx To Go takes is giving every patient a supportive care kit with every therapy. They use a combination of kits from the manufacturer with their own supplemental material added and the NCODA Treatment Support Kits (www.ncoda.org/treatment-support-kits/). Khrystolubova explains it is better for the practice to provide information up front to the patient instead of the patient having to go “on google and search and find all this information which could be scary.” The MID pharmacy trains their pharmacists how to speak on the kits and use them as an educational tool. Khrystolubova shares, “that is why support care kits are important, and anything additional that can be sent to a patient in a nice package that looks professional and well done represents us in a good way.” She says patients appreciate having something to start with when beginning therapy.

RCCA-CJ also has close follow up with their MID patients. Peng describes their process, “the pharmacy team calls the patient constantly before a refill goes out. We will contact the patient and ask them how many pills they have left and set up the delivery date and ask the patient if they have any questions or anything that we need to know. There are many times when in fact that patient will mention something to the pharmacy team. The team will reach out to the physician and voice the patient’s concern. We also read the physician visit note before we reach out to the patient and read the com-



The nursing triage team at RCCA-CJ.

munication with the physician and nurses.” In this process she says the pharmacy team often picks up on adverse events and possible dose changes. She adds that the patient often mentions something to the MID pharmacy team that they do not mention to the physician and this can be communicated to the physician and documented in the EMR.

Garland is a manager for a full team of technicians and explains FCS uses her team “to contact patients to check on them and see how they are doing with their medication.” She shares, “we actually ask the patient some quality of life questions, and ‘have you missed any doses?’ If so, we try to figure out why.” They keep track of refills and look for opportunities for re-counseling for the patient. If they find this opportunity, “we would get a pharmacist involved or contact the clinic for the nurse or physician to touch base and re-education.” Creating and maintaining a good relationship between the patient and the healthcare provider is an important aspect of medication adherence.⁹ Maintaining open communication can help a patient feel like they can be honest with their health care team and that the team is there to assist them.⁹

PQI SUPPLEMENTAL INFORMATION: PROVIDING ADDITIONAL VALUABLE INSIGHTS

The last section of the PQI (other than references) is the Supplemental Information Section. This section can contain additional tables, graphs, background, billing information, or other information. The darolutamide PQI provides a table on adverse reactions from the ARAMIS trial that compares 6 adverse reactions to placebo. As a provider, Henson uses elevated liver enzymes as an example and shares, “I love the supplemental information. I can always look at this and see that this is an adverse reaction and go from there.” Dr. Vijay Patel also likes the side effect profile documented in this section. Peng utilized this section when building out the care plan in her EMR system as discussed earlier.

	Darolutamide		Placebo	
	All grades (%)	Grade ≥ 3	All grades (%)	Grade ≥ 3
AST increased	23	0.5	12	0.2
Decreased neutrophil count	20	4	9	0.6
Billirubin increased	16	0.1	7	0
Fatigue	16	0.6	11	1.1
Pain in extremities	6	0	3	0.2
Rash	3	0.1	1	0

MID: PROVIDING UNMATCHED SERVICE FOR PATIENTS

In addition to close follow up and detailed education, MID renders the practice able to provide excellent customer service and unmatched patient care. Many times, insurance mandates require that prescriptions must be filled outside of the practice in a PBM owned mail-order pharmacy instead of by the MID pharmacy inside the clinic. This can cause delays in therapy and more anxiety for the patient. Garland says that patients of the MID pharmacy “know us and are talking to the same people.” She says when going to outside mail-order pharmacies they “might not have the same comfort level. I think that knowing you are going to be talking to the same pharmacist every time is very comforting to the patient.” Dr. Ronnen agrees and adds “I think wait times are much better when we are filling medications for patients. I also think we are more invested in it.

They are our patients, so our staff feels a sense of responsibility. I think other places might try very hard, but they are one step removed.” Dr. Vijay Patel says “it is so fast. Our patients get their medications so quickly compared to other places that you have to get medicine.” Sarmiento comments, “we pride ourselves in doing everything consistently really fast and taking care of our patients on a level where we would want somebody to take care of us if we were in their situation.” She also says “a lot of these patients are anxious and nervous about it, they want to be treated as soon as possible, they want to be sure they are priority and we try to give them that.”

Even when a prescription is not able to be filled by the MID pharmacy, the MID staff still works tirelessly on behalf of the patient. The FCS MID had a vision of starting a val-

ue-added service for their patients that has come to fruition. Rx To Go Director of Pharmacy and Pharmacist In Charge (PIC) Kathy Hogan, RPh discusses their unique service and says, “our main focus was on patient care, patient access and how that was supported. We need to support the clinic. We integrated everything so that we fast track. We have a queue system in our software so that we take ownership of the patient. We guarantee basically that once the physician sends the order to us that we will take care of everything. That includes prior authorization, patient access, co-pay cards. The team will even call the outside mail order pharmacy and walk them through how to attach a co-pay card.” They have developed relationships with the outside mail-order pharmacies to help take care of their patients. Hogan says in the beginning many of these relationships were verbal and “we still do a lot of verbal because that is the most beneficial.” The relationships have grown to include email concierge, fax, and web portals. They now have points of contact at each outside mail-order pharmacy that they meet with on a quarterly basis. Hogan elaborates, “We have really strong relationships and they will address bottlenecks, problem trends, lack of follow-up, that kind of thing.” Rx To Go has an intake team and part of that responsibility is following up with the outside mail order pharmacies. This team follows the prescription from receipt from physician to receipt by patient and goes into a portal and documents notes in their system during the process. These notes auto-post into the patient chart so that any clinic staff can see where the prescription is in process at any time. She says other practices can develop this relationship and follow up strategy as well, and advises that they must remember this does not happen overnight and “all of this takes time, you have to map it out, you have to have a strategy, a plan, and a vision to build relationships.” She says it helps to have a physician champion inside the practice. She recommends networking at events to build relationships with outside pharmacies and slowly bringing on more staff when possible for follow-up.

Hogan also says this system allows the FCS MID pharmacy to “always have the opportunity to reassess benefits” because patients often have life changes and may not be aware that their benefits also change. This may allow the pharmacy to begin filling for a patient that was previously required to fill in an outside pharmacy. She explains, “we really believe that we provide better service than any outside mail-order pharmacy because our pharmacists follow up and interact with the patients.” She says to her the biggest value of MID is better outcomes. She says outside mail-order pharmacies typically

base their value data on Medication Possession Ratio (MPR). MPR is the sum of the days’ supply for all fills of a given drug in a particular time period, divided by the number of days in the time period.¹⁰ This calculation is relatively simple but it does have its faults.¹⁰ Hogan discusses the faults of using MPR and says that “anyone can auto-ship, in reality that is a lot of waste. Not just waste, it is also not safe. There is a quality management piece in there.” She goes on to say that every time one of their patients is due for a refill, a member of their pharmacy team asks, “how many pills do you have left?” She adds, “if the patient’s answer is not consistent with the number of expected remaining pills, the staff member gives the call to the pharmacist who talks to the patient to uncover possible problems.” Peng agrees that RCCA-CJ also provides this high-quality care and says her team follows the patient and provides pharmacy services “from the beginning of their care to the time the medication gets in their hands, including financial toxicity. We handle everything.” She does mention that filling with their MID pharmacy “is not segmented like if it goes out to a mail order pharmacy” and adds when using a mail-order pharmacy it is a lot “harder to know where the patient is in the process.”

**“THEY ARE OUR PATIENTS, SO
OUR STAFF FEELS A SENSE OF
RESPONSIBILITY. I THINK OTHER
PLACES MIGHT TRY VERY HARD,
BUT THEY ARE ONE STEP
REMOVED.”**

Ellen Ronnen, MD

MID AND PQI: BETTER STAFF COMMUNICATION PRODUCES BETTER CARE FOR PATIENTS

One of the biggest benefits of the MID and the PQI is less fragmentation of care, and ease of communication between the health care team. It has been shown that fragmented care can lead to increased spending and worse patient clinical outcomes.¹¹ It has also been shown that prostate cancer survivors may be particularly prone to the effects of this fragmented cancer care.¹¹ MID is one more step the practice can take towards reducing this fragmentation. When coupled with following the steps of the PQI, better communication amongst the health care team can take place. Sarmiento says the RCCA MID pharmacy communicates across the team, “we are constantly reaching out to the physician or nurse for whatever it is that patient may need based on what they prescribed.” She says it is easy to communicate via email whenever they need to reach out. The PQI can alert the team to possible issues that may require communication between various members.

Garland thinks MID has improved staff engagement and describes a beneficial process that FCS uses for all staff, the pharmacy help desk. She says a lot of communication between clinic staff and the MID pharmacy takes place through this help desk email. A nurse or physician can make status requests through this email such as “this patient’s Nubeqa is due for a refill, I do not see any notes about it being shipped,” and the pharmacy team can investigate and respond before the patient leaves the physician office. Khrystolubova shares that the creation of the pharmacy help desk email arose out of the need for communication to be simplified between the offices and pharmacy. She explains “we have assigned personnel to this pharmacy help desk email that reads email. All day long they check this pharmacy help desk email from clinics, and they triage the emails to a specific group of people within Rx To Go pharmacy.” The staff will respond within 30 minutes and the email “is continually addressed so we don’t have the physician sitting on the phone waiting.” Garland reiterates that anyone in the clinic can use this including, “financial counselors, doctors, nurse practitioners, medical assistants, and the care management



RCCA pharmacy technician Claudia Sarmiento prepares a prescription for a patient.

team.” It has the same type of email address as anyone else in FCS would have (the same ending), “so all they have to think about is pharmacy help desk,” Henson confirms it is easier to communicate with her MID pharmacy than outside mail order pharmacies. Dr. Vijay Patel agrees, “I have everything under our Onco (EMR) and I know everything that’s going on.”

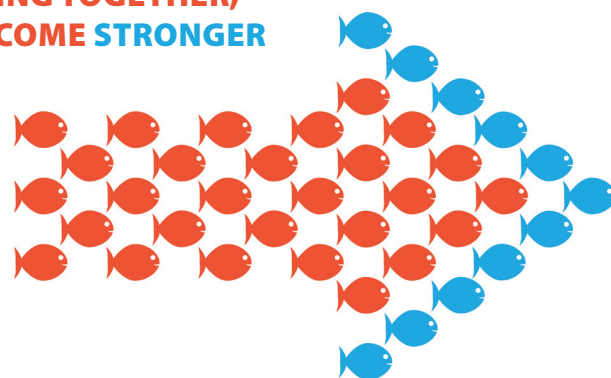
CONCLUSION: NCODA, THE MID AND PQI: OPTIMIZING PATIENT OUTCOMES

All team members agree that the MID model and the PQI Clinical Resource are valuable to the team and to patients. Hogan comments that the MID process, including utilizing resources like the PQI, “totally benefits the patient and not just in their quality of care. It is a continuation of the clinic.” She adds that for the patient that means, “oh my goodness I get extra care. They have better intel, they have the labs, they have all facets of the care, so it is more holistic. It means better quality of life because I know that my nurse cares about me, I know that my pharmacist knows my nurse and has a relationship with my doctor.” Dr. Vijay Patel says “I don’t have to worry about billing, auths, the specifics. Things just get done behind the scenes, that, I love, so I can just focus on practicing medicine.”

Every day the MID team can 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 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. Darolutamide gives a specific population of non-metastatic prostate cancer patients another treatment option to help improve metastasis-free survival and overall survival.¹² The PQI gives the MID program 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 PQI meets NCODA’s Guiding Values of being Patient-Centered and Always Collaborative.

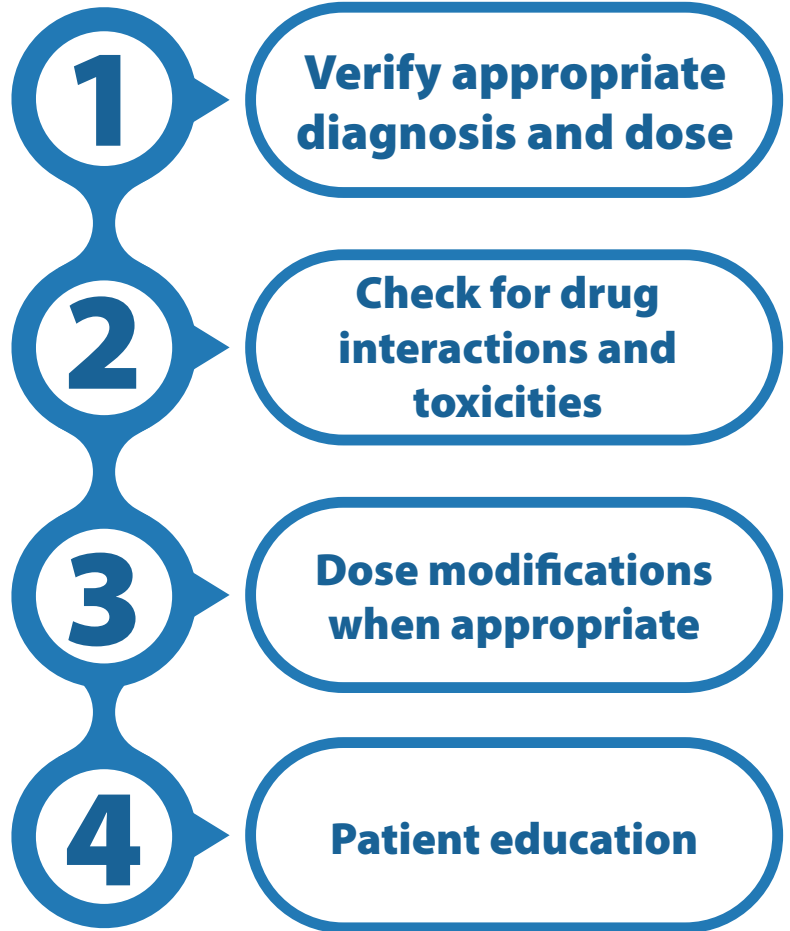
**WORKING TOGETHER,
WE BECOME STRONGER**



REFERENCES

1. Centers for Disease Control and Prevention. Prostate Cancer Statistics. <https://www.cdc.gov/cancer/prostate/statistics/index.htm>. Accessed September 2020.
2. Fizazi K, Shore N, Tammela TL, et al. “Darolutamide in Nonmetastatic, Castrate-Resistant Prostate Cancer.” *N Eng J Med*. 2019; 380:1235-1246.
3. Bastos DA, Antonarakis ES. Darolutamide for castration-resistant prostate cancer. *Onco Targets Ther*. 2019; 12: 8769 – 8777.
4. NCODA. NCODA Announces the defining of the Medically Integrated Dispensing Pharmacy. <https://www.ncoda.org/medically-integrated-dispensing-pharmacy/>. Accessed September 2020.
5. 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 September 2020.
6. National Comprehensive Cancer Network. Prostate cancer. NCCN Clinical Practice Guidelines in Oncology. Version 2.2020 – May 21, 2020. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed September 2020.
7. Nubeqa (darolutamide) [prescribing information]. Whippany, NJ; Bayer HealthCare Pharmaceuticals Inc: 2019.
8. 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.
9. McCue DA, Lohr LK, Pick AM. Improving Adherence to Oral Cancer Therapy in Clinical Practice. *Pharmacotherapy*. 2014;34(5):481-494.
10. Crowe M. Pharmacy Times. Do You Know the Difference Between These Adherence Measures? <https://www.pharmacytimes.com/contributor/michael-crowe-pharmd-mba-csp-fmpa/2015/07/do-you-know-the-difference-between-these-adherence-measures>. Accessed October 2020.
11. Skolarus TA, Zhang Y, Hollenback BK. Understanding Fragmentation of Prostate Cancer Survivorship Care Implications for Cost and Quality. *Cancer*. 2012; 118(11) 2837-2845.
12. 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:



Helpful Online Resources

- www.ncoda.org
- www.ncoda.org/pqi
- www.oralchemoedsheets.com
- <https://www.ncoda.org/darolutamide-in-nmcrcp/>

ON THE COVER (from left):

- A Nubeqa bottle.
- RCCA Medical Oncologist Dr. Ellen Ronnen.
- FCS Rx To Go Pharmacy celebrates the opening of their new pharmacy facility.

NOTES:

NCODA's POSITIVE QUALITY INTERVENTION IN ACTION >>>>

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

Important notice: National Community Oncology Dispensing Association, Inc. (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.

