

# PQI IN ACTION



**ENZALUTAMIDE (XTANDI®) IN CASTRATION-  
RESISTANT PROSTATE CANCER OR METASTATIC  
CASTRATION-SENSITIVE PROSTATE CANCER**



**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 XTANDI® (enzalutamide) PQI and explores how the medically integrated teams at Minnesota Oncology and Clearview Cancer Institute incorporate PQIs as part of their daily workflow. It will discuss how utilizing the **Enzalutamide (XTANDI®) In Castration-Resistant Prostate Cancer or Metastatic Castration-Sensitive Prostate Cancer PQI** elevates patient care at each and every fill.

Clearview Cancer Institute, located in Alabama, boasts 10 practice sites and over 50 providers. Clearview Cancer Institute provides comprehensive oncology care through diagnostic imaging, genetic testing and counseling, lab and therapy services, hematology, medical oncology, radiation oncology, and a Utilization Review Accreditation Commission (URAC) and Accreditation Commission for Health Care (ACHC) accredited oncology-specific pharmacy.

Minnesota Oncology is the Twin Cities' largest and most experienced cancer treatment provider. The practice is giving patients access to more than 100 cancer care experts, evidence-based treatment paths, 12 locations, and comprehensive services to support the whole person. For more than 25 years, Minnesota Oncology has been an independent, community based oncology practice providing services for pain management, nutrition therapy, social work and patient advocacy, medication therapy management, clinical pathways based on research evidence, clinical research trials, genetic counseling and risk evaluation, patient and family education and support, survivorship program. They also offer medical oncology, benign hematology, radiation oncology, gynecologic, thoracic, aesthetic and reconstructive surgery, advance care planning, remote symptom monitoring, laboratory services, diagnostic Imaging, care coordinators, palliative care, and Quality Oncology Practice Initiative (QOPI®) certification and an Accreditation Commission for Health Care (ACHC) accredited oncology-specific pharmacy.

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## THE PARTICIPANTS

### **Clearview Cancer Institute** *Huntsville, Alabama*



**Cleo Valdez, NP**  
Nurse Practitioner



**Leigh Ann Childress, NP**  
Nurse Practitioner



**Meg Butler, PharmD**  
Ambulatory Pharmacy Manager

### **Minnesota Oncology** *Maplewood, Minnesota*



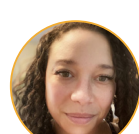
**Robert Delaune, MD**  
Oncologist/Hematologist



**Paul Forsberg, PharmD, BCOP, MHA**  
Director of Pharmacy



**Brian Meger, PharmD**  
Manager of Pharmacy Services



**Marie Rotter, CPhT**  
Certified Pharmacy Technician



**Linh Veire, PharmD, BCOP**  
Pharmacist

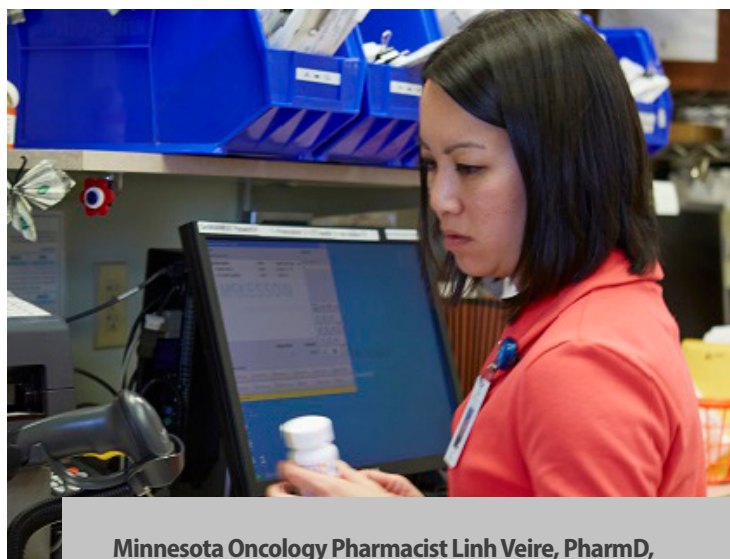


**Rachel Backer**  
Pharmacy Concierge

# 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.<sup>1</sup> It is also one of the leading causes of death in men of any race.<sup>1</sup> Enzalutamide is FDA approved for castration resistant prostate cancer (CRPC) and castration sensitive metastatic prostate cancer (mCSPC).<sup>2</sup> Enzalutamide therapy in mCSPC is recommended both by National Comprehensive Cancer Network (Category 1)<sup>3</sup> and American Urological Association Guidelines (Strong Recommendation; Evidence Level: Grade A).<sup>4</sup> However, it is interesting to find that enzalutamide is underutilized among new patients both in oncology and urology settings.<sup>5</sup>

NCODA defines Medically Integrated Dispensing (MID) as a dispensing pharmacy within an oncology or urology 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.<sup>6</sup> Minnesota Oncology's Linh Veire, PharmD, BCOP discussed the difference the MID makes, saying "I really appreciate the chance to help patients in the way that it should be done, and not have to rush through things. I feel like we can provide good quality care. In other pharmacies, you can't always take time due to staffing or time restrictions, but here I feel like we really can take that time. I am able to give the patient the quality care that they deserve." The MID model can improve management of patients on therapies like enzalutamide in several ways including improved communication, measuring adherence, managing regimen changes,



Minnesota Oncology Pharmacist Linh Veire, PharmD, BCOP preparing a prescription.

speed to therapy, increased patient satisfaction, financial assistance, cost avoidance and producing less waste.<sup>7</sup> Marie Rotter, CPhT, also from Minnesota Oncology touched on the MID, "we have doctors and nurses coming in all the time to collaborate, ask questions, and bounce ideas off of different member of the team." The MID is not siloed, offering patients a superior experience. NCODA offers multiple tools to aid the MID practice in managing the dispensing of oral and injectable 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 OCE sheets, and the Positive Quality Intervention (PQI) clinical resource. As cancer treatment continually grows in complexity containing injectable, oral, and combination regimens, the MID continues to offer an instrumental option for exceptional 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, just like Clearview Cancer Institute and Minnesota Oncology.

**"I AM ABLE TO GIVE THE  
PATIENT THE QUALITY  
CARE THAT THEY DESERVE."**

Linh Veire, PharmD, BCOP

# THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

In an effort to promote higher quality patient care NCODA created the 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 simple-to-use resource for managing patients receiving oral or IV oncolytics, like enzalutamide. Clearview Cancer Institute's Meg Butler, PharmD, states that "PQIs enhance the understanding of how we can care for our patients and help us and providers manage their medications better." The PQI fosters better care for patients through appropriate identification, treatment selection, increased speed to therapy, reduced cost and hospitalization, and by improving adherence techniques for the patient and their medically integrated teams. Minnesota Oncology and Clearview Cancer Institute 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 **Enzalutamide (XTANDI®) In Castration-Resistant Prostate Cancer or Metastatic Castration-Sensitive Prostate Cancer** benefits their staff and patients, and how they advance patient care on a daily basis. Minnesota Oncology's Brian Meger, PharmD states, "with the PQI, the nice thing is it is very short and concise. It helps to give a better knowledge of the medication. It is a good refresher

[CLICK HERE  
TO VIEW  
THIS PQI](#)



Clearview Cancer Institute located in Huntsville, Alabama.

for things we may not see come through the pharmacy that often." This sentiment was echoed by Robert Delaune, MD, also of Minnesota Oncology who stated, "I like the PQIs because they are concise and structured nicely."

**"POSITIVE QUALITY INTERVENTIONS  
ENHANCE THE UNDERSTANDING OF  
HOW WE CAN CARE FOR OUR PATIENTS  
AND HELP US AND PROVIDERS MANAGE  
THEIR MEDICATIONS BETTER."**

Meg Butler, PharmD

## MEDICALLY INTEGRATED DISPENSING: ELEVATING CARE

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. Bridging the communication gap is key to increasing compliance and patient care. Minnesota Oncology's Robert Delaune, MD,

shared his thoughts regarding the continuity of care with the MID stating, "I think it's always better for the patient to fill in house because there is a lot more documentation from our staff if the patient is having problems, like side effects and who is telling them how to manage the side effects. I think it is more seamless." Minnesota Oncology has recently added a new position to their MID with the goal of elevating patient care. Minnesota Oncology's Paul Forsberg, PharmD, talked more about this new position, "we chose to develop and

implement a pharmacy concierge position that is specific to the oral oncology team. Due to the increasing amount of oral medications, the increasing complexity of the prior authorization requirements, and the increasing awareness that we need to have around grants and patient assistance programs, we found that having people specialized in this area helps our team to be more efficient.” Rachel Backer is one of these newly added Pharmacy Concierge. She shares that, “the patient assistance portion of my job has especially affected patient care. I see a lot of patients who don't make much money or are on social security or disability, and I help them be able to afford medications they would not otherwise be able to get. It brings me so much joy to be able to help with patient assistance, because otherwise these patients would refuse treatment.” Also regarding the continuity of care, Marie Rotter, CPhT of Minnesota Oncology shared, “patients can talk

**“IT BRINGS ME SO MUCH JOY TO  
BE ABLE TO HELP WITH PATIENT  
ASSISTANCE.”**

Rachel Backer

directly to one of us, which is a huge! We have actually had a few people transfer to our pharmacy because they can talk directly to somebody and it is much easier than going through the automated system and getting lost in the shuffle at a mail order pharmacy.” She goes on to share that, “within our clinic I can actually walk down and talk to the doctor or the nurses.” If there is confusion about a medication, if the patient is experiencing side effect, or if they cannot swallow the XTANDI® capsules, she is able to talk directly with the team

**“PQIs ARE A GREAT TOOL TO  
HELP WITH OUR ACCREDITATION  
STANDARDS.”**

Meg Butler, PharmD

to resolve the issue. It is another example of the Medically Integrated Team elevating care. Positive Quality Interventions (PQIs) are an ASCO/NCODA Quality Standard. They are designed to operationalize and standardize those practices to achieve these positive clinical outcomes. Clearview Cancer Institute’s Meg Butler, PharmD, also shared that PQIs help with accreditation stating that, “PQIs are a great tool to help with our accreditation standards.” Meg goes on to share another of Clearview Cancer Institute’s unique approaches to elevating patient care through their website resources. She says, “our website has a lot of great resources for patients to help navigate their care. There is an extensive area that focuses on side effects and when to call us.” This includes a description of the side effects, tips to help, and a clear indication of when to call the provider. Just another example of providing superior care.

Are you interested in taking part  
in a PQI In Action?

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MINNESOTA ONCOLOGY



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*Caring, down to a science.®*

# PUTTING THE PQI INTO ACTION

The **Enzalutamide (XTANDI®) In Castration-Resistant Prostate Cancer or Metastatic Castration-Sensitive Prostate Cancer PQI** begins by giving the reader a description of what the PQI will cover followed by a background section which gives the reader pertinent information regarding specific trial data and other helpful information for member of the medically integrated team. The efficacy of enzalutamide in patients with either castration-sensitive or castration-resistant prostate cancer was demonstrated in five major clinical trials (AFFIRM,<sup>8</sup> PREVAIL,<sup>9</sup> TERRAIN,<sup>10</sup> PROSPER,<sup>11</sup> ARCHES<sup>12</sup>). The PQI Supplemental Section has a table<sup>14</sup> that provides all of the relevant data from each trial that any healthcare provider may need. Minnesota Oncology's Paul Forsberg, PharmD, said "I think the PQI allows our practice to be able to quickly see the key steps that a pharmacist would need to review

when starting a patient on a new treatment and counseling and educating that patient about that treatment." Brian Meger, PharmD agrees stating "we could definitely go to the package insert, but PQIs are just much better written and so much more concise, with all the information a pharmacist or anyone in the medically integrated team would need, which is great." Echoed by all is the ability to dive into more detail and the relevant studies if desired.

**"THE PQI ALLOWS OUR PRACTICE TO BE ABLE TO QUICKLY SEE THE KEY STEPS THAT A PHARMACIST WOULD NEED."**

Paul Forsberg, PharmD

	<i>AFFIRM</i>	<i>PREVAIL</i>	<i>TERRAIN</i>	<i>PROSPER</i>	<i>ARCHES</i>
<b>Patient Population</b>	mCRPC	mCRPC	mCRPC	nmCRPC	mCRPC
<b>Study Design</b>	Enzalutamide + LHRH therapy (n=800) vs placebo LHRH therapy (n=399)	Enzalutamide + LHRH therapy (n=872) vs placebo LHRH therapy (n=845)	Enzalutamide + LHRH therapy (n=184) vs bicalutamide + LHRH therapy (n=191)	Enzalutamide + LHRH therapy (n=933) vs placebo LHRH therapy (n=468)	Enzalutamide + LHRH therapy (n=574) vs placebo LHRH therapy
<b>Outcomes</b>	<i>Median time to first skeletal event:</i> Enzalutamide 16.7 months vs placebo 13.3 months  <i>Pain progression at week 13:</i> Enzalutamide 28% vs placebo 39%	<i>Median overall survival:</i> Enzalutamide 35.3 months vs placebo 31.3 months  <i>Median radiographic progression-free survival:</i> Not reached with enzalutamide + LHRH therapy vs 3.7 months with placebo + LHRH therapy	<i>Median radiographic progression-free survival:</i> Enzalutamide group 19.5 months vs bicalutamide group 13.4 months  <i>Median progression-free survival:</i> Enzalutamide patients 15.7 months and bicalutamide patients 5.8 months	<i>Median metastasis-free survival:</i> 3 years with enzalutamide therapy vs 14.7 months with placebo  <i>First use of subsequent prostate cancer therapy was delayed by:</i> Median of 3 years with enzalutamide + LHRH therapy vs 17.7 months with placebo + LHRH therapy	<i>Risk of radiographic disease progression or death:</i> 61% reduction with enzalutamide + LHRH therapy vs placebo + LHRH therapy  <i>Risk of starting a new antineoplastic therapy:</i> 72% reduction with enzalutamide + LHRH therapy vs placebo + LHRH therapy

\*mCRPC–metastatic castration-resistant prostate cancer, LHRH–luteinizing hormone-releasing hormone, CRPC–castration-resistant prostate cancer, mCSPC – metastatic castration-sensitive prostate cancer, nmCRPC – non-metastatic castration-resistant prostate cancer

# THE PQI PROCESS: A TEAM EFFORT

Following the background section, is the PQI Process section of the enzalutamide PQI. This section of the document gives readers a step-by-step process to follow after the identification of the appropriate enzalutamide patient. 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 enzalutamide.<sup>14</sup> Linh Veire, PharmD, BCOP of Minnesota Oncology shares that in the process section, “information is put in bullet points, which is always nice. Instead of having to read through everything and try to gather the information, there are little pearls regarding what we should really be paying attention to, counseling the patient on, so it is a nice quick guide to instead of sifting through the package insert where there's a lot of extra information.” Veire also shares, that, “the PQI process really has a lot of good basic information. How the capsules or tablets are made available is always good to know. That way, if there are any potential dose reductions, we can advise the providers.”

**“THE PHARMACISTS BRING A LOT OF VALUE IN THAT FACE-TO-FACE INTERACTION WHEN THE PRESCRIPTION IS FILLED FOR AN ONCOLYTIC MEDICATION.”**

Leigh Ann Childress, ARNP

At Clearview Cancer Institute, they add extensive call backs into their process. Meg Butler, PharmD, expands more, stating, “our pharmacy software and care plans have call backs that are built in so once a patient's XTANDI® is dispensed,



Minnesota Oncology located in Maplewood, Minnesota.

calls are automatically populated. Basically, they will populate for a seven day follow up call and then monthly call based off the first fill and a pop up flags about five days before the prescription is due for a refill.” They leverage technology to make sure patients do not fall through the cracks. Leigh Ann Childress, ARNP, also of Clearview Cancer Institute shared that “the pharmacists bring a lot of value in that face to face interaction when the prescription is filled for an oncology oncolytic medication and with their many follow up calls.”

The next point on the enzalutamide PQI process reminds the MID to screen for drug interactions. Although the pharmacy always screens for these interaction, Cleo Valdez, ARNP at Clearview Cancer Institute shares that she finds this section to be the most valuable. She explains, “potential dose modifications and interactions is always a question. If the patient is having some side effect or some toxicity, where do I go from here?” Although in different practices, in different states, Linh Veire, PharmD, BCOP of Minnesota Oncology feels the same way, “the drug interactions, like the CYP interactions and modifications are the section that I find the most helpful portion of the PQI.”

Are you interested in authoring a PQI?

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# 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 enzalutamide PQI

Patient-Centered Activities is to provide the patient with the enzalutamide Oral Chemotherapy Education (OCE) Sheet. Much of the important educational information for patients can be found in the NCODA-led Oral Chemotherapy

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

**"WE HIT EDUCATION MULTIPLE WAYS FROM DIFFERENT ANGLES AND THE PATIENTS ARE MUCH BETTER EDUCATED WHEN THEY GO THROUGH OUR PHARMACY."**

Cleo Valdez, ARNP

Education sheets. These education sheets are a resource to provide information about oral chemotherapy drugs and their side effects to both cancer patients and caregivers. We know having cancer or caring for someone who has it can be overwhelming but finding reliable information about the medicines should not. We aim to help caregivers by providing them a tool to pass on to their patients with cancer that will answer drug related questions and help empower patients to become a more active participant in their cancer treatment. OCE sheets are written with the needs of cancer patients in mind. We have strived to use appropriate language and to present pertinent content in an easy-to-understand format to improve patients' understanding of how to take medications correctly. A medication schedule and an outline of potential side effects, as well as information about how to manage those side effects, are key components of the OCE Sheets. The enzalutamide OCE sheet is the perfect supplement to pair with the PQI.

Both participating practices take patient education very seriously and have it as a foundational element of their oral



Minnesota Oncology Pharmacy Manager Brian Meger, PharmD in the pharmacy.

oncologic programs. Regarding education, Clearview Cancer Institute's Leigh Ann Childress, ARNP shares, "I use the Oral Chemo Education sheet because it's patient friendly, it's something they can take home with them, I can highlight things, and it gives very clear and direct information that is specific to XTANDI®." Her colleague Cleo Valdez ARNP, elaborated on education saying, "the patients get more information regarding the medication, because during the visits we obviously we talked to them about XTANDI®. Our nurse navigators will talk to the patients after the provider, but then the patients move on to our pharmacy and the pharmacist and are also getting education there. So, we hit education multiple ways from different angles and the patients are much better educated when they go through our pharmacy versus the mail order system."

**"HAVING GONE THROUGH CANCER TREATMENT MYSELF, IT GIVES A PERSONAL LEVEL OF EXPERIENCE, WHERE I KNOW WHAT EACH ONE OF MY PATIENTS IS GOING THROUGH."**

Rachel Backer

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.<sup>13</sup> Standard 1.2 of the ASCO/NCODA Standards reads:

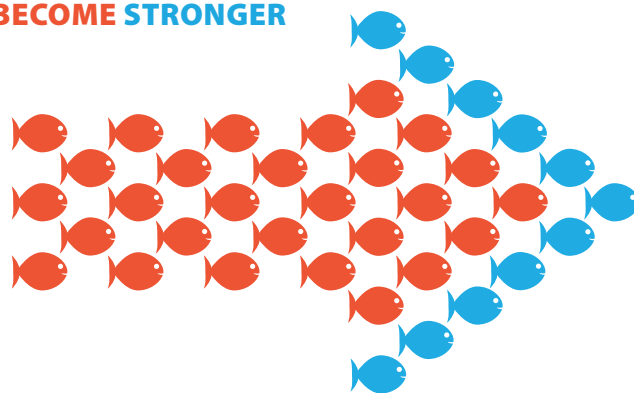
*Prior to initiation of an oral anticancer drug, a formalized patient education session should occur with an experienced clinical educator such as a nurse, physician, pharmacist, nurse practitioner, or physician's assistant. The discussion should include drug name (generic and brand), drug dose, schedule, potential adverse effects and how to properly manage them, fertility (where applicable), treatment goal, duration of therapy, and financial and affordability considerations.<sup>13</sup>*

## 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 not only to increased spending, but to more troubling, worse clinical outcomes for the patient.<sup>15</sup> Both Clearview Cancer Institute and Minnesota Oncology 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. Rachel Backer of Minnesota Oncology shares, “having gone through cancer treatment myself, it gives a personal level of experience, where I know what each one of my patients is going through, so I can say ‘I’m on your team, I understand where you are with all of this,’ that’s so powerful!” 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. The PQI gives the MID program an easy to use,

**WORKING TOGETHER,  
WE BECOME STRONGER**



succinct clinical resource guide for identification of the right patient and best practices for the treatment of an enzalutamide 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 enzalutamide PQI meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.

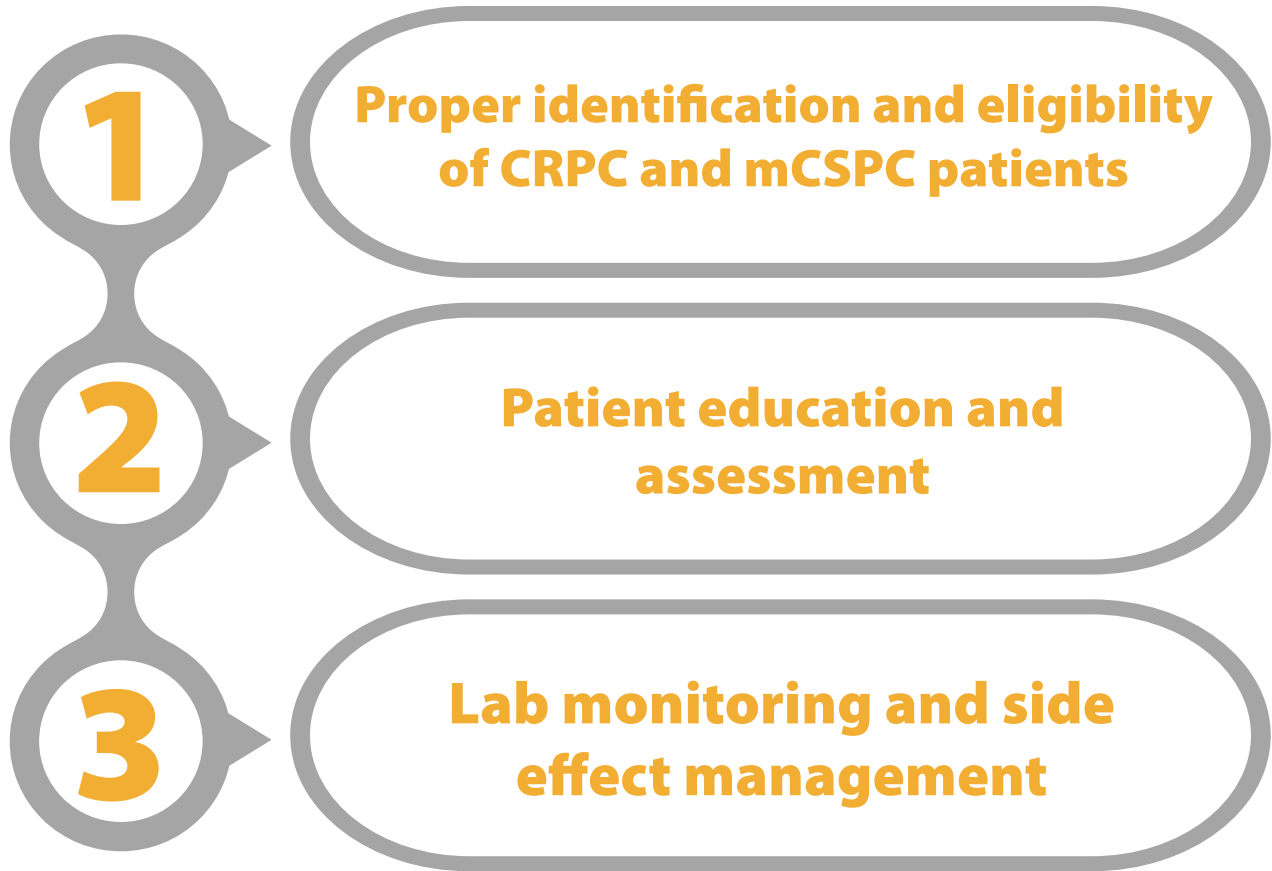
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## ON THE COVER:

- Clearview Cancer Institute Pharmacist Meg Butler, PharmD counsels a patient on XTANDI®.

# PQI PRINCIPLES:



## Helpful Online Resources

- [NCODA Website](#)
- [Oral Chemotherapy Education Sheets](#)
- [Are you interested in authoring a PQI?](#)
- [Positive Quality Interventions](#)
- [Xtandi PQI](#)
- [Are you interested in taking part in a PQI In Action?](#)



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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