PQIIN ACTION





CABAZITAXEL (JEVTANA®) FOR PATIENTS
WITH METASTATIC CASTRATIONRESISTANT 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 resource for healthcare providers. By providing Quality Standards and effective practices around a specific aspect of cancer care, PQIs equip the entire multidisciplinary care team with a sophisticated yet concise resource for managing patients receiving oral or IV oncolytics. This PQI in Action is a follow up to the Cabazitaxel (JEVTANA®) For Patients with Metastatic Castration-Resistant Prostate Cancer PQI and explores how the Medically Integrated Teams at Utah Cancer Specialists (UCS) and Astera Cancer Care incorporate PQIs as part of their daily workflow. This article will discuss how utilizing the Cabazitaxel (JEVTANA®) For Patients with Metastatic Castration-Resistant Prostate Cancer PQI elevates patient care.

Utah Cancer Specialists is the largest community-based oncology and hematology practice in Utah made up of 19 medical oncologists, 15 advanced practice providers, 2 palliative care physicians, and 3 radiation oncologists. They are dedicated to the diagnosis, treatment and management of all forms of cancer and blood-related diseases. UCS providers have expertise in every type of cancer, including rare malignancies. They also actively participate in clinical research. Their pharmacy staff handles inventory management, prior authorizations, and financial assistance through their Medically Integrated Dispensing (MID) pharmacy.

Astera Cancer Care has been providing high quality cancer care for patients residing in the central New Jersey community for over 40 years. They provide state-of-the-art multidisciplinary treatment backed by 37 medical oncologists, hematologists, radiation oncologists and breast surgeons. They also provide more access to leading edge therapies through clinical trials. They offer in-house services for chemotherapy treatments and a Medically Integrated Dispensing Program for oral oncolytics as well as supporting medications. Their team of pharmacists are experts in drug therapy, and central to their ability to offer the highest standard of cancer care.

We would like to thank Sanofi Genzyme for their support of this initiative.

THE PARTICIPANTS

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Kathleen Hernandez, RN *Hematology Oncology Nurse*

DEFINING MEDICALLY INTEGRATED PHARMACY AND THE POSITIVE QUALITY INTERVENTION

edically Integrated Pharmacies (MIP) are a type of service model in which patients receive oral and IV therapies at the site of care with their doctor and are managed by one multidisciplinary staff; state-of-the-art pharmacy services are built within the oncologist's office that help to deliver timely and ongoing care as part of a single, multidisciplinary team. Complexity of cancer treatment has recently increased with a growing number of both oral and IV therapies which are delivered across an often-confusing, payer-driven healthcare system. Various treatment settings including community, institutional, and academic centers have made successful efforts to transition to this integrated service model to maintain continuous care of the patient and achieve the best possible clinical outcomes.

Empowered with innovative tools like the PQI, the Medically Integrated teams have improved the quality of care delivered at their institutions through adoption of NCODA resources. These leading oncology organizations value the PQI which provides concise, clinical guidance information to raise the standard of care across all professional disciplines. In general,

PQIs afford attention to any critical aspect of drug therapy that may be easily overlooked ("if you see 'x', remember to do 'y"). In a world where new and novel treatments arise almost daily, healthcare professionals need an easy-to-use reference to enact the key clinical principles for each therapy. The PQI serves that need.



THE CABAZITAXEL (JEVTANA®) FOR PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER PQI

rostate 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 There are four classes of medical treatments shown to prolong survival among patients with metastatic castration-resistant prostate cancer.² These classes include taxanes, androgen-signaling-targeted inhibitors, immunotherapy, and a bone-targeted radiopharmaceutical agent.² JEVTANA® (cabazitaxel) is a second generation taxane that is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) previously treated with a docetaxel-containing treatment regimen.^{2,3}

The Cabazitaxel (JEVTANA®) for Patients with Metastatic Castration-Resistant Prostate Cancer PQI gives the multi-disciplinary team a concise resource for managing patients on this therapy. The PQI is divided into sections beginning with a description and including the background, PQI process, patient-centered activities, and supplemental information. Kyle Kitchen, PharmD, MBA, Director of Clinical Services at UCS shares, "the PQI provides a framework that can be tailored to each patient's experience. It is really valuable and helps us to provide consistent and high-quality service to each patient." DeAnn Angilau, RN, Nurse Manager at UCS also values the PQI, especially the PQI process and education sections. She emphasizes how they contain valuable

points for the team. She finds the preparation section very beneficial for both nurses and pharmacy technicians since they are the ones who compound medications. Sameer Desai, MD, Medical Oncologist at Astera Cancer Care also shares, "the patient education section is great. My nurse practitioners have the chance to go over things in detail. On my first visit, if I am able to have ready access to this, I can quickly give the patients information that is important to know." Kathleen Hernandez, RN, Hematology Oncology Nurse at Astera Cancer Care, also mentions, "there is great value in the PQI. It acts as a comprehensive guide for the pharmacists, doctors, and nurses." She also mentions that, as a nurse, the monitoring and treatment portions of the PQI are most helpful because they guide her care and allow for a more streamlined approach.

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Kyle Kitchen, PharmD, MBA

THE MEDICALLY INTEGRATED TEAM: A WINNING APPROACH FOR PATIENTS

ealthcare has not always been approached as the "team sport" we currently know and love. The healthcare landscape has changed dramatically in the last 20 years and the clinician operating in isolation is now seen as undesirable. Incorporating multiple perspectives in healthcare offers the benefit of diverse knowledge and experience, and a high-functioning team is an essential tool for building a more patient-centered, coordinated, and effective healthcare delivery system. Teams are defined as two or more people who interact dynamically, interdependently, and adaptively to achieve a common, valued goal. The oncology team plays a vital role in providing high quality patient care with positive outcomes. Pharmacy plays an important part of the team in both of our participating practices.

William Nibley, MD, Medical Oncologist at UCS, shares that the pharmacy team benefits his staff and patients in a number of ways. He states, "they help keep us informed. There are new drugs and indications that are available and it can be difficult to get that information. Our pharmacy team has an assignment to keep looking at those things, including new FDA indications and medications. They have a set time in our meetings to present and update us with that information. With just a single meeting with the pharmacy team monthly, it really helps us to get going seamlessly."

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Aspen Schiess, CPhT at UCS, describes how having the pharmacy team benefits other staff members and patients. She explains, "you don't have one person with the workload of all jobs, it's divided out into specialty. It helps you focus on what you are supposed to be doing. Patients know who they are supposed to contact. It is better for patients to have a personal contact and know exactly who they should talk to." Angilau also describes the value of having a pharmacy team on site. She states, "it makes a huge difference having a pharmacy on site and it saves nursing a lot of time. They are a

DeAnn Angilau, RN

great reference for any questions that we have, including compatibility and sterility."

Sameer Desai, MD from Astera Cancer Care mentions that the pharmacy team has been instrumental for oral, injectable, and IV treatments. He states, "our pharmacy team will check the regimen to make sure it is entered in properly and that the dosing is correct. For oral regimens, they are integrally involved with helping to get approvals for the medications and working with patients to make sure they know about side effects." Additionally, Hernandez states, "the pharmacy team we have is very well engaged and educated. They answer any questions we have regarding medication, dose, route, frequency, etc. If they do not know the answer off hand, they are very quick to research for an answer and help educate the staff as well as the patients."

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Sameer Desai, MD

THE PQI DESCRIPTION AND BACKGROUND

he first two sections of the Cabazitaxel (JE-VTANA®) For Patients with Metastatic Castration-Resistant Prostate Cancer PQI are the Description and Background. The Description gives the FDA-approved indication and purpose of the PQI. The Background lists study information for cabazitaxel. It discusses the 2019 CARD study that evaluated the use of cabazitaxel as a third line option for patients with mCRPC previously treated with docetaxel and an androgen-signaling-targeted inhibitor (abiraterone or enzalutamide) who progressed within 12 months. The study compared cabazitaxel to initiation of another androgen-signaling-targeting inhibitor not previously used (abiraterone or enzalutamide) and showed longer progression-free survival and overall survival. Additionally, the risk of death from any cause was 36% lower in patients who received cabazitaxel compared to those who received an androgen-signaling-targeting inhibitor.^{2,6} Secondary endpoints including pain response and time to symptomatic skeletal events also favored cabazitaxel.2

Dr. Nibley uses cabazitaxel in his practice when they have exhausted their androgen deprivation strategies and utilized docetaxel first. He mentions, "at the point where we are using it, it is not difficult to get it approved. Obtaining the medication is not difficult because we have contracts which increase the accessibility."

The Background section also mentions that the recommended dose of cabazitaxel is now 20 mg/m² every three weeks and the higher dose of 25 mg/m² can be used at provider



and monitoring.

discretion for select patients who are young, healthy, and fit.^{3,6} Isabel Caratenuto, PharmD, BS Pharm, RPh, Director of Pharmacy-Infusion Therapy Services at Astera Cancer Care, mentions, "JEVTANA® is used for the metastatic castration-resistant prostate cancer in patients previously treated with docetaxel, currently on prednisone, and is given at 20 mg/m² once every 3 weeks." Regarding hypersensitivity and tolerability, Angilau mentions, "overall, patients tolerate it well. Giving it is straight forward and easier than docetaxel since it is a 1-hour IV infusion compared to 3 hours." Dr. Desai also mentions, "several patients, over the past few years, have done quite well with cabazitaxel and no one had to stop because of toxicity."

THE PQI PROCESS

he Cabazitaxel (JEVTANA®) For Patients with Metastatic Castration-Resistant Prostate Cancer PQI Process section begins with a review of the patient's treatment plan, which starts with a verification of the pre-medication orders. According to Dr. Nibley, the pharmacy team plays a vital role in reviewing the treatment plan. He emphasizes that the pharmacy team is watching for interactions. He mentions, "I received an email from one of the pharmacy staff about an interaction for a patient who was taking a certain medication that I was not aware of. The pharmacy team figured it out and that was very helpful. I didn't ask for anything, I just ended up getting a call from them because they have been reviewing it. That integrated care has a number of reasons why it's so beneficial to the patients and the practice."

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William Nibley, MD

Caratenuto also values the PQI Process section and mentions, "I think it is a very helpful process. It's concise and easy to follow. It has very important points clearly stated. You don't have to look in multiple sources or search for the information. The information is just very easily found and easy to read." She speaks on the appropriate candidates for cabazitaxel, contraindications, and mentions, "we need to make sure patients

have the pre-medications ordered including antihistamines, corticosteroids, and H2 antagonists." Kitchen highlights the critical role nurses play at UCS and states, "once cabazitaxel is prescribed and the patient comes in for infusion, the process starts. The admixture tech mixes it, then a nurse checks it and provides all of the education to the patient. Nurses are administering the pre-medications and making sure everything is correct before they are administered." Regarding premedication, Angilau comments, "the physicians input the order and we have built in regimens in our EMR, so the pre-medications are there."

The treatment plan review continues with dosing verification. Cabazitaxel is dosed at 20 mg/m² administered every three weeks as a one-hour intravenous infusion.³ Dose adjustments are required for hepatic impairment.³ Hernandez shares, "our lead pharmacist and the doctors enter the treatment plan. Our doctors and the pharmacy team verify doses based on lab work, patient weight and vital signs, and how the patient is feeling on the day of treatment." Additionally, Dr. Desai comments on dose adjustments and mentions, "generally, I'll enter the regimen in, then it goes to the pharmacist to check it. If I didn't notice that the patient had any issues which need to be addressed, it will be double checked by the pharmacist."

The next steps include verifying that a prescription for prednisone has been entered along with antiemetic prophylaxis. Dr. Nibley shares the value the pharmacy team brings to both the team and patients in terms of prophylaxis. He mentions that the pharmacy team, "does all of the investigations in terms of antiemetic potential, neutropenic fever potential, and help tailor these inside the regimen. It standardizes the approach, so we have a good process to make sure we have all of the proper support medications." Additionally, Kitchen shares, "our support medications are famotidine, pegfilgrastim, and diphenhydramine. Patients can be given dexamethasone, or prednisone which is an alternative to that, if it's needed."

The PQI Process also includes an evaluation for the need for primary prophylaxis with G-CSF. Caratenuto mentions that at Astera Cancer Care, "we ensure that the regimens are built with the pre-medications already in there. We make sure there is a G-CSF ordered if the patient qualifies for that and, if they need any extra nausea vomiting prophylaxis, we make sure of that as well." Hernandez discusses, "we give pegfilgrastim and granisetron as G-CSF and antiemetic prophylaxis. The treatment plan usually also contains diphenhydramine, famotidine, IV dexamethasone and oral prednisone. The

ordering doctor or nurse practitioner and the lead pharmacist usually verify that the ancillary medications have been ordered." In addition to this prophylaxis evaluation, the PQI lists out the monitoring parameters for cabazitaxel including a CBC at baseline, weekly during cycle one, and then before each treatment cycle.⁶

The last two steps in the PQI Process include preparation and administration. UCS pharmacy technician Schiess discusses her familiarity with cabazitaxel preparation and how she assisted another technician who was not familiar with how to mix it quickly. She states, "we have a lot of patients on

JEVTANA® right now. I draw out the whole contents of the diluent and dilute it down to the wall of the JEVTANA® vial. Then I invert it back and forth for 45 seconds or so and let it sit until it does not look very oily." Caratenuto highlights how the pharmacy team helps to answer questions that are unfamiliar to other staff members. She mentions, "the staff members often have many questions that need a pharmacist's input and direction. Having us on-site helps with the communication process and delivery. Sometimes they have questions on how cabazitaxel is mixed and if they need a filter; those are all things that we can help with."

PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

he Patient-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. Caratenuto highlights how the pharmacy team at Astera Cancer Care helps to keep the care patient-centered. She comments that having the pharmacy team, "benefits patients because they have another check and a different set of eyes on their medication. There may be something that we might be looking at that another provider might not be looking at. Also, if the patient has any questions, they can ask us and we are happy to help whenever we can."

As part of the Cabazitaxel (JEVTANA®) For Patients with Metastatic Castration-Resistant Prostate Cancer PQI, the team should review the risk of infusion reactions with the patient. With cabazitaxel, the infusion reactions are most likely to occur during the first or second infusion. The PQI also addresses the need for the team to instruct the patient to report any adverse events, to ensure the patient has access to supportive medications, and to provide written information to the patient on the medication. Both the Astera Cancer Care and UCS teams play a significant role on patient education.

At Astera Cancer care, Dr. Desai highlights the critical role that advanced practitioners as well as the nursing team have with patient education. He mentions, "usually when I talk to someone about starting a therapy, on the day of the visit, I would generally talk about the schedule of treatment, major toxicities such as cytopenias, risk of serious infections, nausea, vomiting, alopecia, etc. Then, they will have a separate 45 minute to 1 hour long visit with my nurse practitioners to go over things in more detail." Caratenuto discusses that, "in the beginning of a new treatment, the physician or the nurse

practitioner will have a teach session with the patient and explain everything in the new treatment plan." She mentions that the most important educational points to cover include monitoring for, "any diarrhea, tingling such as peripheral neuropathy, signs and symptoms of rash or itching, dizziness, face swelling, breathing problems, fever, and fatigue."

Additionally, Hernandez shares, "prior to the patient's first treatment, they have a meeting with one of our nurse practitioners for a chemotherapy teach. During the teach, they educate the patient on the drug itself, any side effects they may experience, how to monitor and care for themselves at home including how to stay adequately hydrated, take their as needed medications, monitor their temperatures, and how or when to contact our office for any questions, symptoms, or issues. They usually also explain to the patient what they can expect on the first day such as having labs drawn, vitals taken, how long the treatment may be, etc." Hernandez emphasizes that for these sessions, the most important points to educate patients on when they start cabazitaxel include advising them to stay hydrated, maintaining a healthy diet and weight, infection prevention, when to contact the office, and to take their as needed medications.

At UCS, Angilau teaches a chemotherapy class every Tuesday night to patients. During these sessions, she educates on what chemotherapy is, its side effects and management, and provides guidance on specific regimens with information on expectations, timeframe, and specific side effects. Angilau mentions, "besides just reviewing the basic chemotherapy side effects, the main educational point to cover is that there is a possibility for hypersensitivity reactions. That is why we give patients all of the pre-medications. We explain what that

reaction would look like, and advise them to let us know if those reactions occur. General side effects we cover include fever, nausea, vomiting, diarrhea, and neuropathy including numbness and tingling. We also make sure that they understand their anti-nausea medication."

"BESIDES JUST REVIEWING THE BASIC CHEMOTHERAPY SIDE EFFECTS, I THINK THE MAIN EDUCATIONAL POINT TO **COVER IS THAT THERE IS A POSSIBILITY** FOR HYPERSENSITIVITY REACTIONS. THAT IS WHY WE GIVE THEM ALL OF THE PRE-MEDICATIONS. WE EXPLAIN WHAT THAT REACTION WOULD LOOK LIKE, AND ADVISE THEM TO LET US KNOW IF THOSE REACTIONS OCCUR. GENERAL SIDE EFFECTS WE COVER INCLUDE FEVER, NAUSEA, VOMITING, DIARRHEA, AND NEUROPATHY INCLUDING NUMB-**NESS AND TINGLING. WE ALSO MAKE** SURE THAT THEY UNDERSTAND THEIR **ANTI-NAUSEA MEDICATION."**

DeAnn Angilau, RN

Additionally, Dr. Nibley describes how the nursing, pharmacy, and physician teams all play a unique role in educating patients. He mentions, "you can't separate yourself as a physician entirely from going through what patients can expect from a medication, so we do give quite a bit of information about it. With the infusible medications, we have a second time where nurses are providing educational handouts. With the oral medications, the nursing and pharmacy staff are working together to give that information."

CABAZITAXEL PQI PATIENT EDUCATION ACTIVITIES

- Review the risk of infusion reactions, with cabazitaxel they are most likely to occur during first or second infusion. Signs of a reaction may include rash/itching, feeling dizzy, chest or throat tightness, breathing problems, face swelling
- Instruct patient to report any adverse events, such as fever, diarrhea, nausea/vomiting, numbness/tingling of the hands or feet, or fatigue
- Ensure patient has access to supportive medications
- Anti-nausea medications (ex. 5-HT3 receptor antagonist, metoclopramide, or prochlorperazine)
- Anti-diarrheal medications (ex. loperamide)
- Provide written information to patient on medication

SUPPLEMENTAL INFORMATION: FINANCIAL ASSISTANCE - ADDITIONAL PATIENT-CENTERED CARE

ollowing the Patient-Centered Activities, the Cabazitaxel (JEVTANA®) For Patients with Metastatic Castration-Resistant Prostate Cancer PQI Supplemental Information section gives information on the CareASSIST patient support program and copay program. Cancer is one of the most expensive diseases to treat in the United States and 1 in 3 American families are faced with

healthcare bills they cannot afford.⁷ Practitioners from Astera Cancer Care as well as Utah Cancer Specialists shared insight on how patients are able to obtain financial assistance and guidance for their care.

Kitchen mentions that UCS has, "financial advocates who provide the financial assistance support to connect patient to any resources that are available." Similarly, Angilau mentions,

"we have patient advocates and they're responsible for obtaining any preauthorization. If patients need financial assistance, the patient advocates are the ones who work with them to get them the drug they need." At Astera Cancer Care, Caretenuto mentions, "we have a billing department and financial assistance resources that will help the patient if they need to get setup for the care assist copay program, which helps to decrease their out-of-pocket costs. We also have financial counselors in place who will be able to assist with this." Hernandez also highlights the financial counselors who are available and ready to offer financial assistance for the patients if necessary. Providing patients with resources helping them achieve increased access to care can make a significant impact in their cancer care and outcomes.

"WE HAVE A BILLING DEPARTMENT AND FINANCIAL ASSISTANCE RESOURCES THAT WILL HELP THE PATIENT IF THEY NEED TO GET SETUP FOR THE CARE ASSIST COPAY PROGRAM, WHICH HELPS TO DECREASE THEIR OUT-OF-POCKET COSTS. WE ALSO HAVE FINANCIAL COUNSELORS IN PLACE WHO WILL BE ABLE TO ASSIST WITH THIS."

Isabel Caratenuto, PharmD, BS Pharm, RPh

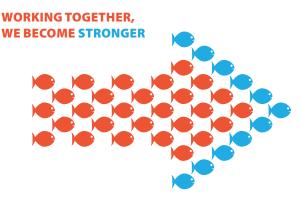
CONCLUSION: NCODA, THE MEDICALLY INTEGRATED TEAM AND CABAZITAXEL PQI: OPTIMIZING PATIENT OUTCOMES

he Medically Integrated Team provides value to patients. UCS has a team approach in terms of building their protocol which provides great value to patients. Kitchen mentions, "the team consists of myself, a physician, nurse, and billing representative. They go through the protocols and make sure the financials work out, see if there is NCCN or FDA support, and then ensure that the structural build is good. They also make sure that the support medications are included." Schiess speaks on the efficient collaboration between nurses and pharmacy technicians in the cabazitaxel mixing process at UCS. She elaborates on several steps that are involved, with the first being an assessment of patient labs by the physician. Schiess then states, "if labs and everything look good, the nurse will print back the JEVTANA® order to us. Then we pull it and mix it for the patient. Angilau discusses the value of having a dedicated pharmacy team for the nursing staff. She mentions, "the pharmacy team saves us a lot of time and research. I think they are great and we love having pharmacy on site. They have also helped improve wait times for patients. When nurses are doing everything by themselves, we can get slowed down. Pharmacy helps us keep on schedule and keeps the patient flow going much better."

At Astera Cancer Care, Caratenuto emphasizes various ways the pharmacy team provides a unique perspective in treatment. She mentions the pharmacy team's knowledge in dosing calculations as well as doing adjustments that need to

be made based on renal function and other issues. Similar to Schiess, Hernandez provides perspective on how nursing and pharmacy collaborate efficiently. She mentions, "as nurses, we check to make sure the patient is safe and able to receive chemotherapy. The dose, route, rate, solution, tubing, and patient medical record are checked with the pharmacy technician while mixing. We then check the medication with another nurse and then the patient themselves."

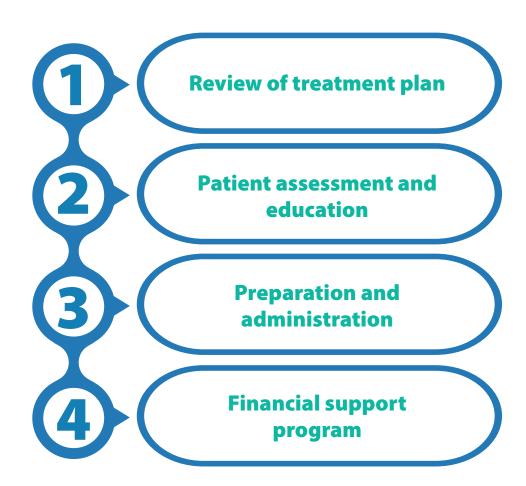
The cabazitaxel PQI provides the Medically Integrated Team with an easy to use, compact clinical resource guide when treating these patients. It helps the team ensure they are providing patients with the tools and education to improve clinical outcomes. Pairing the Medically Integrated Team with the Cabazitaxel (JEVTANA®) For Patients with Metastatic Castration-Resistant Prostate Cancer PQI meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.



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PQI PRINCIPLES:





Helpful Online Resources

- PQI: Cabazitaxel (JEVTANA®) For Patients with Metastatic Castration-Resistant Prostate Cancer
- NCODA Website
- Positive Quality Interventions
- Oral Chemotherapy Education Sheets

ON THE COVER:

• An admixture technician from Utah Cancer Specialists prepared to demonstrate excellence and face any challenges.

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.



