

PQI IN ACTION



**CABAZITAXEL (JEVTANA®) FOR PATIENTS
WITH METASTATIC CASTRATION
RESISTANT 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 Carolina Blood and Cancer Care Associates, P.A. and DuPage Medical Group 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.

Carolina Blood and Cancer Care Associates, P.A. (CBCCA) is a physician-owned oncology practice with two locations in South Carolina. They provide access to care for every patient, regardless of insurance status. They currently have five medical oncologists and one physician assistant, and are in the process of adding two additional providers. They offer infusion and oral pharmacy services.

DuPage Medical Group is an independent physician multi-specialty group with six oncology clinic locations with infusion services in the Chicagoland area. Each infusion center is staffed with pharmacists and technicians and four sites have the capability to compound hazardous drugs. Their team of clinical pharmacists also helps manage oral oncolytics for their patients.

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

THE PARTICIPANTS

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DuPage Medical Group *Chicagoland, IL*



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DEFINING MEDICALLY INTEGRATED PHARMACY AND THE POSITIVE QUALITY INTERVENTION

Medically 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 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 at CBCCA and DuPage Medical group 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 the 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.



Krystal Preston, PharmD, BCPS verifies orders for IV chemotherapy.

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

Prostate cancer is the second most common cancer among men in the United States, following only non-melanoma skin cancer.¹ It is also one of the leading causes of death in men of any race.¹ There are four classes of medical treatments that have been 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 next 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 laid out in sections beginning with a description and including the background, PQI process, patient-centered activities, and supplemental information. Kashyap Patel, MD, Medical Oncologist and CEO of CBCCA shares “the positive quality intervention establishes something similar to a standard operating procedure within the practice and so what happens is it eliminates any possible holes that could arise in delivering care.” Paige Deisner, MMS, PA-C, physician assistant at DuPage Medical Group also values the PQI as a way “to verify and

double check that we have done everything correctly.” DuPage Medical Group clinical oncology pharmacist Udeshi Desai, PharmD, BCPS shares, “what is really valuable out of this PQI is understanding the step by step process. Not just the data behind using JEV TANA® in our metastatic castration-resistant prostate patients, but also understanding how to manage those patients once the patient is on therapy.”



“WHAT IS REALLY VALUABLE OUT OF THIS PQI IS UNDERSTANDING THE STEP BY STEP PROCESS. NOT JUST THE DATA BEHIND USING JEV TANA® IN OUR METASTATIC CASTRATION-RESISTANT PROSTATE PATIENTS, BUT ALSO UNDERSTANDING HOW TO MANAGE THOSE PATIENTS ONCE THE PATIENT IS ON THERAPY.”

Udeshi Desai, PharmD, BCPS

THE MEDICALLY INTEGRATED TEAM: A WINNING APPROACH FOR PATIENTS

Healthcare has not always been approached as the “team sport” we currently know and love.⁴ The healthcare landscape has changed dramatically in the last 20 years and the clinician operating in isolation is now seen as undesirable.⁵ 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.⁵ Teams are defined as two or more people who interact dynamically, interdependently, and adaptively to achieve a common, valued goal.⁴ 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.

Daniel Frank, MD, Medical Oncologist at the DuPage Medical Group shares that pharmacy is “obviously a critical safety net. They are making sure to double check orders, making sure that all pre-medications are appropriate and making sure there is no improper protocol in regards to FDA labeled indications.” DuPage clinical pharmacist Krystal Preston, PharmD, BCPS adds, “having multiple members of the multi-disciplinary team helps the entire team. Drugs are the pharmacist’s expertise so we can focus on all things drug, whether drug interactions or specific mechanisms that

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Krystal Preston, PharmD, BCPS

might help a patient. It helps everyone to utilize their role and gives balance as different areas all come together on one accord.”

Dr. Patel also speaks to the role of pharmacy on the team. “Having pharmacy on-site is a very critical part of having a well-oiled machine to serve patients. Pharmacy is a critical part of delivering cancer care, in both infusion and orals and is an essential component of treatment for cancer patients.” CBCCA nurse Heather Rowland, LPN also shares that having pharmacy as part of the team gives patients more individualized care and takes stress off of nursing. She says it allows nurses to fully concentrate on their nursing duties with patients.

“HAVING PHARMACY ON-SITE IS A VERY CRITICAL PART OF HAVING A WELL-OILED MACHINE TO SERVE PATIENTS. PHARMACY IS A CRITICAL PART OF DELIVERING CANCER CARE, IN BOTH INFUSION AND ORALS AND IS AN ESSENTIAL COMPONENT OF TREATMENT FOR CANCER PATIENTS.”

Kashyap Patel, MD

THE PQI DESCRIPTION AND BACKGROUND

The first two sections of the Cabazitaxel (JEVTA-NA®) 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 and showed longer progression-free survival, overall survival and cabazitaxel was associated with a 36% risk of death reduction.^{2,6} Other efficacy outcomes including pain response and time to skeletal events also favored cabazitaxel.²

Dr. Patel comments that the CARD study added value to the prostate cancer treatment landscape and cabazitaxel has been “extremely helpful in the appropriate patients.” Dr. Frank shares he has been using cabazitaxel “a little more recently because there was data showing that patients who have progressed on docetaxel and one form of oral androgen-signaling-targeted-inhibitor seem to do better with chemotherapy rather than another oral antihormonal agent.”

The Background section also mentions that the recommended dose of cabazitaxel is now 20mg/m² every three weeks and the higher dose of 25mg/m² can be used at provider discretion for select patients.^{3,6} Dr. Frank shares that in general he does start patients at the 20mg/m² dose. He uses extra caution with regards to dosing in his older, frail patients.

THE PQI PROCESS

The Cabazitaxel PQI Process section begins with a review of the patient’s treatment plan. The treatment plan review begins with a verification of the pre-medication orders. According to Desai, at DuPage Medical Group the pharmacists play an active role in ensuring the treatment plan is reviewed. Preston appreciates the PQI Process section and comments, “I like actually going through the PQI process, making sure all of these drugs are on board, to ensure the patient is safely receiving the medication.” When a patient is starting

on cabazitaxel Preston evaluates the patient’s chart, reads the physician’s notes, evaluates the diagnosis and ensures the qualifications are met for the patient to receive therapy based on diagnosis, lab values, and other parameters. She evaluates the medication list for potential drug interactions and then verifies that all of the pre-medications are entered into the EMR correctly. Rowland also values the PQI for the process section and its utility in reminding the staff to ensure the pre-medications are entered correctly and to evaluate if all are warranted if not listed.

The treatment plan review continues with dosing verification. Cabazitaxel is dosed at 20mg/m² administered every three weeks as a one-hour intravenous infusion.³ Dose adjustments are required for hepatic impairment.³ Dr. Frank shares that he dose reduces patients when necessary while prescribing therapy, and his pharmacy double-checks for needed dose reductions. Preston confirms and adds she reaches out to the physician when she comes across anything out of the ordinary where dosing is concerned, “we have these types of conversations to make sure the patient is getting the best care possible.”

The next steps include verifying that a prescription for prednisone has been entered along with antiemetic prophylaxis. Preston shares that at DuPage, supportive care medications are typically filled by their Medically Integrated Dispensing (MID) pharmacy housed within another location and couriered to her clinic for patients to pick up at their appointment. Dr. Patel notes, CBCCA also participates in MID and is able to fill the supportive care medications and steroids for patients. He adds that when treating patients, “we always look at what is less expensive for patients. If the patient’s co-pay is a lot less under the dispensing side and we can coordinate under the pharmacy benefit we do it that way. Our goal is to provide affordable access to care because patients are already stretched with the financial challenges of having cancer itself.”

The PQI Process also includes an evaluation for the need for primary prophylaxis with G-CSF. Dr. Frank discusses G-CSF prophylaxis in his patients, most of which receive the prophylaxis. “The issue at the point when you are talking about patients receiving JEV TANA[®] is that they have already had a lot of chemotherapy with docetaxel or maybe even carboplatin, and the majority of patients are older” so often the prophylaxis is necessary. Desai shares that DuPage pharmacists build G-CSF prophylaxis into care plans to ensure the patient is evaluated when needed. DuPage employs an IT pharmacist that works with the oncology pharmacists to build the entire medication protocol in the EMR. In addition to this prophylaxis evaluation, the PQI lists out the monitoring parameters for JEV TANA[®] 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. DuPage pharmacy technician Demetria Streeter, CPhT, finds the PQI valuable as a quick and easy reference, “like Cliffnotes versus the entire package insert.” She appreciates that the Cabazitaxel PQI includes information on using a PVC-free container and states the



A nurse at CBCCA prepares to administer an IV infusion.

container and IV tubing type can be a source of confusion in some instances and is a question that often arises with IV medications. CBCCA pharmacy technician Jennifer Valentine, CPhT mentions an important point to remember is to gently invert the vial, not to shake. She also makes mention of the required 0.22-µm nominal pore size inline filter.

“OUR GOAL IS TO PROVIDE AFFORDABLE ACCESS TO CARE BECAUSE PATIENTS ARE ALREADY STRETCHED WITH THE FINANCIAL CHALLENGES OF HAVING CANCER ITSELF.”

Kashyap Patel, MD

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. Preston comments “the Patient-Centered activities section is really important. Many times patients do not like to report any type of treatment effects they have and they may not say much about them. What seems like a small thing may be important for future reference and how to best treat the patient.” As part of the cabazitaxel 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 of second infusion.⁶ 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.

“WE TALK ABOUT THE POTENTIAL FOR BOWEL IRREGULARITIES, LIKE DIARRHEA OR CONSTIPATION, BECAUSE WE SEE EITHER. ALSO, THE POTENTIAL FOR NAUSEA AND HOW WE CAN MANAGE THAT TO PREVENT VOMITING, BUT ALSO WHAT HAPPENS IF SOMEONE STARTS VOMITING, WE CAN GET ELECTROLYTE ISSUES AND CONCERNS.”

Paige Deisner, MMS, PA-C

Both the CBCCA and DuPage Medical Group teams place a heavy emphasis on patient education. At DuPage Medical Group the advanced practice providers perform a one-hour education session with patients. Diesner provides patient education in her role as a physician assistant and says she goes over the mechanism of action, potential side effects, and other safety aspects with the patient. When a patient starts treatment with cabazitaxel she instructs patients to “take a mental note based on how you feel right now and if something shifts when you start treatment please let us know.” She adds she always discusses the potential for cytopenias and using extra precautions to prevent infections, especially in the current environment. She continues, “we talk about the potential for bowel irregularities, like diarrhea or constipation, because we see either. Also, the potential for nausea and how we can manage that to prevent vomiting, but also what happens if someone starts

vomiting, we can get electrolyte issues and concerns. The potential for neuropathy is high on my list of things to bring up with patients.” She shares it is important for patient to let the team know what is going on so the providers can determine if the problem is due to the chemotherapy, the cancer, or something else that is going on.

In addition to the advanced practice providers giving patient education, the nurses at both practices provide education as well. DuPage nurse Nancy McClarn, BSN, RN, OCN comments “we are doing a lot of the teaching during the infusion and actually all of the time. We just want to make sure that if patients have any questions they know not to hesitate to ask us. We are reinforcing all of the education that has already been provided.” At CBCCA Dr. Patel and his team are also providing education on potential side effects and an explanation of what to expect at the infusion visit. He explains that it is important to let patients know about potential symptoms they may experience and not to hesitate to call the office when experiencing anything. Rowland also plays a role in educating patients and shares the nurses go over new treatment orders, what to expect, and any questions with patients. She tells patients “to ask any question they can think of and don’t think anything is silly to ask because there is never a silly question when you are having something put in your body.” She also lets them know “there is always someone on call, even after hours and on the weekends. When you go home after the infusion if anything seems off make sure you call us.” She explains to patients the potential for electrolyte imbalance with diarrhea or vomiting and that the office can help provide fluids and other medications to help alleviate these side effects.

Patient-Centered 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

FINANCIAL ASSISTANCE: ADDITIONAL PATIENT-CENTERED CARE



DuPage Medical Group pharmacy technician Demetria Streeter, CPhT compounds an IV medication.

Following the Patient-Centered Activities, the cabazitaxel PQI Supplemental Information section gives information on the CareASSIST patient support program and co-pay 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 All practice participants have staff dedicated to the billing and financial assistance for patients. Dr. Patel is no stranger to the financial toxicities patients can face from their cancer care. He is involved in sev-

“CANCER TREATMENT HAS TO EVOLVE, FROM THE MICROSCOPIC LEVEL AT THE PATIENT TO THE SYSTEM LEVEL AS A WHOLE. WE HAVE TO BE ENGAGED IN THE PROCESS OF TRANSFORMATION, RATHER THAN BEING ON THE SIDELINES.”

Kashyap Patel, MD

eral organizations outside of his practice “because I feel that cancer treatment has to evolve, from the microscopic level at the patient to the system level as a whole. We have to be engaged in the process of transformation, rather than being on the sidelines.” He chose to drop two days of clinical practice and utilizes those days for administrative work, writing, speaking, and involvement in the healthcare policy space.

The CBCCA team has financial counselors who initiate the process of medication approval on the financial end. Dr. Patel shares, “the most important piece of utilizing the PQI and establishing SOPs is essentially operationalizing the process so that patients, nurses, pharmacy, as well as the financial counselor are all aligned to ensure there is no break in the communication. That seamless communication, at the end of the day, helps the patient. This is patient-centered care, from the financial side, explaining what we will be doing, how long the patient will be here, potential side effects and how to manage those side effects, this all should be centered around the patient.” The DuPage team also has a “patient navigation team” with financial navigators. Preston explains that once the medical team places orders for medication therapy this financial team works on approvals, patient assistance, and manufacturer provided drug if needed.

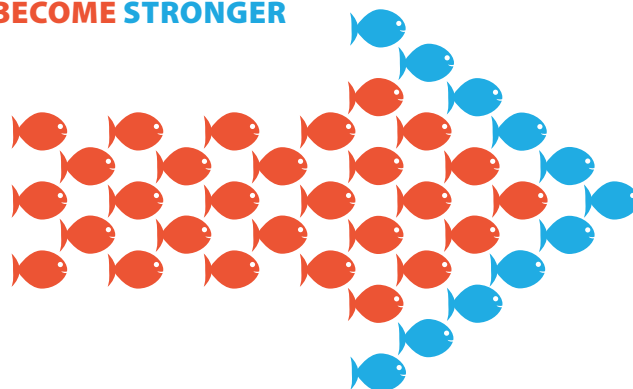
CONCLUSION : NCODA, THE MEDICALLY INTEGRATED TEAM AND CABAZITAXEL PQI: OPTIMIZING PATIENT OUTCOMES

The Medically Integrated Team provides value to patients. Valentine believes the multi-disciplinary team greatly improves patient care and communication because “we all work together to help the same patient.” She explains that as a pharmacy technician she is trained to pay attention to drug detail as part of her role on the team. Streeter feels the team approach benefits the patient because they “can come and see the doctors and get treated in the same day and there is no prolonging of the treatment process.” Desai add that pharmacy can assist in education other team members on the medications, assisting with financial barriers, and being able to help facilitate the entire medication process.

Valentine is a proud NCODA member and advocate, and values the PQI as “a guide everyone can follow.” McClarn adds “resources like this are perfect, because we infuse new drugs all of the time.” She says it helps to keep track of details like if a medication needs a filter, supportive care medications, and other important points. Cabazitaxel gives mCRPC patients an option that Dr. Patel feels is an “effective treatment regimen for patients.” The Cabazitaxel PQI provides the Medically Integrated Team with an easy to use, compact

clinical resource guide when treating the 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.

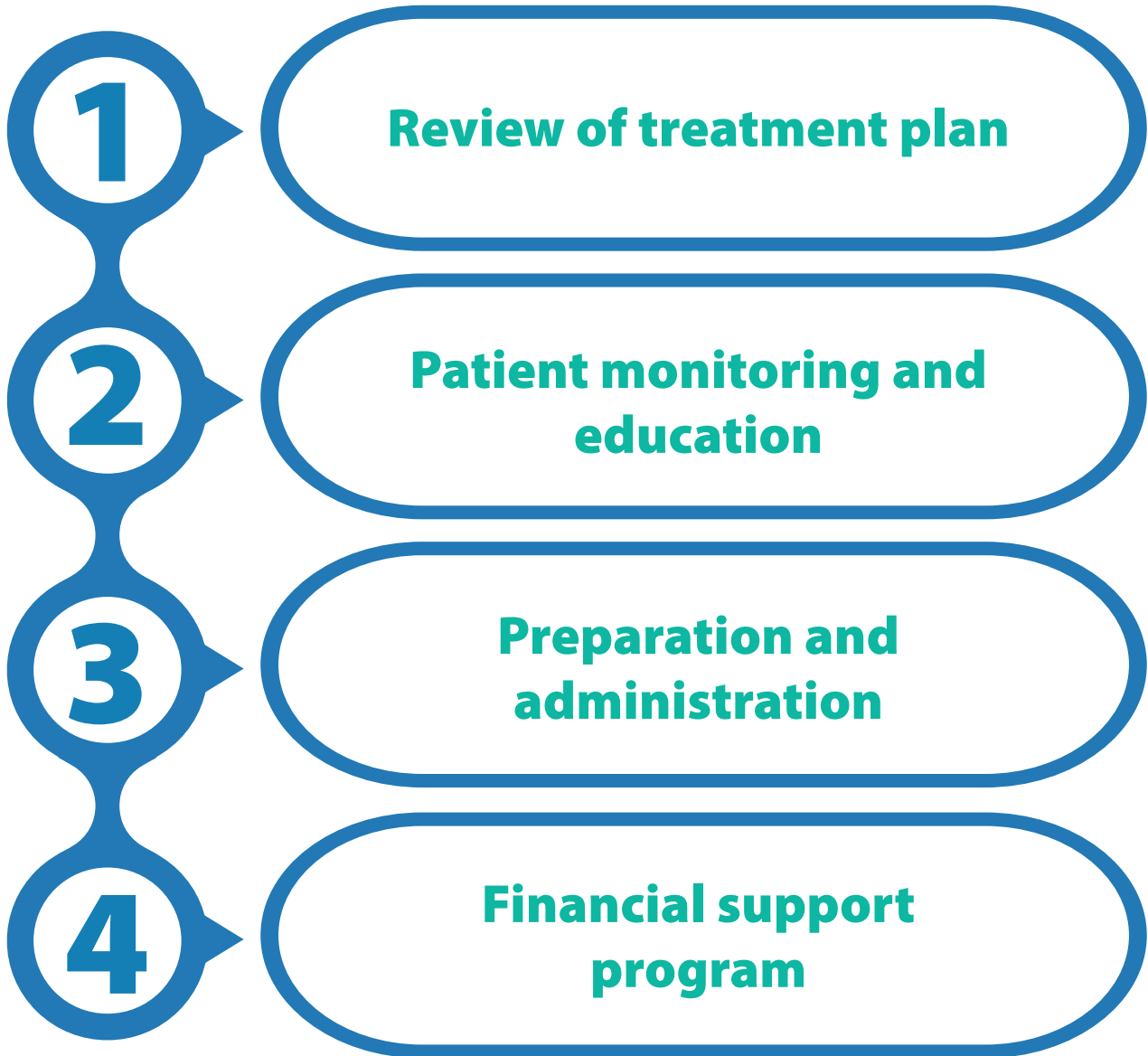
**WORKING TOGETHER,
WE BECOME STRONGER**



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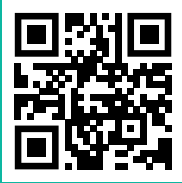
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PQI PRINCIPLES:





Helpful Online Resources



NCODA Website



Positive Quality Interventions



Oral Chemotherapy Education Sheets



PQI: Cabazitaxel (JEVTANA®) For Patients with Metastatic Castration Resistant Prostate Cancer

ON THE COVER:

- Nancy McClarn, BSN,RN, OCN prepares to administer an IV infusion.



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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