# PQIIN ACTION





TIVOZANIB (FOTIVDA®) FOR RELAPSED
OR REFRACTORY ADVANCED RENAL
CELL CARCINOMA



**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 **Tivozanib for Relapsed or Refractory Advanced Renal Cell Carcinoma** PQI and explores how the medically integrated teams at American Oncology Network and Nebraska Cancer Specialists incorporate PQIs as part of their daily workflow. This article will discuss how utilizing the **Tivozanib for Relapsed or Refractory Advanced Renal Cell Carcinoma** PQI elevates patient care.

American Oncology Network, LLC (AON) is the fastest growing network of community oncology practices in the US with over 100 physicians, 89 advanced practitioners and 25 practices located in 16 states nationwide. AON practices strive to bring the best oncology care to patients by working together as one network. The two AON practices that are featured in this PQI in Action are Messino Cancer Center in Asheville, NC and Low Country Cancer Center in Savannah, GA. AON Specialty Pharmacy, located in Fort Meyers, FL, provides a centralized location of distribution of oral oncolytics to patients within the AON practice. AON Specialty Pharmacy is ACHC, URAC and NABP accredited to provide the best service to their patients. In collaboration with several remote and on-site pharmacists in the AON practices, the pharmacy works to provide medication management services, financial assistance and mail order delivery to patients in any area of the United States.

Nebraska Cancer Specialists (NCS) is the largest community oncology practice in the Great Plains Region of the Midwest. They provide state of the art oncology care including imaging/diagnostic testing, chemotherapy, radiation oncology, clinical research and supportive oncology services within 8 metro locations. NCS Outpatient Pharmacy is accredited by ACHC and takes pride in providing quality pharmaceutical care that ensures accurate and timely delivery of oral oncoloytic therapy and supportive medications to their patients while also providing cost efficiency through financial assistance programs. NCS Outpatient Pharmacy also provides extensive medication counseling on all new oral chemotherapy fills and maintains follow up accordingly to address adherence issues, adverse drug reactions or patient concerns while on therapy.

#### THE PARTICIPANTS

American Oncology Network, LLC Low Country Cancer Care, Savannah, GA Messino Cancer Center, Asheville, NC



**Jennifer Yannucci, MD** *Hematologist/Oncologist* 



Beth Dickert, PharmD, BCOP Clinical Oncology Pharmacist



**Katie Mason, CPhT, RPhT** *Prior Authorization Specialist* 

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# MID, THE PQI, AND TIVOZANIB: GIVING PATIENTS ADDITIONAL OPTIONS FOR TREATING RELAPSED OR REFRACTORY ADVANCED RENAL CELL CARCINOMA

enal cell carcinoma (RCC) comprises approximately 4.1% of all new cancers, with a median age of diagnosis of 64 years old.1 Of these cases of RCC, approximately 70% have a clear cell histology (ccRCC).1 Smoking, obesity, and hypertension are established risk factors for RCC development in the United States, with hereditary factor von Hippel-Lindau (VHL) comprising the majority of inherited RCC.1 According to the National Comprehensive Cancer Network (NCCN), approximately one-third of RCC patients present with metastatic disease.1 Prior to 2005, treatment for metastatic RCC consisted of the immunotherapy agents IFN-alpha and IL-2.2,3 The introduction of the targeted therapies against VEGF, VEGFR, and mTOR drastically changed this treatment landscape of metastatic RCC over the last decade. 1-4 In addition, immune checkpoint inhibitors that block PD-1, PD-L1 and CTLA-4 have shown promise in the landscape of metastatic RCC.<sup>2,4</sup> FOTIVDA® (tivozanib) is a targeted VEGF inhibitor, comprised of a small molecule that inhibits phosphorylation of VEGFR-1, VEGFR-2 and VEGFR-3.5 In March 2021, tivozanib was approved by the FDA for the treatment of advanced or metastatic renal cell carcinoma in patients who have previously received two or more systemic therapies, based on the phase III trial TIVO-3.4-7 Tivozanib continues to remain an NCCN category 1 option in metastatic RCC for patients who have received 2 or more prior systemic therapies.1

As stated in the background section of the Tivozanib for Relapsed or Refractory Advanced Cell Carcinoma, the TIVO-3 trial results gave tivozanib the advantage over sorafenib in progression free survival (5.6 months verses 3.9 months, hazard ratio of 0.73, p=0,016) and objective response rate (18% verses 8%). In a recently updated analysis, tivozanib also increased quality-adjusted time without symptoms of disease and toxicity (Q-TWiST) as compared to sorafenib (15.04 months verses 12.78 months, respectively).

Tivozanib can be dispensed by the Medically Integrated Team, and thus offers patients more comprehensive care. NCODA defines Medically Integrated Dispensing (MID) as a dispensing pharmacy within an oncology center of excellence that promotes a patient-centered, multidisciplinary team approach.10 The MID is an outcome-based collaborative



AON Specialty Pharmacy, located in Fort Meyers, FL, dispenses and ships oral oncolytics overnight to oncology patients at Messino Cancer Center and Low Country Cancer Center, as well as AON practice patients across the country.

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. 10 Both practices attest to the quality of care that a MID team can offer to patients that they may not get elsewhere. Beth Dickert, PharmD, BCOP of AON comments, "Our pharmacists at AON check every oral oncolytic that is prescribed to our patients. Having access to the AON system allows us to check renal function, hepatic function, all prior therapies patients were exposed to and any side effects they endured on previous treatments. Knowing this information is key to ensuring the patient's dosage is correct and allows us to better educate the patient on side effects. Patients often tell us that by calling them so quickly after they are prescribed a new medication that they feel more comfortable with their diagnosis."

The MID model can improve management of patients on therapies like tivozanib in several ways including improved communication issues, measuring adherence, managing regimen changes, quicker therapy initiation, increased patient satisfaction, financial assistance, cost avoidance, and producing less waste. Ralph Hauke, MD, FACP, medical oncologist at Nebraska Cancer Specialists, played a key role in bringing the medically integrated dispensing pharmacy to his practice. He remembers the waste of medication before NCS Outpatient Pharmacy was part of their service. "When these specialty

drugs were being dispensed from mail order pharmacies, they were shipping refills to our patients before we had a chance to see re-staging tests or assess toxicities and they were not checking in on our patients. Financial burdens were also not being addressed and many patients were developing financial toxicity and discontinuing medications without our knowledge or us being able to assist with financial assistance. When we started the pharmacy here and took on all of this for the patients, the cost savings was close to 1.4 million dollars just in drugs that would have been wasted by being sent out before checking with us on the plan of the patient."

NCODA offers multiple tools to aid the MID practice in managing oncolytics. This toolbox contains a Patient Survey that is practice-customizable, a Cost Avoidance and Waste Tracker tool, a Financial Assistance database, Treatment Support Kits, Oral Chemotherapy Education sheets, and of course the Positive Quality Intervention clinical resource documents. Kami Nolan, PharmD, at NCS Outpatient Pharmacy recently ordered in several Treatment Support Kits

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from NCODA for tivozanib. "We recently started 4 patients on tivozanib and I reached out to NCODA and ordered more Treatment Support Kits. We love the convenience of having the kits to hand out to our patients starting on a new therapy."

# THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

his Positive Quality Intervention titled "Tivozanib for Relapsed or Refractory Advanced Renal Cell Carcinoma," offers providers valuable information on a newer therapy option in patients who are refractory or intolerant to other agents. Jennifer Yannucci, MD, a Hematologist/Oncologist at the AON practice Low Country Cancer Care in Savannah, GA comments, "I have a complicated RCC patient who experienced terrible hand/foot syndrome from previous therapies. We started her on a low dose of tivozanib and she is currently doing well and not having the side effects she was having with the other treatments."

This article will explore the benefits of PQI utilization as a core standard of the MID and how adoption can benefit any practice. The processes within an oncology pharmacy can be overwhelming to anyone with all the new drugs and new indications consistently entering our space. This can be especially challenging to those employees who transition from another department or are new to oncology altogether. Kelly Hotaling, PharmD of NCS describes, "I am a veteran user of PQIs, as I found them extremely helpful when I was new to oncology practice. After reading over a PQI, especially on newer oncology drugs, I can confidently counsel a patient on the important points."

CLICK HERE TO VIEW PQI

Prior Authorization Specialist Katie Mason, CPhT, RPhT, at the Messino Cancer Center, an AON practice in Asheville, NC, finds the NCODA PQI reference helpful in her practice. "I use the NCODA PQI reference to ensure that the reference guides we use as prior authorization technicians are

up to date. I will add in any helpful charts or pieces of information in the PQI that are not in our guides, and this information serves to enhance our tools at the practice."

Both AON practices featured in this article and the team at Nebraska Cancer Specialists all found successful ways to incorporate the PQI clinical resource. The practices position their Medically Integrated Teams in a way to ensure appropriate treatment, increase compliance, and maximize clinical outcomes. We will explore their practice settings, how implementing the **Tivozanib for Relapsed or Refractory Advanced Renal Cell Carcinoma** PQI benefits their staff and patients, and how they advance patient care on a daily basis.

### **MEDICALLY INTEGRATED DISPENSING: ELEVATING CARE**

s cancer treatment continually grows in complexity containing IV, oral and combination regimens, MID continues to offer an invaluable option for patient care. The MID and multidisciplinary staff has unparalleled access to patient information and means of direct communication with other members of the team. The pharmacy members of the team also have direct access to communication with patients and can easily report information back to the providers. This model greatly reduces fragmentation of care.

Nebraska Cancer Specialists Nurse Practitioner, Sarah Schutt, DNP, APRN stresses the important role that the pharmacy team plays in her practice. "Our pharmacy team is very accessible compared to any outside pharmacy. When I am seeing a patient and have a question about an adverse reaction or have a new start chemotherapy, I know I can quickly call over and speak to one of the pharmacists. For the drug teach or counseling piece, I then let the patient know which pharmacist I spoke to and who will reach out to them. That personal connection right away is priceless to our patients. They know they will be expecting a call from our pharmacy, who will be calling and what will be discussed."

Dr. Yannucci comments, "having the medically integrated pharmacy has made a huge difference in patient satisfaction and is very beneficial for patient care." She reflects on her time before becoming an AON practice and the struggles they endured. "Before joining AON, we did not have an integrated pharmacy in our system. There are more benefits than I can count with having the medically integrated pharmacy including quicker access to drugs, better tolerability due to the intense monitoring provided, and the counseling patients receive on what to expect and when to call us. The pharmacy team is the key to bridging the gap between provider and patient."

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# PUTTING THE TIVOZANIB FOR RELAPSED OR REFRACTORY ADVANCED RENAL CELL CARCINOMA PQI INTO ACTION

he 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. The **Tivozanib for Relapsed or Refractory Advanced Renal Cell Carcinoma** PQI is written in sections beginning with a Description and ending with Patient-Centered Activities and References.

The Description section states the purpose of the PQI. In this case, we are reviewing the clinical considerations around the use of tivozanib in the setting of relapsed or refractory advanced cell renal carcinoma. Next, the Background section gives pertinent historical data and information, clinical trial experience and the focus of the intervention. Regarding tivozanib, the drug is a VEGFR inhibitor that first gained approval for the indication of advanced or metastatic renal cell carcinoma in patients who have previously received two or more prior systemic therapies, based on the phase III TIVO-3 trial in March 2021. Tivozanib has recently received an NCCN category 1 recommendation as a subsequent therapy option

for patients with ccRCC, based on the Q-TWiST analysis. The TIVO-3 trial showed patients receiving tivozanib had significantly longer PFS than those receiving sorafenib (5.6 months vs. 3.9 months, HR 0.73, p=0.016) and higher objective response rates (18% vs. 8%) than sorafenib. Treatment-related adverse events with tivozanib were common (84%) but manageable with grade 3 or higher adverse events occurring in less than 5%, with the exception of hypertension (20%).4 Of the patients experiencing adverse events, 48% led to dose interruptions and 24% led to dose reductions.

Dr. Hauke comments on early use of tivozanib in his practice. "We were actually involved in the early phase 1 trials for tivozanib and it was very well tolerated in the research setting. Following the approved indication, one may definitely consider tivozanib in the relapsed/refractory RCC setting." Dickert from AON points out helpful areas in the background section of the PQI. "The background section of the PQI comes in handy when we are speaking to patients that have been on prior treatments. They actually do ask about this and want to know how this treatment differs from others they have taken. I like to compare them and tell them that in the clinical trial,



there were patients just like you that have been on lots of previous treatments and had positive outcomes with this new therapy."

## THE PQI PROCESS: STEPS INVOLVED FOR ENHANCING TREATMENT SUCCESS

he next section of the **Tivozanib for Relapsed**or Refractory Advanced Renal Cell Carcinoma
PQI is the PQI Process. This section lays out the
intervention in step by step points, contains clinician directed guidance, including monitoring parameters and
dose reduction guidelines, that can benefit the entire team.

There are 6 steps to the PQI process in this tivozanib PQI. The first step is to verify the dosage for the indication of relapsed or refractory advanced renal cell carcinoma. The recommended starting dose is 1.34mg once daily, with or without food, for 21 days followed a 7 day off period for a 28-day cycle.<sup>8,12</sup>

The second step refers to the table that points to dose interruptions or dose reductions based on adverse events. The table outlines the reaction, severity of the reaction based on grading system and finally recommends the dose modification to hold or discontinue the drug based on the graded reaction. Schutt, Oncology Nurse Practitioner at NCS provides "I think the PQI is a great reference. I find the chart for dose modifications helpful and I like that it lists the grades of severity and how to modify according to this."



#### DOSE MODIFICATIONS FOR ADVERSE EVENTS

Adverse Reaction	Severity	Dose modifications
Hypertension	Grade 3	Hold for Grade 3 that persists despite optimal antihypertensive therapy
		Resume at reduced dose when hypertension is controlled at less than or equal to Grade 2
	Grade 4	Permanently discontinue
Cardiac Failure	Grade 3	Hold until improves to Grade 0 to 1 or baseline
		Resume at a reduced dose or discontinue depending on the severity and persistence of adverse reaction
	Grade 4	Permanently discontinue
Thromboembolic Events	Any Grade	Permanently discontinue
		Hemorrhagic Events
	Grade 3 or 4	Permanently discontinue
Proteinuria	2 grams or greater proteinuria in 24 hours	Hold until ≤ to 2 grams of proteinuria per 24 hours
		Resume at a reduced dose
		Permanently discontinue for nephrotic syndrome
Reverse Posterior Leukoencephalopathy Syndrome	Any Grade	Permanently discontinue
Other Adverse Reactions	Persistent or intolerable Grade 2 or 3 adverse reaction	Withhold until improves to Grade 0 to 1 or baseline
	Grade 4 laboratory abnormality	
	Grade 4 adverse reaction	Permanently discontinue

The PQI process continues with labs to monitor while patients are on therapy. Total bilirubin levels (Tbili) and Aspartate Aminotransferases levels (AST) should be followed to assess hepatic function/impairment and thyroid levels should be checked at baseline and every 2-3 months while on treatment. Tbili greater than 1.5-3 times the upper limit of normal with any increase in AST will require dose reductions. Females of reproductive potential should have pregnancy status monitored.

The final point of the PQI Process section covers reviewing medication lists for possible drug interactions, specifically anything that is a strong inducer of CYP3A4. Any strong CYP3A4 inducers should be avoided in patients taking tivozanib. Stress the importance of knowing when patients start on new medication. If patients are started on new medications, they will call us right away to ask if they interact with their chemotherapy and ask us to look into it. This is important for drugs like tivozanib that have this strong CYP3A4 interaction. They don't have to wait on hold or for someone to call them back for the information – we can answer and tell them right away."

### PATIENT-CENTERED ACTIVITIES: KEEPING PATIENTS FIRST

he Patent-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. The **Tivozanib for Relapsed or Refractory Advanced Renal Cell Carcinoma** PQI Patient-Centered Activities suggests providing the patient with an Oral Chemotherapy Education (OCE) sheet. OCE sheets are an NCODA-led initiative and provide information about oral chemotherapy drugs and their side effects to both cancer patients and caregivers. In 2019 the Patient-Centered Stan-

CLICK HERE
TO VIEW
OCE SHEET

dards 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 antican-

cer drug, a formalized patient education session should occur

with an experienced clinical educator such as a nurse, physician, pharmacist, nurse practitioner, or physician 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>

Dr. Hauke of NCS adds, "I feel this PQI could be a valuable tool for my colleagues who don't use this drug often in practice. The background section and highlights on the adverse reactions gives a quick snapshot of what providers need to know about the drug. The OCE sheet link leads the clinician to another valuable reference to use for patient education."

The next section of the Patient-Centered Activities focuses on the Treatment Support Kits available for patients, specifically what is needed to help assist any side effects encountered with tivozanib treatment. Treatment Support Kits (TSKs) are an additional resource provided by NCODA for practices to order for patients who are receiving oral oncolytic treatment. The TSK for tivozanib includes the following:

- Treatment Booklet with OCE Sheet
- PQI Document
- Treatment Calendar
- Digital Pedometer
- Water Bottle
- BP Monitor

All participants from AON and NCS agree that increases in blood pressure must be closely monitored and having a blood pressure monitor and keeping a log is key to monitoring this side effect. Ashley White, RN, BSN, OCN of NCS alludes to blood pressure

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TSK

increases in her patients. "Because this is a subsequent line of therapy for these patients and these drugs as a class can increase blood pressure, patients may already be familiar with the potential and have the devices they need to monitor. I really like to reiterate the key points of blood pressure monitoring to the patients, such as taking more than one reading to ensure accuracy, keeping a log or journal of readings to note trends and then stressing the importance of reaching out to us if they experience high readings or abnormal trends." Hotaling, Staff Pharmacist at NCS adds "having the blood pressure monitors in the TSK's for tivozanib is a major plus. Even patients who are already familiar with taking blood pressure and may already have a machine, this may provide an extra for another area of their home

or to keep at work or in a car." Diarrhea is also seen in tivozanib patients (43%), so loperamide is recommended to keep on hand for patients who may experience this side effect.<sup>8,12</sup>



The final piece of the Patient Centered Activities section is the NCO-DA Financial Assistance Tool. The impact of cancer treatment on patient financial well-being is a topic of major concern in the oncology community.<sup>14</sup> Financial toxicity has been linked to

an increased patient risk of medical noncompliance.14

Dr. Hauke found that prior to opening and using the medically integrated specialty pharmacy at NCS, he was often unaware of the costs and troubles his patients were dealing with; and the outside pharmacies were not helpful in communicating or doing anything about this. Hauke comments "we often were not aware of patients who were dealing with financial toxicity or could not afford medications because the pharmacy would not call and let us know. This was very frustrating as a physician trying to treat and care for a patient." With the addition of their specialty pharmacy, he adds "now our case managers, pharmacists, nurses and physicians work together and are aware of all the steps. Once the medication is prescribed and goes through the processing procedures, the pharmacy lets us know how much it costs the patients and their start date. We then can log this start date and we have a better handle on what is happening to the patient. This process helps everyone financially in the end, especially the patient."

Andrea Nelson, CPhT of NCS, reflects on her transition to pharmacy. "I transitioned over to the pharmacy after working the front desk at one of our offices. It was challenging, but my favorite part of my job is getting to know all the patients by assisting them in the pharmacy. Much of what I do consists of finding financial assistance and the direct link to this NCO-DA tool from the PQI is very helpful for my job."

"MUCH OF WHAT I DO CONSISTS OF FINDING FINANCIAL ASSISTANCE AND THE DIRECT LINK TO THIS NCODA TOOL FROM THE PQI IS VERY HELPFUL FOR MY JOB."

Andrea Nelson, CPhT

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

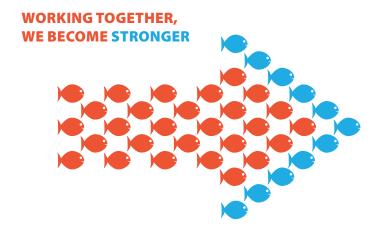
Il team members of AON and NCS agree that the MID model and the PQI Clinical Resource are valuable to the team and to patients. Communication and teamwork are essential components of what make this model work effectively and efficiently. Schardt of NCS adds, "communication is a stellar piece of what I love about the MID model. As employees, we aren't just the pharmacy department. We all work together as a team, every day, for the patient."

To provide the best quality care, cancer patients should always have a direct line of communication to their medical team. This personalized care is what the MID model can offer and is the key to distinguishing MID over outside pharmacies. White, Nurse Case Manager at NCS, comments on her collaborative relationship with the pharmacy, "I am really proud that we are able to offer the service of the MID pharmacy to our patients. The personal relationships we have built together as a practice allows us to extend that offering to our patients and I feel that they truly appreciate this type of care over what outside pharmacies can provide."

The essential components of the **Tivozanib** for Relapsed or Refractory Advanced Renal Cell Carcinoma PQI ensure appropriate patient identification, selection, monitoring, increased speed to therapy, and reduced cost and hospitalizations by improving adherence techniques for the patient and their Medically Integrated Teams. Nolan, the Pharmacy Manager at NCS confirms "The PQI is helpful as it serves a vital

role in guiding the pharmacists before calling the patients. It focuses on the important points to ask patients about during counseling and follow-up calls."

Tivozanib gives patients with relapsed or refractory advanced renal cell carcinoma another treatment option. The PQI provides the MID program with an easy to use, compact clinical resource guide when discovering the right patient and dispensing FOTIVDA®. It helps the team ensure they are providing patients with the tools and education to improve clinical outcomes. Pairing Medically Integrated Dispensing with the Tivozanib for Relapsed or Refractory Advanced Cell Renal Carcinoma PQI meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.

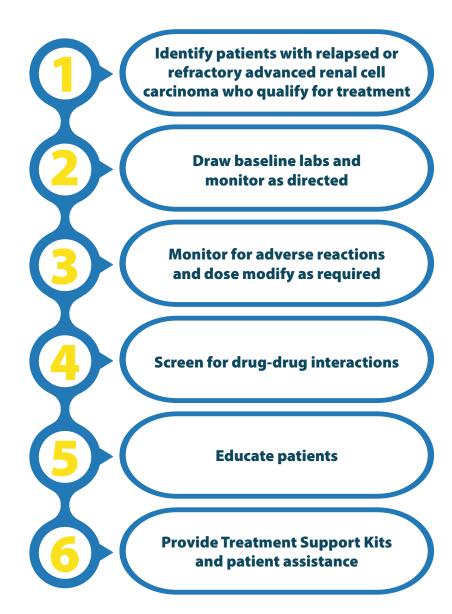


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## **PQI PRINCIPLES:**





### **Helpful Online Resources**

- Tivozanib (Fotivda®) for Relapsed or Refractory
  Advanced Renal Cell Carcinoma
- **Positive Quality Interventions**
- Tivozanib Oral Chemotherapy Education Sheet
- Oral Chemotherapy Education Sheets
- NCODA Website
- NCODA Financial Assistance Tool

#### **ON THE COVER:**

• The Pharmacy Team at NCS Outpatient Pharmacy provides oncology pharmacy services to Omaha, Nebraska and its surrounding communities. Pictured left to right are Leah Schardt, PharmD, Kelly Hotaling, PharmD, Andrea Nelson, CPhT, and Kami Nolan, PharmD.

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.



