

PQI IN ACTION



TUCATINIB MANAGEMENT



**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 **Tucatinib Management PQI** and explores how the medically integrated teams at Johns Hopkins Kimmel Cancer Center - Sibley Memorial Hospital and Miami Cancer Institute incorporate PQIs as part of their daily workflow. This article will discuss how utilizing the **Tucatinib Management PQI** elevates patient care.

Johns Hopkins Kimmel Cancer Center at Sibley Memorial Hospital (SMH) gives patients access to some of the most innovative and advanced therapies in the world. Because Kimmel Cancer Center clinicians and research scientists work collaboratively, new drugs and treatments developed in the laboratory are quickly transferred to the clinical setting, offering patients cutting edge therapeutic options. Sibley Memorial Hospital serves patients in the Washington D.C. area and has a team of two Clinical Pharmacist Specialists that manage patients on oral oncolytic therapy. Johns Hopkins offers specialty pharmacy services through the Weinberg Outpatient Pharmacy, located inside of inside of Johns Hopkins Hospital in Baltimore, MD.

Miami Cancer Institute (MCI) at Baptist Health South Florida is a next-generation cancer treatment destination known for its leading clinical care and research, compassionate patient experience and state-of-the-art technology. Miami Cancer Institute is considered one of the "hybrid" cancer centers of the future that combines high-quality, community-based cancer care with the best of an academic cancer center. MCI has clinical pharmacist specialists and one solely dedicated to their breast team. Kendall Pharmacy dispenses outpatient medications on site.

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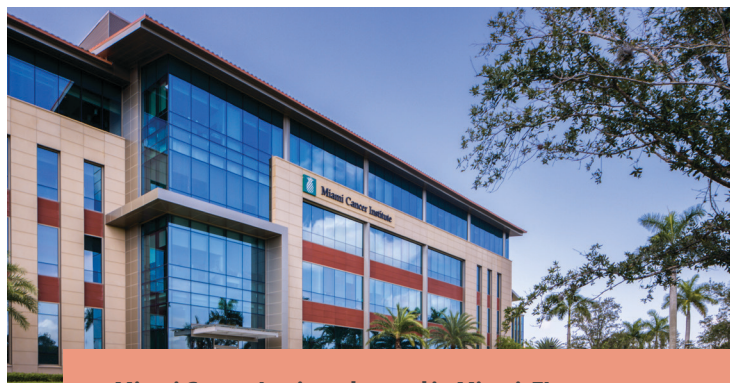
MID, THE PQI, AND TUCATINIB: GIVING PATIENTS ADDITIONAL OPTIONS FOR TREATING HER2-POSITIVE BREAST CANCER

Breast cancer is now the most commonly occurring cancer worldwide and accounts for one in every eight cancers in 2020.¹ 5-20% of breast cancers may over-express human epidermal growth factor receptor 2 (HER2) and up to half of patients with metastatic HER2-positive disease may develop brain metastases.² Patients with HER2-positive metastatic breast cancer whose disease progresses following therapy with multiple HER2-targeted agents have limited treatment options.² TUKYSA® (tucatinib) is a kinase inhibitor indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.³ In heavily pretreated patients with HER2-positive metastatic breast cancer, including those with brain metastases, adding tucatinib to trastuzumab and capecitabine resulted in better progression-free survival and overall survival outcomes than trastuzumab and capecitabine alone.²

HER2CLIMB Trial	Tucatinib Group	Placebo Group
PFS at 1 year	33.1%	12.3%
Median PFS duration	7.8 months	5.6 months
OS at 2 years	44.9%	26.6%
Median OS duration	21.9 months	17.4 months

As stated in the **Tucatinib Management PQI** background section, an exploratory analysis in the HER2CLIMB trial of intracranial efficacy in patients with brain metastases who received tucatinib combination versus placebo group showed a 42% reduction in the risk of death, a 68% reduction in the risk of CNS disease progression or death, and an increase in intracranial response rate (47% vs. 20%) for patients who had active measurable intracranial lesions at baseline.⁴

Tucatinib 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. 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.⁵ The MID model can improve management of patients on therapies like tucatinib in several ways including improved communication issues, measuring adherence,



Miami Cancer Institute located in Miami, FL.

managing regimen changes, quicker therapy initiation, increased patient satisfaction, financial assistance, cost avoidance, and producing less waste.⁶

NCODA offers multiple tools to aid the MID practice in managing oncology. 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. MCI Clinical Pharmacy Specialist Janine Smith, PharmD, MBA, MSRA, BCOP, BCPS, believes in the value of MID and patients having a relationship with their pharmacy. She explains, “patients who are taking multiple medications and have comorbid disease states have better healthcare outcomes when they have regular contact with their pharmacists. Patients that have close contact with their pharmacists are able to call the pharmacist and ask pertinent questions that may affect their healthcare.”

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Janine Smith, PharmD, MBA, MSRA, BCOP, BCPS

THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

Sibley Memorial Hospital's Clinical Pharmacy Specialist Charita Marthone, PharmD, BCOP shares the PQI “is a great, easy, one stop resource to go to.” She continues, “the PQI is a really valuable, quick resource for

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“I THINK FOR ME, AS A PROVIDER, IT IS VALUABLE BECAUSE THE ONE PAGE WILL GIVE ME WHAT I REALLY NEED TO TELL THE PATIENT.”

Ana Sandoval Leon, MD

“THE PQI IS A REALLY VALUABLE, QUICK RESOURCE FOR THE CLINIC.”

Charita Marthone, PharmD, BCOP

the clinic.” MCI Hematologist-Oncologist Ana Sandoval Leon, MD also finds value in the PQI and comments, “I think for me, as a provider, it is valuable because the one page will give me what I really need to tell the patient. It also helps the pharmacists as educators to summarize everything. It helps them know exactly what the most common side effects are and then to educate patients regarding those side effects. I think it is a very valuable tool.”

This article will explore the benefits of PQI utilization as a core standard of the MID and how adoption can benefit any practice. SMH and MCI each found successful ways to incorporate the PQI clinical resource. Both 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 **Tucatinib Management** PQI benefits their staff and patients, and how they advance patient care on a daily basis.

MEDICALLY INTEGRATED DISPENSING: ELEVATING CARE

As cancer treatment continually grows in complexity containing IV, oral and combination regimens, MID continues to offer an invaluable option for patient care. The 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.

Johns Hopkins Medical Oncologist Cesar Santa-Maria, MD, MSCl shares “pharmacy plays a central role in our multidisciplinary team, and they are involved in different aspects of patient care from helping with oral chemotherapy orders and teaching, to providing assistance when there are pharmaco-

“PHARMACY PLAYS A CENTRAL ROLE IN OUR MULTIDISCIPLINARY TEAM, AND THEY ARE INVOLVED IN DIFFERENT ASPECTS OF PATIENT CARE FROM HELPING WITH ORAL CHEMOTHERAPY ORDERS AND TEACHING TO PROVIDING ASSISTANCE WHEN THERE ARE PHARMACOLOGIC ISSUES.”

Cesar Santa-Maria, MD

logic issues. Our pharmacists are involved in monitoring, so once a drug therapy is prescribed they will follow up with patients and make sure toxicity is managed and help address patient clinical questions. Beyond that, in terms of other IV therapies, they are very involved in helping us get those set up, managing side effects, adjusting medications, and over-viewing the patient's treatment."

Freddie Navas, reimbursement specialist in the Baptist Health Specialty Pharmacy at MCI feels MID is the perfect arrangement for patients. She comments that a big benefit of MID is that the full multidisciplinary team all has access to the same EMR system. In her role she can read patient notes right away and begin work on billing insurance for the prescription or obtaining a prior authorization on behalf of the patient if required. She adds the MCI staff all has access to the same messaging system and can also email the providers or other team members very quickly if needed. SMH clinical pharmacy technician Penny Muza, R-CPhT echoes this sentiment. She shares, "once the prescription comes over, we determine whether we have the drug in stock or it needs to be ordered. We also determine the co-pay of drug. Depend-

"THE BENEFIT OF MID IS THAT RIGHT FROM THE BEGINNING, WHEN THE PATIENT COMES IN, IT IS ALL HANDS ON DECK. THAT MAKES IT EASIER FOR THE PATIENT TO MAKE INFORMED DECISIONS WHETHER ON THEIR TREATMENT, FINANCES, OR REFILLS. EVERYTHING JUST STARTS OUT RIGHT."

Penny Muza, R-CPhT

ing on the amount, our patient assistance team would look into finding eligible programs to assist with patient cost. The benefit of MID is that right from the beginning, when the patient comes in, it is all hands on deck. That makes it easier for the patient to make informed decisions whether on their treatment, finances, or refills. Everything just starts out right."

PUTTING THE TUCATINIB MANAGEMENT PQI INTO ACTION

The PQI is a peer-reviewed clinical guidance document that provides Quality Standards and effective practices around a specific aspect of cancer care. The Medically Integrated Pharmacy team is in a unique position to ensure appropriate treatment, increase compliance, and maximize clinical outcomes. Positive Quality Interventions (PQIs), an NCODA Quality Standard, are designed to operationalize and standardize those practices to achieve these positive clinical outcomes. The **Tucatinib Management PQI** is written in sections beginning with a description and ending with patient-centered activities and references.

Following the description, the background section gives pertinent historical data and information, clinical trial experience and the main focus of the intervention. Regarding tucatinib, the background discusses the approval, indication and published data leading to approval. Again, it discusses the exploratory analysis in the HER2CLIMB trial of intracranial efficacy in patients with brain metastases who received tucatinib combination versus placebo group.⁷

Dr. Santa-Maria comments, "a unique aspect of the HER-2CLIMB study was that they were able to demonstrate benefit in patients with brain metastases, so certainly those are the kind of patients that I would think about." Dr. Sandoval Leon adds that it is approved for second line. She says for patients with brain metastases she will potentially use as second line therapy. She explains that the physicians at MCI attend tumor boards and meetings amongst their group to discuss patient cases and when to consider tucatinib use. Her center also has an ongoing trial using the drug.

"A UNIQUE ASPECT OF THE HER2CLIMB STUDY WAS THAT THEY WERE ABLE TO DEMONSTRATE BENEFIT IN PATIENTS WITH BRAIN METASTASES."

Cesar Santa-Maria, MD

THE PQI PROCESS: A TEAM EFFORT



Johns Hopkins Kimmel Cancer Center at Sibley Memorial Hospital located in Washington, DC.

The next section of the **Tucatinib Management PQI** is the PQI Process. This section lays out the intervention in step by step points, contains clinician directed guidance and critical clinical criteria that can benefit the entire team. Smith comments, “I think the PQI Process section is very beneficial to my role.”

The first step of the **Tucatinib Management PQI** Process states to identify eligible HER2 positive patients as potential candidates for tucatinib. The combination of tucatinib, capecitabine and trastuzumab has a Category 1 recommendation by NCCN Guidelines for second-line systemic treatment of HER2-positive metastatic breast cancer.⁸ Marthone comments that determining if a patient is a candidate for a therapy at her center is patient-specific, insurance-specific, and based on NCCN guidelines.

The PQI process continues with steps when receiving a prescription for tucatinib, and includes a table outlining possible dose adjustments and how to supply the medication when adjusted. It discusses when to adjust each agent in the triplet therapy. At MCI, Navas find the table of dose adjustments a beneficial part of the PQI and something that the pharmacy staff always evaluates. At SMH, Marthone also finds this table useful. She comments, “The PQI for tucatinib does have dose recommendations for reduction, which can really help. Even knowing how it is supplied can help with these dose reductions.”

TUCATINIB DOSE ADJUSTMENTS

Dose Reduction	Recommended Dose	How to Supply
1 st dose reduction	250 mg PO BID	One 150 mg tablet + two 50 mg tablets BID
2 nd dose reduction	200 mg PO BID	One 150 mg tablet + 50 mg tablet BID
3 rd dose reduction	150 mg PO BID	One 150 mg tablet BID

The final point of the PQI Process section discusses drug interactions and the need to avoid concomitant strong CYP3A4 and CYP2C8 inhibitors and inducers. Pharmacists at both MCI and SMH screen patients for drug interactions. When Smith receives a prescription for tucatinib at MCI she reviews the prescription “for drug allergies, drug interactions, proper dose frequency, proper route of administration and duration of therapy.” Marthone follows a similar process. When a provider starts a patient on therapy at SMH a request is sent to the prior authorization team and Marthone is copied on the request. She then performs a drug interaction check, verifies lab values and makes sure it is appropriate for a patient to start therapy.

PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

The Patient-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. The **Tucatinib Management 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 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.⁹ Standard 1.2 of the ASCO/NCODA Standards reads:

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Prior to initiation of an oral anticancer drug, a formalized patient education session should occur with an experienced clinical educator such as a nurse, physician, pharmacist, nurse practitioner, or physicians assistant. The discussion should include drug name (generic and brand), drug dose, schedule, potential adverse effects and how to properly manage them, fertility (where applicable), treatment goal, duration of therapy, and financial and affordability considerations.⁹

SMH Lead Oncology Nurse Navigator Jennie McLaughlin Tarica, MSN, RN, shares that in her practice patients are very receptive of written educational materials. Most of her patients expect and appreciate “well thought out information for them to walk away with or to be given about their medication.” In the clinic Marthone counsels patients on all new start oral oncolytics. Her education is provided virtually and she uses OCE sheets as a guide to counsel patients. She comments that while patients do sometimes miss person to person contact, they are often relieved that the education is virtual and does not require them to leave home for another visit. They find it convenient that they do not have to get up and go.

The Patient-Centered Activities section also discusses tucatinib administration. Tucatinib can be taken with or without food at the same time twice each day. It can be taken at the same time as the capecitabine in the regimen.³ The Patient-Centered Activities outlines important storage instructions for tucatinib. It should be stored at room temperature in the original bottle and the desiccant should not be removed

from the bottle. Once the bottle is opened the medication should be used within three months.³ At MCI, Smith shares that the prescription does not go out until the pharmacist has counseled the patient on the drug. The clinical pharmacist, in this case the Clinical Breast Specialist, discusses the dose and goes over administration instructions prior to the medication ever being dispensed.

“I THINK IT IS VERY IMPORTANT TO SET EXPECTATIONS WITH A PATIENT AND LET THEM KNOW THIS IS A SIDE EFFECT THAT IS COMMON. THE PATIENT KNOWING WHAT TO EXPECT DEFINITELY HELPS.”

Cesar Santa-Maria, MD

The final Patient-Centered Activity is to recommend antidiarrheal agents to have on hand when starting tucatinib. Diarrhea was reported as a side effect in 81% of patients in the HER-2CLIMB trial and was reported to be manageable with short courses of antidiarrheals.³ Dr. Sandoval Leon shares “I always discuss the diarrhea and I will usually instruct the patient to take loperamide every two hours as needed and to call us if it does not improve.” Dr. Santa-Maria comments “I think it is very important to set expectations with a patient and let them know this is a side effect that is common. The patient knowing what to expect definitely helps. The other thing I tell patients is that they should always have a little threshold to reach out to us and that communication is going to be really key when getting started with a new therapy.”

According to Smith, the number one thing the patient should be aware of when starting this therapy is “this drug does cause diarrhea and how they can manage diarrhea if it should happen.” She says that the team should ensure the patient has loperamide on hand at home when starting therapy. She also gives patients information about what to eat if they experience diarrhea. She gives patients information on the BRAT diet and eating smaller, more frequent meals. She says patients can keep food diaries and she instructs them to record episodes of diarrhea in the diary.

FINANCIAL ASSISTANCE: A BENEFIT OF MID AND THE MULTIDISCIPLINARY TEAM

In addition to close follow up and detailed education, MID renders the practice able to provide excellent customer service, unmatched patient care, and help with finding funding so the patient can afford to take the medication. Many times, insurance mandates require that prescriptions must be filled outside of the practice in a PBM owned mail-order pharmacy instead of by the MID pharmacy inside the clinic. Dr. Sandoval Leon

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**“I THINK WE SHOULD ALL
HAVE PHARMACIES AS PART
OF OUR CLINICS.”**

Ana Sandoval Leon, MD

shares “I think we should all have pharmacies as part of our clinics.” She sees the benefit of MID “for patient safety and for patients to be able to get their prescriptions in a timely manner.” She adds that when patients are mandated to fill at outside mail order pharmacies they often see a lot of delays.

She says that communication is much easier with her internal pharmacy and she feels they are more on top of things and only filling specific drugs for their center.

Following the Patient-Centered Activities, the **Tucatinib Management PQI** contains a Financial Assistance section. The impact of cancer treatment on patient financial well-being is a topic of major concern in the oncology community.¹⁰ Financial toxicity has been linked to an increased patient risk of medical noncompliance.¹⁰ Muza discusses the positive impact of her pharmacy team on financial assistance and shares “right away you know if the patient needs help or not on the financial side. You can redirect the patient either to the patient assistance program or find out why the copay is so high. I go as far as calling the insurance to find out why the copay is high.”

Smith shares MCI also helps patients with the manufacturer based assistance programs. Members of their team get involved and help patients fill out forms and submit these when necessary. Navas is in the role of reimbursement and billing technician and completes prior authorizations for patients, reaches out for appeals when necessary, and helps find funding for high copays. Once again she shares that having access to the same system and notes in the EMR is a benefit for patients.

SIDE EFFECTS: SUPPLEMENTAL EDUCATION FOR PATIENT-CENTERED MEDICATION MANAGEMENT

The final section of the **Tucatinib Management PQI** is Supplemental Information and includes common side effects reported by the HER-2CLIMB trial.⁷ The tucatinib side effects highlighted in the PQI include diarrhea, palmar-plantar erythrodysesthesia syndrome, nausea, vomiting, fatigue, increased liver transaminases, stomatitis, headache, and decreased appetite.⁷

Marthone shares the oral anticancer therapy services were added to her clinic at SMH around a year and a half ago. Her position was added as a clinical specialist to manage patients

on oral oncolytics. In this position Marthone counsels patients on new start oral oncolytics. She says, “what this entails is going over how to properly dispose, store and handle the medication as well as going over side effects, how to manage side effects and when to call the clinic for serious side effects.” She provides longitudinal follow-up services that assist in tracking patients after they begin therapy. After one week of therapy the team calls patients to see how they are doing and assess adherence. She adds “clinically we are able to recognize any side effects with patients and we can manage these early

on so we don't get into any serious side effects that may delay or stop therapy."

At MCI, Smith also counsels patients on oral oncolytics. When patients start tucatinib she not only discusses the diarrhea potential but also the "subtle signs of liver toxicity." She also goes over the potential for palmar-plantar erythrodysesthesia syndrome, also known as hand-foot syndrome. She goes over the need to properly moisturize the patient's hands and feet. Tarica also provides patient education at SMH and shares she tries to focus on the side effects that are going to be the most common. With tucatinib, she discusses the potential for nausea, vomiting and fatigue. She says that the provider typically provides the initial education with the follow-up consultation from pharmacy. She sees a benefit in multiple sources of education because "on that initial consultation patients only remember a small percentage of information."

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COMMON SIDE EFFECTS REPORTED IN THE HER2CLIMB TRIAL:

Diarrhea (80.9%; reported to be manageable with short courses of antidiarrheals)

Palmar-plantar erythrodysesthesia syndrome (63.4%)

Nausea (58%), vomiting (35.9%)

Fatigue (45%)

Increased liver transaminases (20%; reported to be transient and reversible)

Stomatitis, headache, decreased appetite also reported

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. Every day the MID team can make a difference in the life of patients. Dr. Sandoval Leon shares, "Janine is an awesome pharmacist for our team. We have a weekly meeting where we go over cases or updates. Janine is always a part of that meeting, so if there are new drugs or any updates she will present and that has been really helpful. Also, when new drugs are approved, she is always sure to send us an email and let us know of the approval. It is always good to know she is there to help us. I think that it is really good for our patients as well." Navas adds she feels the MID model benefits patients because her pharmacy "treats patients like family." Marthone also loves being part of the medically integrated team. She comments that the clinical specialist service is "a very rewarding service to have implemented. As far as the breast team, it is wonderful to work with such knowledgeable and professional people."

The team can continually learn something new or can begin a process that optimizes care. The PQI fosters this through appropriate patient identification, selection, increased speed to therapy, reduced cost, and hospitalization and by improving adherence techniques for the patient and their Medically Integrated Teams. As a clinical pharmacy technician working closely with her clinical pharmacist team, Muza finds the PQI to be "a very valuable resource" because it gives her a background when reaching out to her clinical pharmacist.

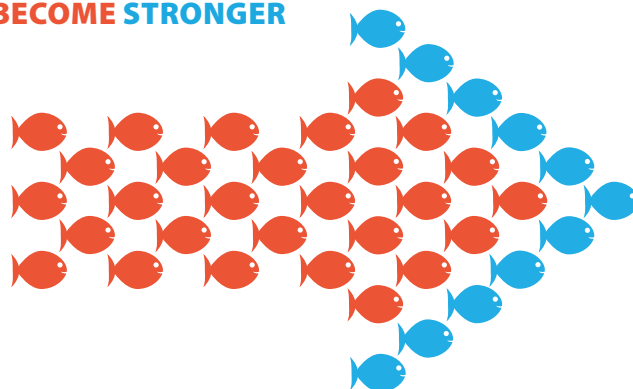
Smith finds value in the PQI because "it helps to improve communication and collaboration with patients, providers, and other health care practitioners to improve patient care outcomes, patient safety, and patient education." Smith has good working relationships with her providers and shares "you have to build relationships with the people you work with and you get in touch with the person if there is a problem and you offer solutions. Don't just identify the problem and focus on the problem but

focus on a solution. Be someone who is very supportive and trying to help the patient, focusing on the patient. I think that's very important."

Tucatinib gives patients with advanced unresectable or metastatic HER2-positive breast cancer 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 TUKYSA®. It helps the team ensure they are providing patients with the tools and education to improve clinical outcomes.

Pairing Medically Integrated Dispensing with the **Tucatinib Management PQI** meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.

**WORKING TOGETHER,
WE BECOME STRONGER**



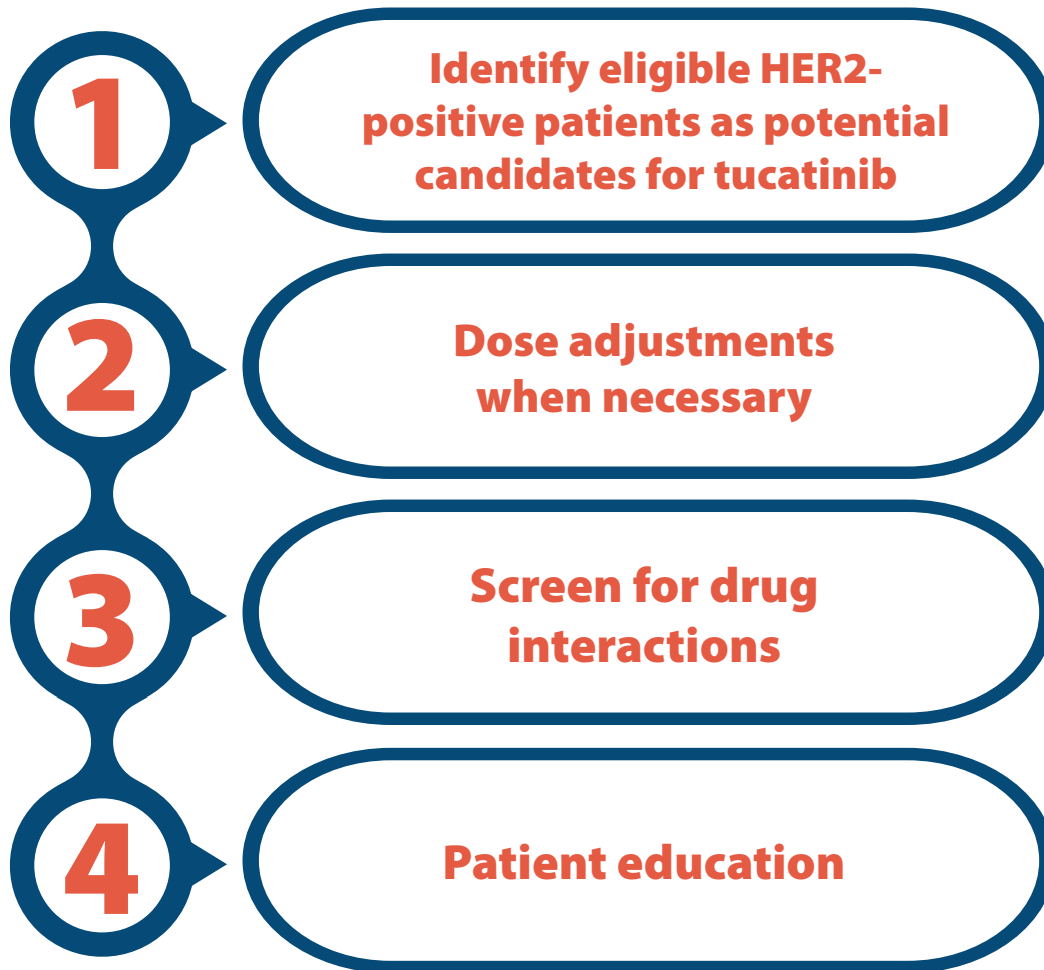
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ON THE COVER:

- Pharmacy staff members at SMH work together to provide superior patient care.

PQI PRINCIPLES:



Helpful Online Resources

- [NCODA Website](#)
- [Oral Chemotherapy Education Sheets](#)
- [Positive Quality Interventions](#)
- [Tucatinib Management PQI](#)



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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