# **PQI IN ACTION**

NCODA's POSITIVE QUALITY INTERVENTION IN ACTION >>>>>



**TELOTRISTAT ETHYL: CARCINOID SYNDROME DIARRHEA** 



## INTRODUCTION

In an effort to promote higher quality patient care the National Community Oncology Dispensing Association, Inc (NCODA), created the NCODA Positive Quality Intervention (PQI) as a peer-reviewed clinical guidance document for healthcare providers. By providing Quality Standards and effective practices around a specific aspect of cancer care, PQIs equip the entire multidisciplinary care team with a sophisticated yet simple-to-use resource for managing patients receiving oral or IV oncolytics. This *PQI in Action* is a follow up to the Xermelo (telotristat ethyl) PQI and explores how the medically integrated teams at Boston Medical Center and Oklahoma Cancer Specialists and Research Institute incorporate PQI's as part of their daily workflow. It will discuss how utilizing the telotristat ethyl PQI elevates patient care.

Boston Medical Center (BMC) is a private, not-for-profit, 514-bed, academic medical center located in Boston's historic South End. They are the primary teaching affiliate for Boston University School of Medicine. Boston Medical Center cares for patients with malignant and non-malignant blood disorders and cancer. The Center provides diagnostic services, innovative treatments, and comprehensive care to patients. The Center houses an infusion center where patients receive IV chemotherapy. BMC's Specialty Pharmacy is conveniently located on this floor, allowing patients to fill many of their medications without leaving the area.

Oklahoma Cancer Specialists and Research Institute (OCSRI) is a physician-owned group practice with more than 20 blood and cancer specialty physicians and over 200 support staff. They have three locations and provide medical oncology, hematology, gynecologic oncology, cutaneous oncology, clinical research and other services. They own OCS pharmacy which is located onsite in their Tulsa location. OCS pharmacy offers the convenience of patient pick-up and also delivery services.

## **THE PARTICIPANTS**

#### Boston Medical Center Boston, MA



Matthew Kulke, MD Section Chief -Hematology and Medical Oncology, Co-Director of the BU/BMC Cancer Center



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Linda Purdom, RN, OCN Oral Chemotherapy Consultant

#### **CARCINOID SYNDROME DIARRHEA AND FRAGMENTED CARE: TWO DISTINCT PROBLEMS FOR PATIENTS**

he number of patients with neuroendocrine tumors (NETs) has been increasing over the years and it is currently estimated that more than 12,000 people in the United States are diagnosed on a yearly basis.1 It is also estimated that approximately 175,000 people are living with this diagnosis.<sup>1</sup> NETs arise from enterochromaffin cells. They have traits of both nervous system and hormone-producing cells. Neuroendocrine tumors are characterized by originating site, grade, stage, and functional status. Well-differentiated NETs were previously referred to as "carcinoid tumors." This term is still often used by clinicians and patients. These tumors can be functional or non-functional and the functional tumors secrete compounds such as serotonin that can result in carcinoid syndrome.<sup>2</sup> Around 75-80% of patients with carcinoid syndrome will experience diarrhea.<sup>2,3</sup> Several studies have found that patients experiencing diarrhea experience decreased quality of life.3 Xermelo (telotristat ethyl) is a first-in-class oral tryptophan hydroxylase inhibitor indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog therapy (SSA) in adults inadequately controlled by SSA therapy. Through inhibition of tryptophan hydroxylase, telotristat and telotristat ethyl reduce the production of peripheral serotonin, and the frequency of carcinoid syndrome diarrhea.4

#### **Tryptophan and Serotonin Metabolism**

	Monoamine oxidase aldehyde dehydrogenase
	$\checkmark$
Tryptophan → 5-hydroxytryptophan → Serotonin (blood) → 5-hydroxyindoleacetic acid (urine)	
^	$\uparrow$
Tryptophan hydroxylase	Aromatic L-amino acid decarboxylase

Telotristat ethyl is an oral medication and can be handled through Medically Integrated Dispensing and the Medically Integrated Team. 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 health care professionals and other stakeholders who focus on the continuity of coordinated, quality care and therapies for cancer patients.<sup>5</sup> Fragmentation of care has been associated with increased costs of care, a higher chance of having a departure from clinical best practice, and higher rates of prevent-



BMC Clinical Pharmacist David Hughes, PharmD counsels a patient on Xermelo.

able hospitalizations.<sup>6</sup> As the number and complexity of oral oncolytics on the market continues to rise, it is important for teams managing cancer patients to collaborate and become one seamless unit.

The MID model can improve management of patients on these therapies in several ways including improved communication issues, measuring adherence, managing regimen changes, speed to therapy, increased patient satisfaction, financial assistance, cost avoidance and producing less waste.<sup>7</sup> 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, a Financial Assistance database, Treatment Support Kits, Oral Chemotherapy Education sheets, and of course Positive Quality Intervention clinical resources.

# THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

oston Medical Center's Clinical Pharmacy Specialist David Hughes, PharmD, BCOP values the PQI (https://www.ncoda.org/telotristat-ethylcarcinoid-syndrome-diarrhea/) because it is like a "cheat sheet." He adds it is "a condensed version of everything you would be looking at for this patient." OCS's Director of Pharmacy Darrell Willyard, PharmD, finds great value in the Patient Centered Activities section of the PQI. This section is just as it implies and contains activities that can assist in making sure the patients have the best experience with the medication. The goal of using any oncolytic medication is to ensure the best outcome for the patient.

He believes that having this information laid out in one tool brings one big asset: that of saved time.

This article will explore the benefits of PQI utilization as a core standard of the MID and how adoption can benefit any practice. BMC and OCSRI have both found successful ways to incorporate the PQI clinical resource tool. Each practice positions their Medically Integrated Teams in a way to ensure appropriate treatment, increase compliance, and maximize outcomes. We will take a look specifically at their MID settings, how implementing the **Telotristat Ethyl for the Management of Carcinoid Syndrome Diarrhea** PQI benefits their staff and patients, and how they advance patient care on a daily basis.

## MEDICALLY INTEGRATED DISPENSING: MAXIMIZING OUTCOMES

With the growing complexity of cancer treatment, Medically Integrated Dispensing and the Medically Integrated Team continues to offer an invaluable option for patient care. The Medically Integrated Team has unparalleled access to patient information and means of direct communication. Lisa Keller, NP, Nurse Practitioner at Boston Medical Center appreciates how Medically Integrated Dispensing has improved engagement with patients and staff. "It is amazing. This is the third cancer center I have been in and I have never worked this closely with the pharmacy." She adds that MID has really grown in the last 10 years at their facility and says the MID model "has been phenomenal." She goes on "I cannot tell you how helpful it is as a very busy clinician/provider- that if you have a specialty drug like this (telotristat ethyl) and there is any issue, having someone right there that you can talk to about it who is an expert and knowledgeable. It is life-changing, it completely changes your clinical practice."

"MID WITHIN THE PRACTICE ALLOWS FOR A SMOOTH TRANSITION BETWEEN PATIENT, PHYSICIAN, AND PHARMACY. NEEDED INFORMATION CAN QUICKLY BE OBTAINED AND POTENTIAL PROBLEMS CAN BE IDENTIFIED QUICKLY."

Linda Purdon, RN, OCN



OCSRI team Linda Purdom, RN, Darrell Willyard, PharmD, and Scott Cole, MD.

OCS Pharmacy Oral Chemotherapy Consultant Linda Purdon, RN, OCN shares that "MID within the practice allows for a smooth transition between patient, physician, and pharmacy. Needed information can quickly be obtained and potential problems can be identified quickly." The MID model serves the patient and the medical team as a whole in many ways. This model provides convenience, cost savings, immediate verification of insurance coverage, support and assistance with investigation of options for financial assistance, on time fills, and more personalized follow up with patients resulting in higher adherence rates.<sup>8</sup> Boston Medical Center Hematologist-Oncologist Matthew Kulke, MD believes the MID's biggest values lies in two things, "the direct interaction between the pharmacy and the provider and the direct interaction between the pharmacy and the patient, so it forms a triad."

#### **POSITIVE QUALITY INTERVENTIONS BETTER CARE FOR PATIENTS**

he PQI is a peer-reviewed clinical guidance document that provides Quality Standards and effective practices around a specific aspect of cancer care. The PQI is a resource that can assist a practice in meeting the "Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards." According to the publication, adoption of standards can help MID practices obtain optimal adherence and persistence rates, minimize the risk of toxicity with therapy, and positively affect patient health outcomes.<sup>8</sup>

Keller appreciates the PQI as a guide to ensure all important points are being covered. "It just adds to the thoroughness and the quality of what you are doing. It is very helpful," she says. OCSRI Director of Pharmacy Darrell Willyard, PharmD finds value in using the PQI when constructing his questions for his oral adherence program. He elaborates, "they give me insight into the questions that my patients may have and what I could be asking to best serve the patient." At OCSRI, Purdom also uses the PQI to assist in building oral "THE DIRECT INTERACTION BETWEEN THE PHARMACY AND THE PROVIDER AND THE DIRECT INTERACTION BETWEEN THE PHARMACY AND THE PATIENT, SO IT FORMS A TRIAD."

Matthew Kulke, MD

regimens in the EMR system, having an oral care plan with standardized points helps capture details pertinent to each therapy. OCSRI Medical Oncologist Scott Cole, MD sits on the practice's P&T committee and finds value in the PQI as an educational tool when the committee is discussing medications.

#### TELOTRISTAT ETHYL PQI: EMPOWER PATIENTS WITH THE MID

arcinoid syndrome diarrhea has a major effect on a patient's quality of life. Patients can have multiple watery loose stools per day. They may have urgency and fecal incontinence. These problems correlate to a decreased quality of life and patients often have higher rates of depression, anxiety and fatigue.<sup>2</sup> These symptoms can make it difficult to attend events and carry on with life. In patients with carcinoid syndrome receiving treatment with SSA's, telotristat ethyl was associated with a significant decrease in bowel movement frequency.<sup>9</sup>

The starting point on the telotristat ethyl PQI process is to consider EMR review of all patients with neuroendocrine tumors and assess adequate control of diarrhea. Boston Medical Center's pharmacy team has done just that, Hughes describes the process in more detail. BMC pharmacists conduct a chart review of patients who are on SSA therapy, they run a report of these patients. They then take their list of patients and review length of duration of SSA therapy and complete a chart review to see if each patient's symptoms are controlled. If the patients meet the team's criteria, they are able to make recommendations to the physician. Being part of the integrated team, they are able to "actually talk with the prescriber and ask, are they a candidate for Xermelo based on this?" As part of this integration the provider may also approach the clinical



pharmacist and let the pharmacist know of a specific patient that may be a good candidate for the drug and ask the pharmacist how they can help. BMC's clinic pharmacists are also integrated into the clinic and can check on a patient's symptom control when verifying clinic orders for an SSA, and then make recommendations to the physician and team if warranted.

# COLLABORATIVE CARE: INCREASING VALUE AND EFFICIENCY



**Boston Medical Center located in Boston, Massachusetts** 

MC's pharmacists are even more easily able to help manage patients on telotristat ethyl because they work in a collaborative practice setting. Collaborative Practice has been a growing hot topic in the medical community and within NCODA in recent years, with a 2020 NCODA Fall Summit panel dedicated to the topic as well as articles in NCODA's Publication Oncolytics Today (https://www. ncoda.org/oncolytics-today/). Healthcare in the United States continues to undergo changes in delivery of care and financing and this change provides increased opportunities for pharmacists to integrate as team members to assist with responsibility of medication outcomes.<sup>10</sup> This collaborative care has been shown to improve pharmacotherapeutic outcomes and increase value and efficiency of the healthcare system.<sup>11</sup>

At BMC, pharmacists are able to actually prescribe therapy under a collaborative practice agreement with their physicians. Hughes explains that when a physician wants to start a patient on a medication like telotristat ethyl, that provider simply writes a referral to one the Clinical Pharmacy Specialists like Hughes. Following the referral, the Clinical Pharmacy Specialist will review for appropriateness of therapy and correct dose of therapy and will send the order and route it to the pharmacy onsite. The pharmacist can also route the order to the insurance mandated pharmacy when required. Hughes believes collaborative practice "allows the pharmacist to serve as an extender to a provider, so you are able to help offset a lot of the providers workload and work collaboratively as a team to help take care of our patient." He also believes that collaborative practice helps with supportive care for issues like diarrhea, in this setting the pharmacist can help triage and obtain help for the patient in real time instead of the patient waiting for a return call in the next 24 hours.

## THE PQI: GUIDANCE FOR TELOTRISTAT ETHYL

nce initial EMR review and patient screening takes place, the PQI continues with additional process points and patient centered activities. Many of these points are the items OCSRI uses when building the oral regimen into their EMR system and when developing their patient adherence questions. Willyard says the PQI helps him determine the types of questions he should be asking the patient without "having to re-invent the wheel." He goes on "As the only full time pharmacist at our pharmacy, I appreciate items like PQI that help lessen the time I would otherwise lose in searching through package inserts."

The patient centered activities list out various educational points that can assist Willyard and others with making sure the patients are receiving the best information possible from the team. Regarding educating patients on telotristat ethyl, Dr. Kulke states that "one of the most important points is that this is not an anti-diarrheal in the sense of where you take a pill and the diarrhea stops or you take it as needed. You have to take it consistently. It doesn't work right away-in fact, benefits increase over time." Hughes also says it is important to educate patients on adherence and "setting expectations that you might not see the effects of it immediately like you would with a traditional anti-diarrheal, but that in the next three months you're going to see the number of bowel movements go down." Setting the expectations from the beginning will help with adherence over time.

Hughes also thinks it is important to educate patients on the dosing and administration of the drug. The telotristat ethyl PQI reminds the team to verify the initial starting dose of 250mg three times a day and BMC pharmacists do just that. He says it is important to educate patients on constipation as a potential side effect. Both he and Keller recommend that patients track their quantity of bowel movements so they can discuss with the provider at each visit.

"ONE OF THE MOST IMPORTANT POINTS IS THAT THIS IS NOT AN ANTI-DIARRHEAL IN THE SENSE OF WHERE YOU TAKE A PILL AND THE DIARRHEA STOPS OR YOU TAKE IT AS NEEDED. YOU HAVE TO TAKE IT CONSISTENTLY. IT DOESN'T WORK RIGHT AWAY, IN FACT, BENEFITS INCREASE OVER TIME." Matthew Kulke, MD

## **FINANCIAL ASSISTANCE**

he telotristat ethyl PQI also provides a supplemental information section that provides links for financial resources. Dr. Kulke finds value in having the MID pharmacy help with financial assistance for patients. He comments, "that is the huge value because as providers we are not as intimately involved in all of these process issues so having a pharmacist right there on site to help out is a huge benefit." Both MID sites utilize copay cards and other assistance tools to help their patients afford their medications, if a patient cannot purchase the medication the benefit can never be realized.

Willyard says his pharmacy "absolutely" makes use of copay cards. They research and help obtain assistance for their patients whether or not they are able to fill the medication inside of the practice. BMC does likewise and has "pharmacy liaisons" to help with this process. One of these liaisons is Manuel Arias-Soto, CPhT. Arias-Soto works on obtaining prior authorizations and financial assistance for patients. He finds the PQI tool to be very helpful in the financial role. He makes the point that if the practice did not have these liaisons helping patients find financial help and going through the authorization process the patients may not be able to afford the medications and ultimately take them. He explains "we work together trying to find a solution for patients."

Dr. Kulke finds the MID model advantageous for coordinating access for patients for specialty medications. He elaborates "it's particularly helpful for patients for whom English may not be the first language, who are not as familiar with the complex medical system that we have, so I just think it is a phenomenal model."

**"WE WORK TOGETHER TRYING TO FIND A SOLUTION FOR PATIENTS."** Manual Arias-Soto, CPhT

# THE MID: BREAKING DOWN BARRIERS TO CARE

s Dr. Kulke mentions communication barriers above, it has been shown that good patient-provider communication is critical and can help prevent adverse events. Not only is it an ethical imperative, it may also potentially provide healthcare savings of 3.4 million dollars by the most conservative estimates.<sup>12</sup> Hughes comments that many BMC patients have "a lot of disparities and have a lot of limitations in the health system... there are a lot of language barriers, a lot of our patients don't speak English." He goes on, "so having our dedicated team and resources available we are able to continue to provide and get all of these patients the drugs with minimal delay in therapy." Their clinic provides all patients with vital patient education on medications as recommended in every PQI, and they make their education available in other languages as well for patients who do not speak English as their primary language. There are many other barriers to care that the Medically Integrated Team can help alleviate. One other example given by Willyard is that of patients who are elderly and have dementia. Research shows that dementia presents particu-

lar clinical challenges and that this patient group and their families require specific support regarding cancer treatment decisions, dementia adds an extra layer of vulnerability when treating these patients.<sup>13</sup> Willyard has specific instances of their MID model and clinic working together to help these patients and states, "we offer solutions that just could not happen in other ways."



Manual Arias-Soto, CPhT assists a patient at BMC's MID pharmacy.

# CONTINUING TO DELIVER PATIENT-CENTERED CARE

hen speaking with members of both Medically Integrated Teams one thing stands out, the teams firmly believe that having this integrated model of care truly benefits the patient. Willyard comments on the team's close relationship with patients, "I know them by name, they wave at me. We know them, we know their kids. You have a rapport with them." He believes patients can miss out on this relationship when required to use outside mail order pharmacies and also says he can most often provide same or next day refills, whereas it normally takes longer with an outside mail order pharmacy. He also makes the point that his physicians have easy access to him and vice versa, "I am 4 numbers away" versus outside mail order pharmacies that often transfer

staff from person to person have long wait times. Purdom elaborates on this difficulty when dealing with outside mail order pharmacies, "one of the most common complaints from nursing and patients is trying to get in touch with someone to answer their questions. After navigating through most systems computer operator, they often have long wait times, sometimes over 30 minutes, to reach a live person. Phone records show that it takes an average of around 10 seconds for persons calling into OCS Pharmacy to reach a live person."

The BMC team agrees with the benefits of the Medically Integrated model. Arias-Soto says the benefits of having the pharmacy on site are many, the pharmacist counsels the patient on how to take the medication, side effects of the



Oklahoma Cancer Specialists and Research Institute located in Tulsa, Oklahoma

medication, and more. If patients have any questions they can come directly to the pharmacy and receive answers, again it is about the relationship. As a provider Keller speaks to the pharmacy staff reaching out to patients and checking in on them, she says the staff makes "telephone notes in the chart so I can look at that and see if a patient has been symptomatic or when and if they have started taking the drug or not." She continues, "it's invaluable having them right there, everything is in one place...they just make it so easy for our patients to get the drug and then to monitor them." She also says that when using outside mail order pharmacies there can be a void, she is no longer able to see dispensing information in EMR and closing of the loop does not always happen. She also points out that her pharmacy team does follow up with all outside mail order pharmacies, so she relies on her dispensing team as an intermediary and appreciates all they do in that respect. Dr. Kulke adds, "It's incredibly helpful to have the pharmacist right on site to be able to ask them questions about drugs when there are issues with getting prior authorization and approval, and I think one of the most important aspects is the ability of the pharmacist to meet and talk directly with the patient onsite."

#### EDUCATE PATIENTS RECEIVING TELOTRISTAT ETHYL:



#### "IT'S INVALUABLE HAVING THEM RIGHT THERE- EVERYTHING IS IN ONE PLACE...THEY JUST MAKE IT SO EASY FOR OUR PATIENTS TO GET THE DRUG AND THEN TO MONITOR THEM."

Lisa Keller, NP

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

Il team members agree that the MID model and the PQI Clinical Tool are valuable to the team and to patients. How do other Medically Integrated Teams around the country implement programs like the ones in BMC and OCSRI? Hughes believes the first step is coming up with a process and that is the nice thing about the PQI. He says a pharmacist or other team member can use the PQI to start taking initial steps in the right direction. It serves as a guide and gives directions to assist in starting. Hughes also suggests providing early education of what the team would like to accomplish, and even a pilot to show the benefit, as actions other clinics can take to further optimize clinical services and care.

Every day the MID team can make a difference in the life of patients. Every day the team can 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. Telotristat ethyl gives patients with carcinoid syndrome diarrhea an option that may help better control their symptoms and in turn allow a better

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7. Wimbiscus, Bill. "Medically Integrated Dispensing: An Alternative to How Oral Drugs Get Dispensed." Am J Manag Care. March 14, 2019. <u>https://www.ajmc.com/view/medically-integrated-dispensing-an-alternative-to-how-oral-drugs-get-dispensed.</u> Accessed August 2020. quality of life. The PQI gives the MID program an easy to use, compact clinical resource guide when discovering the right patient and dispensing telotristat ethyl. It helps the team ensure they are providing patients with the tools and education to improve clinical outcomes. Pairing Medically Integrated Dispensing with the telotristat ethyl PQI meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative. We are all in this together; let us move forward confidently.

#### WORKING TOGETHER, WE BECOME STRONGER



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#### Helpful Online Resources

- www.ncoda.org
- www.ncoda.org/pqi
- www.oralchemoedsheets.com
- www.ncoda.org/telotristat-ethyl-carcinoid-syndrome-diarrhea

#### **ON THE COVER** (from left):

• Lisa Keller, NP talks with a patient at Boston Medical Center and the reception staff welcomes patients at Oklahoma Cancer and Research Institute.

# NCODA's POSITIVE QUALITY INTERVENTION IN ACTION >>>>>

Practice panelist's comments reflect their experiences and opinions and should not be used as a substitute for medical judgement.

Important notice: National Community Oncology Dispensing Association, Inc. (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 medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

