NCODA’s

POSITIVE QUALITY INTERVENTION IN ACTION

MULTIDISCIPLINARY MANAGEMENT OF ACUTE MYELOID LEUKEMIA PATIENTS WITHIN MEDICALLY INTEGRATED PHARMACY PRACTICES

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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. The PQI fosters better care for patients 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.

The PQI in Action incorporates opinions and experiences from oncology experts within the medically integrated teams at both The University of Minnesota Health (UM) in Minneapolis/St. Paul as well as Rocky Mountain Cancer Centers (RMCC) throughout the state of Colorado. These two organizations are respected leaders in oncology and were selected based on their historic partnership and alignment with the NCODA Mission. Both cancer treatment centers have successfully implemented medically integrated pharmacies (MIP) and the use of Positive Quality Interventions throughout their care teams to improve the clinical outcomes of patients receiving gilteritinib for treatment of relapsed refractory acute myeloid leukemia.

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Practice panelist’s comments reflect their experiences and opinions and should not be used as a substitute for medical judgement.
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. University of Minnesota Health (UM) medical oncologist Armin Rashidi, MD, PhD, stated, “Today we need a clearly defined group of experts to take care of the oral therapy needs,” referring to the organization’s medically integrated pharmacy team that was established to do just that. 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.

University of Minnesota Health Oncology Nurse Care Coordinator, Judi Butler, MSN, RN, OCN, shared that the clinical outcomes can vary depending on the manner in which the patient receives their oral medications. For both the initial dispensing and the refills, she stated, “The biggest roadblock to the coordination of care within the medically integrated model is insurance-mandated pharmacy care.” As prescriptions are sent to mail-order pharmacies, the care can become disjointed and visibility into that patient case can become clouded. UM Oncology Clinic Pharmacy Liaison Dominique Cloutier, CPhT, added, “We have all the resources from writing the prescription to dispensing to managing the patient all in-house.” Further, she shared that if their pharmacy does not have access to a particular drug then the prescribing habits may steer to the prescriber to an option that allows on-site dispensing. Prescribers know through experience with their medically integrated dispensing model that the patient is more closely cared for and positive outcomes are more readily achieved within this model.
Pharmacy Manager at Rocky Mountain Cancer Centers (RMCC), Derek Burns, PharmD, BCPS, DPLA, shared that, “Patient outcomes will be far greater when you have an integrated model.” Organizations like NCODA, ION, McKesson, and Cardinal are compiling data that demonstrates the improved outcomes for patients who receive consistent care directly from the doctor’s office. Small, single-provider practices can also achieve improved patient outcomes by utilizing uniform clinical information like that which is contained in the Positive Quality Intervention. “The challenge is getting payers and manufacturers to understand that model. It’s about telling our story. The old model does not work and it is a constant challenge to patients, payers, and manufacturers,” said Burns.

For these reasons and more, Rocky Mountain Cancer Centers made the decision to establish their medically integrated pharmacy (MIP) in 2014 and have since seen both challenges and benefits within that new service model. RMCC Lead Pharmacy Technician Jessica Rush, CPhT, explained “I believe we offer incredible service at Rocky Mountain Cancer Centers Pharmacy, including various forms of tools like the PQI that can help patients benefit from their treatment. Working in a medically integrated pharmacy has a distinct advantage to obtain pertinent patient information and expedite prescriptions.” Much like at the University of Minnesota, the medically integrated team at RMCC shares that the most significant issue impacting patient care is delays with insurance, prior authorizations, and drug-delivery. RMCC nurse clinician, Erick Blakely, RN, stated, “Prior authorizations become confusing when the pharmacy team initiates the case but the insurance company replies back to the other practice location(s) for the prescriber. I often end up addressing these denials but the insurance doesn’t include the reasoning behind their decision; the process is inefficient and impacts the patient.”

WHEN WE CAN DIRECTLY DISPENSE I’M NOT STRESSED OR WORRYING IF MY PATIENT WILL RECEIVE THEIR DRUG ON TIME.

In one example, the personalized service that the pharmacist offered to one of his patients is something that a mail-order entity could not emulate; that individual drove an hour across town to hand deliver a medication to a patient that required an urgent interventional dose change. Where the old process used to take significant time for the new dose, new prescription, and new delivery to reach the patient, with a Medically Integrated Pharmacy (MIP), drug-delivery generally occurs within a few days (or on same day, as in this example). Logistical acuity in drug procurement is one area that MIP teams provide advanced service. Moving beyond the basics of drug-delivery, the clinical guidance information contained within NCODA PQIs empower medically integrated teams to provide value to prescribers and patients alike.

Over time through case-by-case examples the MIP has become a trusted source for critical information related to oral anticancer medications for the organization as a whole. RMCC Associate Chair of the US Oncology Hematology Research Program, John M. Burke, MD, stated, “The pharmacy team does a high quality job and it speeds up the time for the patients to receive their drug.” When the internal pharmacy is unable to dispense the medication, the mail-order prescriptions may not arrive in a timely fashion. Dr. Burke said, “In some instances, patients will come in for their IV portion of their regimen but have not yet received the oral portion, which delays treatment.” Comparatively, Dr. Burke stated, “When we can directly dispense I’m not stressed or worrying if my patient will receive their drug on time.”
A consistent and streamlined workflow for processing, delivering, and managing patients on oral therapies is an imperative piece in today’s oncology care puzzle. Both the University of Minnesota and Rocky Mountain Cancer Centers have established procedures which place the pharmacist at the center of all oral orders for their respective patients. As such, the pharmacist is best positioned for disseminating sophisticated drug therapy recommendations to the entire medically integrated team; the NCODA Positive Quality Intervention tools help them to consistently accomplish and deliver exceptional care as a standard. At both UM and RMCC, the clinical pharmacist reviews every prescription during Drug Utilization Review (DUR), assessing appropriate diagnosis, line of therapy, pathway check, labs, patient status, and drug interactions. By reviewing the clinical information as part of the initial assessment, these teams ensure appropriate therapy and accurate correspondence is submitted to the insurance as a prior authorization request. Therein, the cancer center quickly places the impetus on the insurance company to expedite and approve coverage of the drug and prevent potential delays.

At the University of Minnesota Health Masonic Cancer Clinic, the oral chemotherapy monitoring team (clinical pharmacists and pharmacy residents) reviews all orders before they are triaged to the mail-order pharmacy, when applicable. Patient education is primarily the responsibility of the clinical pharmacist within the doctor’s office where they can meet with the patient face to face. According to clinical pharmacist Jeff Engle, PharmD, “We prefer that patient education is done upfront while in the clinic where we can immediately begin to understand the patient’s needs and strengthen our relationship with them.” The pharmacist ensures patients are equipped with the information and products they need to succeed with their oral therapy. By utilizing the NCODA Oral Chemotherapy Education (OCE) Sheets, Engle and the oral team references a consistent resource tool and standardizes the delivery of patient-facing information.

**Complimentary public access to OCE sheets available here:** [www.oralchemoedsheets.com](http://www.oralchemoedsheets.com)
After the clinical pharmacist reviews and releases the prescription for further processing, the oncology liaison team at UM, which largely consists of pharmacy technicians and financial navigators, takes swift action to take care of the patient. Working through prior authorizations, financial assistance, and other logistical pieces, these liaisons move toward their goal of initiating an outbound introductory call to all patients within two hours of receipt of the prescriptions. By keeping the patient well informed of the current status of their life-sustaining drug and the next steps for receiving it, these medically integrated teams deliver unmatched customer service.

Other professionals quickly noticed the improved care that was resulting from the standardized process for oral orders. UM physician Armin Rashidi, MD, shared that the efficient timing of care is an essential component to cancer care today. “The oral team keeps me updated throughout the process, reviews clinical criteria and offers recommendations that are helpful.” Nurse care coordinator Judi Butler, MSN, RN, OCN, agreed saying, “It is really nice to have the oral team looking at those prescriptions and the more pharmacists we can get, the better it will be for everybody.”

WE ALL WORK AS A REALLY FLUID TEAM.

At Rocky Mountain Cancer Centers, nurse clinician Erick Blakely, RN, also appreciates the continuity of care within the MIP team and shared that he isn’t the only one who benefits from this coordinated care effort: “Patients feel like they are better taken care of when all services come from one source.” Through the Electronic Medical Record (EMR), he is able to receive timely updates from the MIP regarding the approval, shipping, and start dates of the oral therapies which helps all disciplines to be aware of the most current components affecting the patient. Blakely added, “We all work as a really fluid team.” Indeed, the MIP model allows for open communication across the entire patient care team. With preferred local delivery by courier, MIP teams at both practices often provide drug to patient on the same day or within two days of it being prescribed. On average, the time to delivery is about three days for prescriptions filled at the MIP versus about eight days for those prescriptions that must be filled by a mail-order pharmacy.

BEYOND THE FIRST FILL: PATIENT FOLLOW-UP

After a patient receives the initial prescription for a new oral therapy from the medically integrated pharmacy, both UM and RMCC have robust, multidisciplinary follow-up processes to help maximize the outcome. A one-week follow-up and assessment call is initiated by the pharmacist at both practices. Refill calls occur at least seven days before the next treatment cycle starts; many medications require more frequent phone calls beyond the standard protocol in order to effectively manage the side effects.

Medication refills are coordinated and sent out as dictated by certain lab values, toxicity, tolerance, medication reconciliation, scans, and other data obtained through medically integrated team interaction with key criteria available on demand in the EMR. Seeing each team member’s notes within the EMR, they are able to work in concert together to proactively intervene when appropriate. Because dose holds and dose modifications occur so frequently with these anti-cancer medications, the timing of required refills can be best accomplished through communication within the medically integrated team. In this way, the pharmacy can avoid dispensing expensive and unnecessary medications. When the prescription must be filled via a third party, visibility into the dynamic and ever-changing patient status becomes challenging. A coordinated care effort ensures the most critical aspects are not overlooked or mismanaged; by filling in any potential gaps across the team and working together in real-time, the patient who can receive all of his or her care from one source is well-positioned for a successful outcome from oral therapy.

The Cost Avoidance and Waste Tracker Tool, an NCODA resource, helps pharmacy teams to document such inefficiencies and is available here: www.NCODA.org/cawt

One manner in which the MIP team can better care for the patient is through routine monitoring of necessary lab tests.
and adverse effects (AE). As these clinical aspects are identified by Jeff Engle, PharmD, MS, for example, he can collaborate with the nurse or the prescriber for further coordination of care. Judi Butler RN, BSN, OCN, stated, “The dispensing pharmacy works closely with the oral chemotherapy monitoring team, the prescriber, and the nurse care coordinator to adjust the schedule as needed and intervene sooner along the critical path. We are notified of any delays in real time and have a firm grasp on the patient case and its trajectory.” The MIP team at UM tracks all patients and makes every effort to support them regardless of where the medication is dispensed. Both UM and RMCC identified that significant pitfalls exist with the patients who must use a payer-mandated pharmacy, leaving providers, pharmacists, technicians, nurses, and practices as a whole yearning for a better model or new system for the sake of their patients.

Without much indication as to any significant overhauls on the current payer-driven system and model, practices have been forced to find more efficient methods for caring for patients prescribed oral therapies. The MIP teams sought resources that could raise the bar to not only increase the patient’s speed to therapy, but to deliver advanced patient care services. The NCODA Positive Quality Intervention is a clinical guidance tool in which both UM and RMCC have found great value for providers, patients, and the whole MIP team.
Each oral oncolytic imparts unique challenges in patient compliance, adherence, and toxicity management. Keeping up with the nuances of the many new medications being researched and approved can be overwhelming for any care team. The NCODA Positive Quality Intervention resource tool (www.NCODA.org/pqi) was created to provide concise and timely guidance information for health care professionals to effectively address those unique challenges within a specific drug or side effect. In just a few minutes of reading a PQI, any clinician can quickly understand the key components needed to safely identify, counsel, dispense, and effectively manage a patient on a new medication.

One way in which sophisticated delivery of care takes place at these two leading oncology organizations is via the PQI on gilteritinib (brand name Xospata), an oral therapy option for Relapsed/Refractory Acute Myeloid Leukemia (AML) patients that exhibit a FLT3 mutation. Both organizations revealed that they recognize the inherent value that the gilteritinib PQI provides in bringing more awareness to this valuable option for patients that previously had extremely limited alternative therapy options.

University of Minnesota Health oncologist Armin Rashidi, MD, PhD, described how AML differs from many other cancer disease types: “AML patients are in an urgent situation. With no time to wait for treatment, quick turnarounds on drug procurement are required; the MIP model is best equipped to handle that demand.” Indeed, according to Dr. Rashidi, “Timeframes help determine the course.” Oncology pharmacy liaison Dominique Courtier, CPHT, expressed how one case took almost two months for the patient to receive the gilteritinib. Due to restricted access, the prescription had to be sent to a mail-order pharmacy. Unfortunately, that pharmacy ended up putting the prescription on hold and failed to notify the patient or the doctor’s office regarding the delay. The MIP Team relentlessly continued to follow up with the mail-order pharmacy until the patient finally received the approved medication.

“Quick turnarounds on drug procurement are required [for AML patients]; the MIP model is best-equipped to handle that demand.”
Identifying patients who would be candidates for this therapy is a primary purpose of the document, “Positive Quality Intervention: Gilteritinib (XOSPATA) for Relapsed/Refractory Acute Myeloid Leukemia (AML)”. According to Dr. Rashidi, “Gilteritinib is often the first choice for more frail patients or those who haven’t recovered well from induction therapy. This is an exciting option to have something that is outpatient. I think it is a good choice.” Medical oncologist John M. Burke, MD, shared a similar perspective on the type of patient that will potentially benefit from the Gilteritinib treatment option: “Patients don’t always want more chemo.” In fact, he shared the experience of one patient who faced this new path head-on. Following induction and consolidation therapy, Dr. Burke recommended additional treatment but the patient was unwilling to undergo the rigorous and demanding course of more chemotherapy. Inevitably, that patient relapsed. Yet today, instead of resorting to best supportive care, there is a new targeted oral therapy outpatient option for that patient. As it is seen, gilteritinib grants patients an option that did not exist before. For them, this treatment option can make the difference between hope and despair.

Both physicians have started utilizing this new option for patients. Proper monitoring of key lab values is one component that the gilteritinib PQI covers in detail. Dr. Rashidi completes a baseline EKG, CBC/CMP, specifically keeping an eye on uric acid, creatinine, and INR. In addition, he might initiate therapy with daily monitoring, including weight and fluids, to address risks for Tumor Lysis Syndrome (TLS) and differentiation syndrome.

Dr. Burke was an investigator on the extended clinical trial for gilteritinib and gained useful clinical experience with several patients before the drug was FDA approved. During the extended clinical trial, his team completed weekly EKG tests but did not see any significant issues. Today, he’ll employ an initial EKG, another at two weeks, and then as needed thereafter. UM Nurse Care Coordinator Judi Butler, RN, BSN, OCN, also finds this guidance information to be useful and especially appreciates the dose modification information that is easy to find and follow.

As gilteritinib creates its place as a standard course of therapy for AML patients with a FLT3 mutation, Dr. Burke shares a helpful perspective on this paradigm shift, “Historically, next generation sequencing was not routinely done in AML. Today, doctors should be aware of the need to be looking for FLT3, IDH1 and IDH2 mutations and identify the most efficacious treatments.”

**PQI PROCESS**
*(UPON RECEIPT OF NEW PRESCRIPTION FOR GILTERITINIB)*

- Verify genetic testing is complete with positive FLT3 mutation and appropriate prior lines of therapy.
- Ensure that the correct dose is prescribed (3 x 40 mg oral tablets [120 mg total]) by mouth daily.
- Verify that baseline blood counts, chemistries, as well as creatine phosphokinase (CPK) have been assessed prior to initiation of gilteritinib. Schedule these labs for every week for the first month, every other week for the second month, and once monthly thereafter.
- Ensure ECG results obtained prior to initiation of gilteritinib as well as appointments scheduled to receive follow-up ECGs on days 8 and 15 of the first cycle.
- Monitor for any signs/symptoms of pancreatitis, PRES, differentiation syndrome
- Fever, dyspnea, hypoxia, pulmonary infiltrates, pleural effusions, edema
- Call office at first sign of fever (temperature >100.4F)
- Consider the use of antidiarrheals
- Important: Upon refill, check and clarify dosing, quantity, and instructions to the patient (number of tablets per dose, etc.)
Implementation of the PQI into the workflow at these two organizations varies much like it does across the country. The clinical principles presented within the NCODA PQI are the critical factors needed to educate professionals and improve patient outcomes. This clinical guidance information can originate from any professional, but it should always be communicated across the wider team in an effort to exchange consistent strategies and effective practices. NCODA is accepting qualified authors who are eager to highlight a critical aspect of patient care by writing and sharing their clinical experience in a new PQI.

Apply to author or review a PQI by emailing: Contact@NCODA.org

Nurses at both the University of Minnesota Health and Rocky Mountain Cancer Centers described how the gilteritinib PQI provides useful information at their fingertips. Judi Butler, RN, BSN, OCN, stated, “This PQI likely has more readily-available information compared to the other resources we’ve used like VIA Oncology. Although those education materials are helpful, they don’t have everything I want or need for the oral drugs.” Furthermore, Butler could see the advanced practice providers (APP) utilizing the PQI resource as well with actionable information like the dose modification guidance. Erick Blakely, RN, shared that the US Oncology resources that they have for drug information are comprehensive, but the PQI database is easier, faster, with better peer-reviewed information, “The PQI and OCE Sheets are resources that nursing supervisors find valuable.” Dr. John M. Burke agreed, “Having the critical information all on one page, short and sweet and to the point about what you need to know is always helpful.”

TODAY, DOCTORS SHOULD BE AWARE OF THE NEED TO BE LOOKING FOR FLT3, IDH1 AND IDH2 MUTATIONS AND IDENTIFY THE MOST EFFICACIOUS TREATMENTS.

OVERCOMING EDUCATIONAL GAPS WITH THE PQI

† Today, doctors should be aware of the need to be looking for FLT3, IDH1 and IDH2 mutations and identify the most efficacious treatments.

DIFFERENTIATION SYNDROME

- Systemic steroids until resolved for 3 days (interrupt gilteritinib if signs remain >48H)
- Resume when symptoms improve to Grade 2

POSTERIOR REVERSIBLE ENCEPHALOPATHY SYNDROME (PRES)

- Confirm with ECG on day 9
- If confirmed, consider gilteritinib dose reduction to 80 mg (2 x 40 mg tablets) daily

QTc INTERVAL > 500 MSEC

- Interrupt gilteritinib and resume at reduced dose of 80 mg (2 x 40 mg tablets) daily when QTc interval returns to within 30 msec of baseline or > 480 msec

QTc INTERVAL INCREASED BY > 30 MSEC ON ECG ON DAY 8 OF CYCLE 1

- Confirm with ECG on day 10
- If confirmed, consider gilteritinib dose reduction to 80 mg (2 x 40 mg tablets) daily

PANCREATITIS

- Interrupt gilteritinib until pancreatitis is resolved and resume at a reduced dose of 80 mg (2 x 40 mg tablets) daily

OTHER GRADE 3 OR HIGHER TOXICITY (RELATED TO TREATMENT)

- Interrupt gilteritinib until pancreatitis is resolved and resume at a reduced dose of 80 mg (2 x 40 mg tablets) daily

Indeed, the PQI equips the entire healthcare team with a useful medium for communication of clinical information that benefits patients. In today’s care model with multiple layers and professional disciplines, the PQI can help deliver a robust and consistent method for maximizing outcomes for gilteritinib patients. As a pharmacy technician who does not provide clinical recommendations, Dominique Cloutier, CPhT, shared that for her, having some information about drugs is still very valuable.

With this knowledge she is better prepared for more meaningful conversations with the patient and can deliver higher quality care: “I wish I would have known about these PQIs a long time ago.”
Both leading oncology organizations see the value in providing consistent drug education from the pharmacy team across the entire medically integrated team. Multiple benefits exist in that model, stated Derek Burns, PharmD, BCPS, DPLA, “When it comes to oral oncology drugs, I would prefer the pharmacy team be the owner of educating the practice sites. If that information is reaching our providers internally from our pharmacy team, it will strengthen that relationship.” Further implementation could arise in the form of a bi-weekly email to providers with links to the new PQI information, “That stimulates dialogue and interaction coming directly from the pharmacy team”.

Clinic sites and providers are pressed for time and the idea of coming in early or staying late for an educational in-service is not always feasible. As the pharmaceutical industry continues to partner around how to best communicate critical information to the providers and the practice, the PQI offers a solution. Burns stated, “I believe there is true value in a document like the PQI. In the past, it may have been cumbersome to look through multiple resources provided. Now, we have concise, peer-reviewed resources to utilize.” As it is seen, Burns grasps a clear vision of ways to improve the current drug dispensing, educating, and managing model. He shared, “Having something in a digital format like this is key. 10 years ago, few patients had an email; now everybody has a smart phone and information should be right at our fingertips.”

Indeed, both the Positive Quality Intervention and the Oral Chemotherapy Education Sheets are NCODA resources that are available to the public, complimentary, at one easily-accessible website address with full digital download capacity. These tools provide consistent and valuable information for healthcare professionals and patients alike.

"I WISH I WOULD HAVE KNOWN ABOUT THESE PQIS A LONG TIME AGO.

MELISSA SHIMANEK, PHARMD, EVAN SLATER, PHARMD

I BELIEVE THERE IS TRUE VALUE IN A DOCUMENT LIKE THE PQI... HAVING SOMETHING IN DIGITAL FORMAT LIKE THIS IS KEY.

Complimentary Access to all PQIs available at:
ncoda.org/pqi

Complimentary Access to all OCE sheets available at:
oralchemoedsheets.com

Through the NCODA PQI in Action, experts have collaborated to highlight the Gilteritinib PQI and empower healthcare professionals to deliver higher quality care to their AML patients. Through this medium, NCODA brings awareness to the fact that PQIs are publicly available on the website. Furthermore, NCODA recommends a wider adoption of new procedures to utilize clinical guidance information and employ the consistent principles contained within all PQI documents to help professionals to deliver improved outcomes for oncology patients.

Author: Matthew Schulz, PharmD

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, dosages, precautions, warnings, 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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