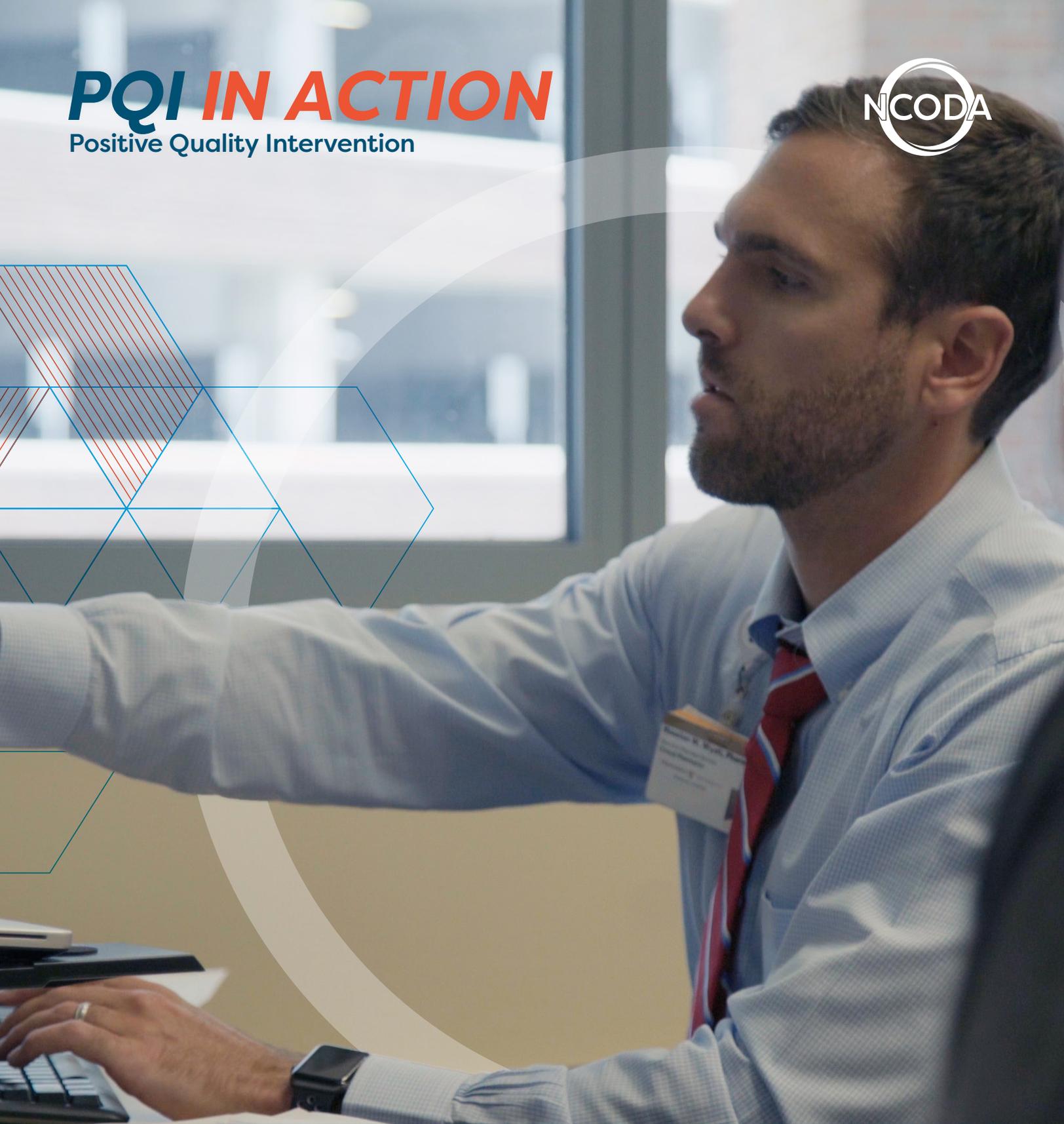


PQI IN ACTION

Positive Quality Intervention



Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI

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 Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI and explores how the medically integrated teams at Arizona Oncology, Carolina Blood & Cancer Care Associates, and Vanderbilt-Ingram Cancer Center incorporate the information found in the PQIs as part of their daily workflow. This article will discuss how utilizing the Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI elevates patient care.

Arizona Oncology (AO) delivers world-class care and research with passion and precision. With highly specialized providers, leading-edge technology and access to clinical trials, the focus lies in

Medical Oncology, Radiation Oncology, Gynecologic Oncology, Breast Surgical Oncology, Colorectal Surgery, Hematology, Urology, Clinical Trials, Genetic Risk Assessment, and Patient Ancillary Programs. As one of the largest groups of medical professionals in the state, the Arizona Oncology team is devoted to providing compassionate cancer care and breakthrough research close to where patients live and work. The team treats patients in many locations throughout the state including Good-year, Green Valley, Prescott, Prescott Valley, and Tucson.

Carolina Blood and Cancer Care Associates, P.A. (CBCCA) is a physician-owned oncology practice with two locations in South Carolina. The team of five medical oncologists and one physician assistant facilitates the healing process with the help of state-of-the-art tools including chemotherapy, biotherapy, immunotherapy and radiotherapy. They strive to empower patients to take control of their treatment and their life, and are dedicated to ensuring that at every stage, patients remain well informed about their conditions and

choices. CBCCA is committed to utilizing and providing all the resources to educate cancer prevention measures, early detection strategies, and lifestyle modifications that can promote both the community and individual health physically, emotionally, and spiritually.

Vanderbilt-Ingram Cancer Center (VICC) is a National Cancer Institute (NCI)-designated Comprehensive Cancer Center located in Nashville, Tennessee (TN). VICC is one of only two NCI-designated Comprehensive Cancer Centers in TN and 51 in the country to earn this prestigious distinction. VICC ranks in the top 10 nationwide for cancer research. Their mission is to alleviate cancer death and suffering through pioneering research, innovative patient-centered care, and evidence-based prevention, education, and community activities. VICC's world-renowned team of experts is committed to providing a personalized, integrated, and patient-centric approach to cancer treatment, research, support, education, and outreach.



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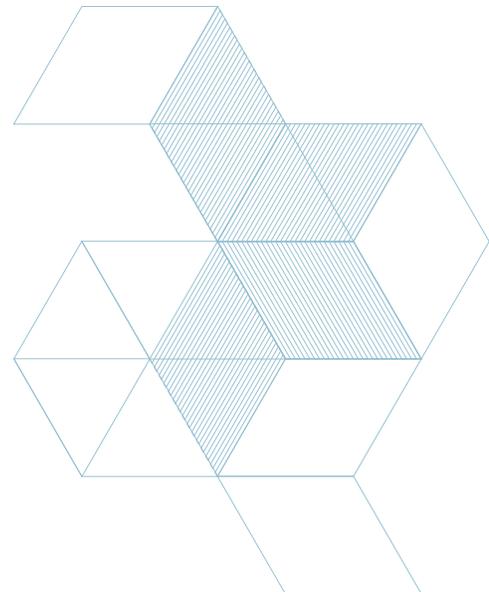
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MID, THE PQI, AND BRUKINSA: AN EXCEPTIONAL OPTION IN THE TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA

CHRONIC lymphocytic leukemia (CLL) is the most common form of leukemia among adults in the Western world.¹ It is characterized by the clonal expansion of CD5+ B cells in blood, marrow and second lymphoid tissues.² Genetic mutations such as deletions in chromosomes 13q and 17p, and mutations in genes such as TP53 and NOTCH1 can cause CLL.² Dysregulation of apoptosis, microenvironment interactions and chronic antigen stimulation can further contribute to the development and progression of CLL.² Recent advancements have transformed the management and outcomes for CLL patients, particularly the Bruton's tyrosine kinase (BTK) inhibitors, which have become a drug class of choice for many clinicians treating CLL.¹

Zanubrutinib is a potent, highly specific, and irreversible second-generation BTK inhibitor with a favorable side effect profile.¹ It was intentionally designed for sustained BTK occupancy to enhance its efficacy. In the ALPINE trial, zanubrutinib was found to be superior with respect to progression-free survival among 652 patients with relapsed/refractory CLL in a head-to-head trial against a first-generation BTK inhibitor (hazard ratio 0.65, 95% CI 0.49 to 0.86; p=0.002).³

Since its initial approval in 2019 for Mantle Cell Lymphoma (MCL), zanubrutinib has expanded its indication profile to Waldenström's Macroglobulinemia (WM) and Marginal Zone Lymphoma (MZL) in 2021, and CLL in 2023.^{3,4} At present, the National Comprehensive Cancer Network (NCCN) guidelines recommend zanubrutinib as a preferred

regimen for all four indications.^{5,6,7}

Niyati Nathwani, MD, Oncologist and Hematologist at CBCCA explained her reason for utilizing zanubrutinib (BRUKINSA®). "CLL is the most common cancer that we see in the hematology space. When we treat CLL patients, BTK inhibitors are the treatment of choice as they are oral medications, readily available, and can be dispensed through our pharmacy. When we consider the side effect profile, dosing flexibility, and the range of indications offered, zanubrutinib becomes the medication of choice for my patients."

Zanubrutinib can be dispensed through the Medically Integrated Team, enhancing the scope of care for patients. Medically Integrated Dispensing (MID), as defined by NCODA, refers to a dispensing pharmacy within an oncology center of excellence that champions a patient-centric, multidisciplinary team approach. This collaborative and comprehensive MID model, centered on outcomes, engages oncology healthcare professionals and other stakeholders to ensure the seamless coordination and quality of care and therapies for cancer patients.⁸ The MID approach holds the potential to enhance the management of patients undergoing therapies like zanubrutinib through improvements in communication, adherence measurement, regimen adjustments, expedited therapy initiation, heightened patient satisfaction, financial assistance, cost reduction, and minimized waste production.⁹

Teri Roberts, CPhT, Pharmacy Supervisor at AO emphasized the benefit of MID for patients. "For the patients, I think it's

tremendous that they don't have to run to different places to obtain their medications at multiple pharmacies. They can come in and pick up their medication during their visits to the office. It's kind of like a one-stop-shop."

NCODA offers multiple tools to aid the MID practice in managing oncolytics. This toolbox contains a Patient Satisfaction Survey that is practice-customizable, a Cost Avoidance and Waste Tracker tool, a Financial Assistance Tool (database), Treatment Support Kits, Oral Chemotherapy Education sheets, and of course the Positive Quality Intervention clinical guidance resource.

"CLL is the most common cancer that we see in the hematology space. When we treat CLL patients, BTK inhibitors are the treatment of choice as they are oral medications, readily available, and can be dispensed through our pharmacy. When we consider the side effect profile, dosing flexibility, and the range of indications offered, zanubrutinib becomes the medication of choice for my patients."

-Niyati Nathwani, MD



THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

OLA Gulledge, CPhT, CMA, Lab Manager at CBCCA, described why she finds PQIs valuable. “It helps me understand more about the important aspects of the medication and enables us to take better care of our patients. It also improves communication between team members and the physician.”

“My favorite thing about the PQI resource is that it summarizes everything in a manner such that all the important information about the drug can be skimmed quickly,” shared Charisse Puckett, CPhT, Specialty Pharmacy Clinic Technician at VICC. “This makes the patient care process much more time efficient.”

“The PQI is a valuable resource for all team members,” said Shelton Lacy

Harrell, MSN, ACNP-BC, Outpatient Advanced Practice Manager at VICC. “If I am a new provider or working on a drug for the first time, the Description, Background and PQI Process would be highly valuable. The Patient-Centered Activities section comes in handy when counseling patients.”

This article will examine the advantages of integrating PQIs as a core standard in MID and highlight how its adoption can enhance any practice. AO, CBCCA, and VICC have all discovered effective methods to integrate the PQI clinical resource. Each of these practices strategically positions their Medically Integrated Teams to guarantee suitable treatment, enhance compliance, and optimize clinical results. We will delve into their practice environments, explore the ways in which implementing PQI steps

benefits both staff and patients, and elucidate how they continually advance patient care.

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-Charisse Puckett, CPhT

MEDICALLY INTEGRATED DISPENSING: ELEVATING CARE

AS cancer treatment continually grows in complexity containing IV, oral and combination regimens, MID and a multidisciplinary team continue 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.

Dr. Nathwani asserts that MID enhances the convenience of patients' lives. “With MIDs, patients are able to access pharmacy technicians, pharmacists and physicians under one roof. So, they can get answers to their questions pretty much right away.”

CBCCA's Clinical Research Coordinator, Sandra Nixon, CPhT, RMA believes that MID benefits every single member of the multidisciplinary team. “We are all on the same page about the needs of the patient as well as the status of their medications. We are all able to work together to ensure that the patient

receives the highest level of care.”

Anjana Patel, PharmD, Pharmacist at CBCCA highlighted the biggest value that MIDs bring to her practice. “It is easy to have the patient's medications ready for their appointments. We are able to liaise a pickup time and their appointment, so that they coincide together. It also helps reduce waste as we can be made aware and adjust for any dose changes made by the physician pretty much immediately. So, all things considered, it's a win from a healthcare cost point of view as well!”

Clinical Pharmacists from VICC, Jared

Medically Integrated Dispensing: Elevating Care- continued

Crumb, PharmD, and Stephanie White, PharmD, discussed the potential advantages that patients may overlook when required to obtain their medications from specialty pharmacies. “We have plenty of data to show that patients that use pharmacies embedded within

the health system are able to initiate therapy quicker than when they have to go to another specialty pharmacy,” said Crumb. “I think the biggest difference is access to a patient’s electronic health record. That’s a game changer for us. We are able to review patient

charts and discuss with physicians to make sound judgments as a team. This elevates patient care to another level. Unfortunately, mail order pharmacies are not able to provide this level of care,” added White.

“It is easy to have the patient's medications ready for their appointments. We are able to liaise a pickup time and their appointment, so that they coincide together. It also helps reduce waste as we can be made aware and adjust for any dose changes made by the physician pretty much immediately. So, all things considered, it’s a win from a healthcare cost point of view as well.”

-Anjana Patel, PharmD

PUTTING THE ZANUBRUTINIB (BRUKINSA®) PATIENT SELECTION AND MANAGEMENT PQI INTO ACTION

THE PQI is a peer-reviewed clinical guidance resource 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 Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI is written in sections beginning with a Description and ending with Patient-Cen-

tered Activities and References.¹⁰ It was developed to provide guidance for management of patients treated with zanubrutinib.

Following the Description, the Background section gives pertinent historical data and information, clinical trial experience, and the main focus of the intervention. Regarding zanubrutinib, the Background discusses the approval, indication, and published data leading to approval. The trial data discussed zanubrutinib’s efficacy and favorable safety profile.

Roberts communicated the significance of PQIs to team members. “It gives you the facts that you need. It is helpful for

various team members with information regarding counseling, side effects and monitoring parameters among other things. For me, even when I get a prescription, I utilize it to make sure that things are in the right direction, as the PQI states.”

“I honestly appreciate that it’s like a one-pager. It has all the important points as bullets and that makes it easy-to-read,” shared Crumb as he praised the precise and concise nature of PQIs. “For pharmacists that are just starting out in this space, PQIs can be beneficial with the brief overview and highlighting important points.”

White contends that Positive Quality



Putting The Zanubrutinib (Brukinsa®) Patient Selection and Management PQI Into Action- continued

Interventions (PQIs) result in significant time savings for her. “We have patients that want to know trial information, which is not something that we always

recall off the top of our head. They want to hear the numbers about efficacy data. So, having that really quick resource helps us alleviate the concerns

of the patient a lot quicker instead of having to look through the drug package insert.”

THE PQI PROCESS

THE next section of the Zanubrutinib (BRUKINSA®) Patient Selection and 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.

The first step of the Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI Process is to identify if a patient is an appropriate candidate for zanubrutinib based on indication. As mentioned above, zanubrutinib has four approved indications – MCL, WM, MZL and CLL.³ In the NCCN guidelines for CLL, BTK inhibitors are suggested as a first-line therapy option.⁵ Given its favorable side effect profile, zanubrutinib is regarded as a viable option for patients with comorbidities such as a history of atrial fibrillation, recent hemorrhage, and hypertension.

Zanubrutinib is flexible in terms of dosing with a 160 mg by mouth twice daily or a 320 mg once daily option. VICC’s Hematology Physician Assistant, Sam Osborne, MS, PA-C, conveyed that her patients significantly prefer the once daily dosing regimen over the twice daily option. Osborne also noted that patients find the once daily dosing more convenient and this improves adherence. Her colleague, Harrell, added that while patients would prefer daily dosing

due to convenience, sometimes they are unable to tolerate the dose. In those cases, they proceed with the twice daily dosing.

In the context of dose reduction, members of the multidisciplinary team should exercise caution concerning concomitant medications with CYP3A inhibitors or inducers. If a patient takes medications that are strong CYP3A inhibitors, the recommended dosage is 80 mg once daily, while with moderate CYP3A inhibitors, the recommended dosage is 80 mg twice daily. If they take strong or moderate CYP3A inducers, zanubrutinib is not recommended. A dose reduction to 80 mg twice daily is recommended for patients with severe hepatic impairment (Child-Pugh Class C).⁵

Patel explained how her practice prudently manages concomitant therapies that may require an adjustment in the zanubrutinib dosage. “If a dose reduction is needed, it occurs at the beginning of therapy initiation. Generally, the dose reduction is applied due to concomitant therapy that the patient is on.”

“We verify for any potential drug interactions, if in case we need to make adjustments,” said Crumb as he shared insights on the steps taken at VICC to address potential drug interactions. “If any patients are to undergo any kind

of surgical procedures, they need to let us know, because we will most likely ask them to hold the medication depending on how invasive it is.” He also added, “Obviously, no grapefruit. Most patients are familiar when we say that.”

CLL patients are prone to infections due to the effect of the disease on their immune system and should be monitored for symptoms. As a countermeasure, prophylaxis for herpes simplex virus, pneumocystis jirovecii pneumonia, and other infections is recommended.

Osborne disclosed her observations concerning patients with CLL who experienced infections during zanubrutinib treatment. “Due to the immune dysfunction associated with lymphocytes, I do see higher rates of infections in my CLL population. Common infections include recurrent hypogammaglobulinemia, sinusitis, bronchitis, and pneumonia. However, the population taking BRUKINSA® does not experience higher rates of infection compared to CLL patients taking other medications.”

“Lab monitoring is very important for patients, especially at the start of their BRUKINSA® therapy,” shared Gullede. “Through my role as lab manager, I am able to assist the team with monitoring CBC every week. We’re looking for changes in white blood cells, hemoglobin or platelet count. Hepatic and renal

The PQI Process- continued

functions also need to be monitored.”
AO’s Nurse Director, Jackie Woods, MSN, OCN summarized the adverse effect monitoring process at her prac-

tice. “At the beginning of BRUKINSA® therapy, we monitor for side effects, and check to see if they are staying hydrated. We also monitor closely for any cardiac related issues. If patients

experience any side effects, we work to address them before following up to ensure that side effects have not exacerbated.”

“We verify for any potential drug interactions, if in case we need to make adjustments. If any patients are to undergo any kind of surgical procedures, they need to let us know, because we will most likely ask them to hold the medication depending on how invasive it is. Obviously, no grapefruit. Most patients are familiar when we say that.”

-Jared Crumb, PharmD

PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

THE Patient-Centered Activities section follows the PQI Process and provides direction to the multidisciplinary team on essential counseling points. The Zanubrutinib (BRUKINSA®) Patient Selection and 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. This is followed by counseling on reviewing once daily and twice daily dosing options as well as what measures to take if patients miss a dose. This section also stressed the importance of monitoring for signs and symptoms of adverse effects.

In 2019, the Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards were pub-

lished to provide standards for medically integrated dispensing of oral anticancer drugs and supportive care medications.¹¹ Standard 1.2 of the ASCO/NCODA Standards reads:

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 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.¹¹

Nixon shared about the counseling protocol at CBCCA. The pharmacy team prints out information regarding zanubrutinib to distribute to patients while dispensing the medication. The doc-

ument contains important counseling points such as taking the medication at the same time daily, what to do if they miss a dose, and whether to take the drug with food or water. Their pharmacist, Patel, also stressed the importance of patient education regarding bleeding, cardiac arrhythmias, signs of infections and hypertension.

AO Nurse Practitioner, Holly Swensen, APRN, NP-C, shared about how they alternate counseling responsibilities between team members to alleviate the burden on physicians. “In our practice, we prefer to alternate between nurse practitioners and physicians for each patient visit. This way, we both stay updated on the drug and the patient. In the initial phases of starting a medication like zanubrutinib, we would see the patient every 1-2 weeks until blood counts stabilize. Additionally, if the physician schedule gets demanding, the



Patient-Centered Activities: Keeping The Focus On Patients- continued

NPs may see the patient several times in a row to alleviate the load of the physician.”

AO is also implementing an innovative method to ensure patient adherence while reducing the workload of the team. “We take measures to ensure medication adherence,” shared Woods. “We are piloting an internal health tracker program which will send texts to patients to remind them to take their medications.”

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-Jackie Woods, MSN, OCN

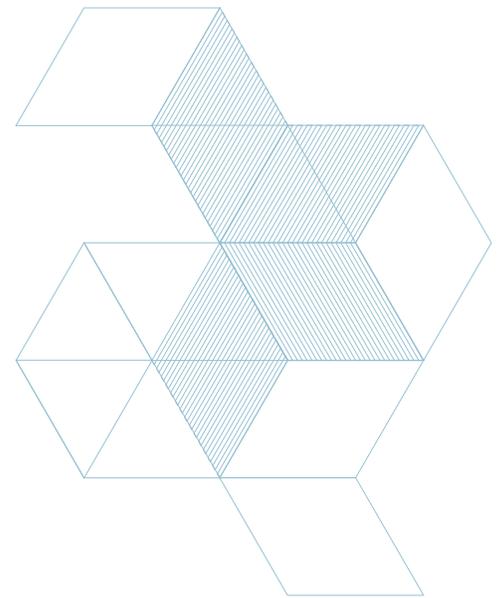
FINANCIAL ASSISTANCE: A CRUCIAL SUPPORT FOR PATIENTS

In conjunction with meticulous follow-up and comprehensive education, MID empowers the practice to deliver outstanding customer service, unparalleled patient care, and assistance in securing funding to facilitate the patient's affordability of the prescribed medication.

The final piece of the Patient-Centered Activities for the Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI contains a financial assistance section. AO, CBCCA, and VICC incorporate financial assistance into their workflows so that delays in care are minimized. Swensen mentions that they work to identify suitable financial assistance for patients who cannot afford medications. They work with patient assistance organizations to find a Patient Assistance Program or grants so that the patient does not miss out on important treatment.

Puckett shared that at VICC, they perform a benefits investigation to see if the patients are covered by their respective insurance before the pharmacy team begins work on the actual approval of the medication.

White went into further detail about how the team works to obtain financial assistance for patients. “If patients have commercial insurance plans, we will enroll them in copay cards. If they are on a Medicare plan, we are the ones helping them obtain and find foundation assistance. At Vanderbilt, we have an internal grant process if patients need it. We also help with the patient assistance programs but that is generally our last resort. We have a dedicated patient assistance program team that assists us with that.”



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 lives of patients. Swensen shares about the value of the MID model. “One of the benefits for patients is that we can verify the medication right then and there. We also go over instructions. That is important because a lot of patients don’t necessarily read the information that we provide and prefer to rely on what we communicate to them directly. I think it increases patient satisfaction, results in greater adherence rates, and greater engagement from patients as well.”

Dr. Nathwani believes that there are positives for patients and practices. “Prior to adopting the MID model, patients

were affected by delays in care. Now, the patient care process is convenient, efficient, and less wasteful. From a practice perspective, our team members are able to deliver higher quality patient care and we found that there is a positive financial on our practice as well. So, a lot of benefits overall.”

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 an NCODA member, I have utilized several PQIs over the years,” says

Roberts. “I am now advocating for my practice to use more PQIs.”

Zanubrutinib gives patients with CLL a valuable treatment option with a favorable side effect profile. The PQIs provide the MID program with an easy-to-use, compact clinical resource guide when discovering the right patient and dispensing BRUKINSA®. The PQIs help the team ensure they are providing patients with the tools and education to improve clinical outcomes. Pairing Medically Integrated Dispensing with the **Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI** meets NCODA’s Guiding Values of being Patient-Centered and Always Collaborative.

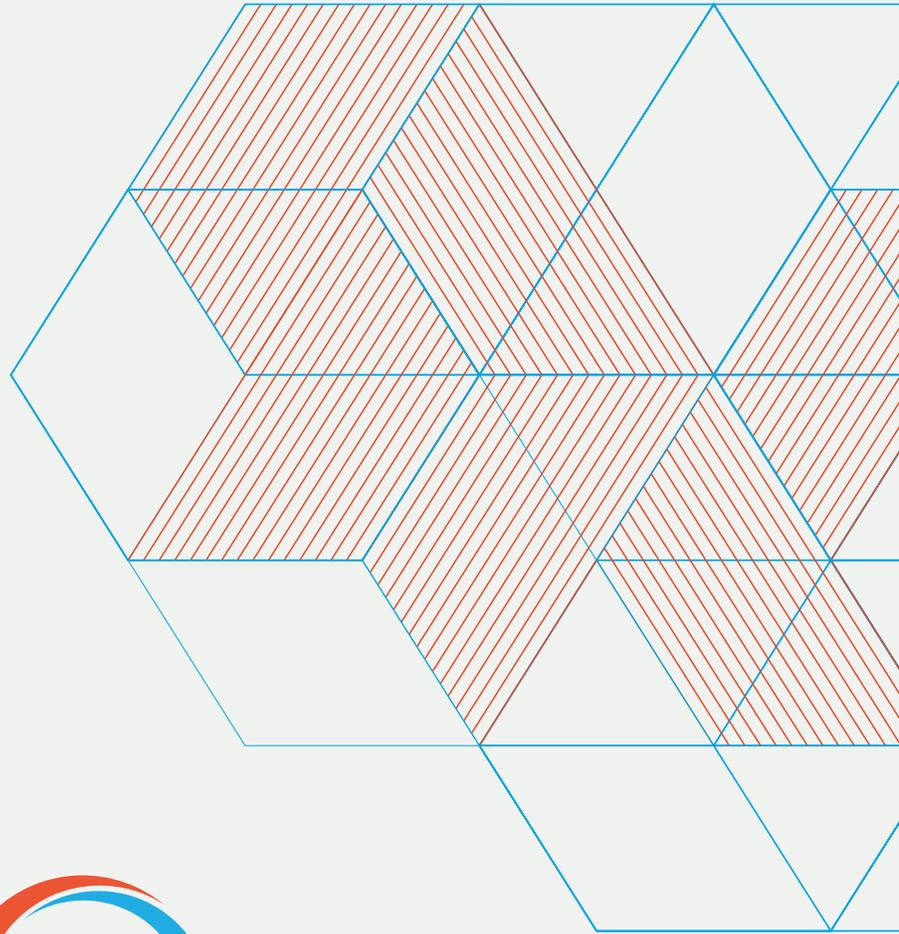
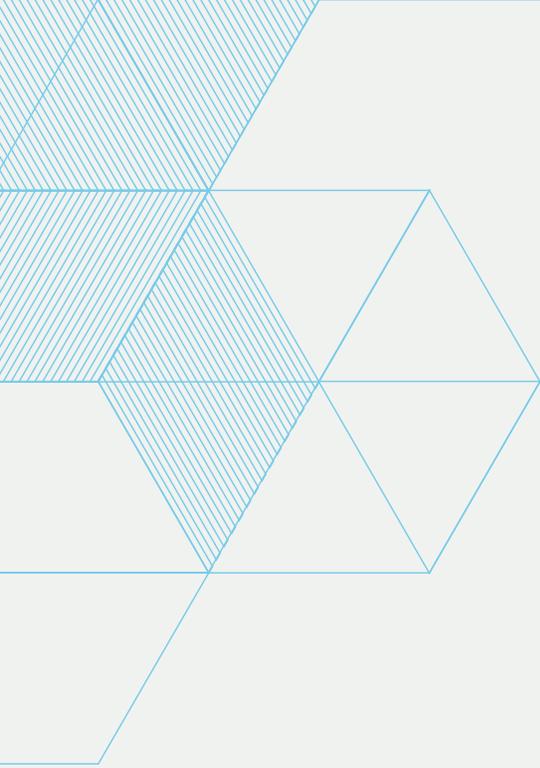
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-Holly Swensen, APRN, NP-C



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

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