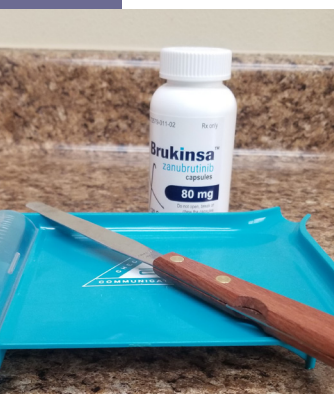


PQI IN ACTION

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



ZANUBRUTINIB PATIENT SELECTION AND MANAGEMENT IN MANTLE CELL LYMPHOMA



PASSION FOR PATIENTS
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INTRODUCTION

In an effort to promote higher quality patient care NCODA constructed the NCODA Positive Quality Intervention to provide healthcare providers with the support and enhanced education to improve the overall management of patients receiving oral oncolytics. The PQI fosters better care for patients through increased speed to therapy, reduced cost and hospitalization, and by improving persistence and adherence within the medically integrated oncology practice. The PQI in Action serves as a follow up to the PQI and incorporates opinions and experiences from a variety of knowledgeable participants, including those from the medically integrated teams at both American Oncology Network, LLC (AON) and Summit Cancer Centers (SCC). Both practices have successfully implemented Medically Integrated Dispensing (MID) as well as the use of positive quality interventions throughout their care teams to improve how they operationalize treatment with zanubrutinib (Brukinsa).

AON was launched in 2018 and is an alliance of community oncology physicians and healthcare providers across the country. They have multiple care sites in 15 states at time of publication. They are a physician-led organization and their services include centralized mail-order pharmacy, diagnostics, pathology, fully integrated electronic medical records, a care management team, and financial assistance programs. AON Pharmacy is their in-house state-of-the-art medically integrated dispensing pharmacy and has access to 99 percent of the oral oncolytics their physicians prescribe. The pharmacy, based in Ft. Myers, Florida, coordinates delivery to patient homes.

Summit Cancer Centers serves eastern Washington, Idaho, Montana, Oregon and western Canada with cancer treatment and imaging services at multiple locations throughout eastern Washington and Idaho. They offer a variety of services including surgical oncology, chemotherapy, immunotherapy, radiation treatments, complementary wellness therapies, and on-site oral chemotherapy. They have nine providers between their four main sites and four satellite clinics and MID staffed by a pharmacist and OPTA member oral chemotherapy technician (www.ncoda.org/oncology-pharmacy-technician-association-opta/) that focuses on oral oncolytic medications for their patients.

THE PARTICIPANTS

American Oncology Network, LLC **Ft. Myers, FL and Columbus, OH**



Sameh Mikhail, MD
Medical Oncologist



Christine Pfaff, RPh
Regional Director of Operations



Doug Braun, CSP, PharmD, RPh
Pharmacy Director, AON Pharmacy



Tamara Weinberg, RN, BSN, OCN, ONN-CG
Pharmacy Nurse Specialist



Ali Grant, CPHT, RPhT
Pharmacy Technician

Summit Cancer Centers **Spokane, WA**



Mirela Andrei, MD
Medical Oncologist



Natasha Olson, PharmD
Oncology Pharmacist



Alicia Barnes, CPHT
Oral Chemo Technician

DEFINING MEDICALLY INTEGRATED DISPENSING AND IMPLEMENTING THIS MODEL OF SERVICE

Medically Integrated Dispensing (MID) is a type of service model in which patients receive oral 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. 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.¹

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. AON Medical Oncologist at the Zangmeister Cancer Center Sameh Mikhail, MD, states, "When I realize prescriptions are going to go through a different pharmacy, communication and coordination of care is much more difficult." He values the ease of using his MID pharmacy. Various treatment settings including community, institutional, and academic centers have made successful efforts to transition to this integrated service model to maintain the coordination of care within the medically integrated model. The "majority of treatment delays have occurred when patients are receiving their therapies not from our pharmacy" he added. 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.

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 AON and SCC 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. The clinical pharmacist reviews every prescription during Drug



SCC oral chemo technician Alicia Barnes, CPhT prepares Brukinsa for a patient.

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.

BEYOND THE FIRST FILL: PATIENT FOLLOW-UP



AON physicians, Dr. Jeanna Knoble and Dr. Sameh Mikhail consult on a patient.

After a patient receives the initial prescription for a new oral therapy in a medically integrated dispensing model, multidisciplinary follow-up processes help maximize the outcome. A follow-up and assessment call is initiated by the pharmacist at these 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. Practice Administrator at the Zangmeister Cancer Center division of AON Christine Pfaff, RPh says that "the biggest benefit of being part of this medically integrated network is that the pharmacist can have access to the chart. They can get in there and see Dr. Mikhail's last progress note, see all the labs, and send reminders of anything that may be outstanding." AON Pharmacy Director Doug Braun, CSP, PharmD agrees that EMR access is vital. He states it is "invaluable to us to make sure we can update notes, check labs, those kind of things" as part of patient care.

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 everchanging 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 BIGGEST BENEFIT OF BEING PART OF THIS MEDICALLY INTEGRATED NETWORK IS THAT THE PHARMACIST CAN HAVE ACCESS TO THE CHART."

Christine Pfaff, RPh

CREATING CLINICAL CONFIDENCE THROUGH POSITIVE QUALITY INTERVENTIONS

Empowered with innovative tools, the MID teams at both AON and SCC have improved the quality of care delivered at their institutions through adoption of NCODA resources. These leading oncology organizations value the PQI which provides concise, clinical guidance information to raise the standard of care across all

the professional disciplines. In general, PQIs afford attention to any critical aspect of drug therapy that may be easily overlooked (“if you see ‘x’, remember to do ‘y’”). In a world where new and novel treatments arise almost daily, healthcare professionals need an easy-to-use reference to enact the key clinical principles for each therapy. The PQI serves that need.

POSITIVE QUALITY INTERVENTION: ZANUBRUTINIB PATIENT SELECTION AND MANAGEMENT IN MANTLE CELL LYMPHOMA

Mantle cell lymphoma (MCL) is a rare subtype of B-cell NHL having a characteristic reciprocal chromosomal translocation (11;14) (q13;q32) leading to constitutive expression of cyclin D1.2,3 The optimal approach to relapsed or refractory (r/r) disease remains to be defined. However, Bruton’s tyrosine kinase (BTK) inhibition with zanubrutinib has demonstrated a well-tolerated efficacy profile for patients with r/r MCL.⁴

Braun and Pfaff of AON believe the NCODA PQI offers clinical considerations unique to zanubrutinib that help in selecting therapy for patients while providing meaningful follow-up information specific to patients with MCL. Selection of therapy for patients with MCL becomes difficult due to the current landscape and available treatment options. The NCODA PQI provides concise information in treatment selection, place in therapy, dosing strategies, and monitoring parameters.

The first step in the zanubrutinib PQI is to ensure the patient is an appropriate candidate based on the indication. The PQI reminds the team to evaluate the patient for comorbidities such as history of atrial fibrillation (Afib), recent hemorrhage, hypertension, etc when appropriate.⁵ Braun states that his pharmacy was excited about zanubrutinib when it came to market because of the safety and tolerability profile. He believes that any drug that has positive tolerability and safety can improve compliance. He adds, “We want our patients to get on therapy and stay on therapy. That is the goal.” Both practices physicians have specifically chosen zanubrutinib for patients at risk of certain side effects. SCC medical oncologist Mirela Andrei shares that when starting a patient on a medication she always takes “age, bleeding risk, blood counts and liver and kidney function” into account.

Dosing is also a consideration on the zanubrutinib PQI. This is a unique medication in that it can be dosed once or twice daily based on the patient. Patients may either receive 160mg twice daily or 320mg once daily depending on their preference and ability to adhere to twice daily medication.⁴

**“WE WANT OUR PATIENTS
TO GET ON THERAPY AND
STAY ON THERAPY. THAT IS
THE GOAL.”**

Doug Braun, PharmD



DRUG INTERACTIONS, DOSING, AND PROPHYLAXIS: A CHANCE FOR PHARMACIST INTERVENTION

One component that plays a key role in the management of pharmacotherapy in oncology patients is detection of interactions. These patients can be especially susceptible to drug interactions due to many factors and interventions should be performed to prevent or minimize the risk of these interactions. It is therefore crucial to analyze all therapy before beginning treatment.⁶ Zanubrutinib can interact with CYP3A inhibitors and inducers and the PQI gives guidance on how to handle these interactions.^{4,5} Both AON and SCC pharmacists screen patients on zanubrutinib and all other medications for drug interactions.

Again, the pharmacists and pharmacy staff of both practices have access to the EMR, which allows them to verify labs such as kidney and liver function. The zanubrutinib dose should be decreased for patients with severe hepatic impairment.⁴ Pharmacists are responsible for ensuring the right dose of the right drug reaches the right patient at the right time by the right route. Many elements can impact these

“five rights,” including patient age, weight, ethnicity, diet, kidney and liver function, allergies to medications and other medications. Oncology pharmacists must evaluate each medication to make certain the medication is the safest and most appropriate and effective choice for the patient.⁷

According to the PQI, the patient should also be assessed for infection prophylaxis as necessary. Since both teams are integrated into the practice and have access to the EMR, this task is easy to perform. SCC Oncology Pharmacist Natasha Olson, PharmD, shares that her MID focuses on oral oncolytics and sends supportive medications out to community pharmacies for patient pick up. Even though her model may not dispense the prophylaxis, she still verifies with each new start that the prescription has been sent out to the local pharmacy. She adds “when I counsel the patient, I ask them have they picked up the prophylaxis prescription and talk to them about why that is important.” Another added value of the Medically Integrated Team.

EDUCATION AND MONITORING

Additional important pieces of the zanubrutinib PQI are monitoring the patient for signs and symptoms of Afib/flutter, bleeding, or infections including opportunistic infections and educating the patient on proper sign/symptom monitoring and other important specifications of the drug. Medically Integrated Teams allow this monitoring to be more seamless as everyone has access to the EMR and can easily and directly communicate with other members of the team including the provider. They also have direct communication with the patient to ensure proper education is received. Dr. Andrei states that she finds it important to educate patients on a medication’s “most common side effects as well as the major side effect profile.” AON has both nurses and pharmacists providing patient education. Braun has a team of phar-

macists and nurses on the pharmacy end that counsel the patient and provide any necessary education. Pfaff explains that the nurses in the clinic also provide education and triage calls from patients when they are experiencing a side effect. It is truly a team effort.

Olson feels the most helpful section of the zanubrutinib PQI is the patient centered activities portion with information on patient education. SCC utilizes NCODA’s Oral Chemotherapy Education (OCE) sheets. The first patient centered activity on the PQI is to give the patient an OCE sheet. OCE sheets are a collaborative initiative led by NCODA. The sheets are provided as a complimentary educational resource for patients with cancer in need of concise, easy-to-understand information about oral cancer drugs. They are available to be downloaded and printed by

EDUCATION AND MONITORING CONTINUED

healthcare providers. The zanubrutinib OCE sheet can be found at (www.oralchemoedsheets.com) The OCE sheets and patient education are a cornerstone of oral therapy as patient education has been demonstrated to improve medication adherence across a broad range of conditions and disease severity. This education should be considered an integral part of any disease management program.⁸ It has been shown that education that includes direct contact with the healthcare provider appears to provide the most benefit in terms of improving health behaviors such as adherence with medication and that the quality of this interaction is a critical factor in adherence.⁸ The practices are continually striving for excellence in patient education and this interaction and the PQI paired with OCE sheets provides a resource to assist in this quest.

BRUKINSA EDUCATIONAL POINTS (EXCERPT FROM OCE SHEET)

Taking zanubrutinib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember:

- 1 Your dose may vary, but the usual dose of zanubrutinib is 160 milligrams (160 mg) to be taken by mouth at a scheduled time twice a day or 320 milligrams (320 mg) to be taken by mouth at a scheduled time once a day.
- 2 Zanubrutinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow zanubrutinib, talk to your care provider or pharmacist for possible options.
- 3 If you miss a dose of zanubrutinib, remember the following guidelines:
 - Only take the missed dose as soon as you remember it on the same day.
 - Do not take two doses at one time.
 - Be sure to write down if you miss a dose, and let your care provider know about any missed doses.

ADHERENCE IMPROVES OUTCOMES

One of the patient centered activities in the zanubrutinib PQI is to evaluate patients for missed doses in case there is a need for interventions such as reminders, pill boxes, etc. It is estimated that 1/3 to 1/2 of US patients do not adhere to their prescribed medication regimens.⁹ An oral treatment option provides convenience, can improve quality of life, alleviate treatment burden, and give the patient some control of their treatment. While an oral option provides a less invasive, sometimes more manageable alternative for cancer patients, the role of the patient in medication administration is crucial when adherence to their treatment regimen depends on self-management.¹⁰ Olson comments that the most important point to educate patients on when starting zanubrutinib is adherence and compliance and as stated earlier this quality of this education is vital. This is one way the MID can provide value over outside mail order pharmacies- they are able to “bridge the gap” she adds. SCC oral chemo technician Alicia Barnes feels adherence and compliance is the biggest value of MID. She says, “We can make sure they take their drug. Compliance is huge.”

Both practices have pharmacists and staff that are trained to monitor patients for adherence. This is done through phone calls and in person conversations with pharmacists, nurses and

technicians. If a problem is detected the medical team can work with the patient on a solution. Possible solutions may include tools such as pill boxes, calendars, electronic reminder systems using the smart phone, and additional calls from the practice. AON uses their own adherence system called ORCA. It is a robust system with tools and scripts tailored to each specific oncology. It contains a drop-down menu that allows staff to add as much information as needed and can tag the nurses or pharmacists if a patient requires an intervention. It is fully customizable, and the introduction of new medications normally coincides with their release onto the market.



AON Pharmacy in Fort Myers, Florida

FINANCIAL BURDEN: THE MID AND PQI HELPING PATIENTS AFFORD TREATMENT

On top of clinical considerations, financial toxicity often leads to treatment abandonment or discontinuation. More importantly, as discussed above it is well established that adherence to BTK inhibitors is often associated with improved outcomes. The NCODA PQI offers financial support information which helps provide patients with options and minimizes the financial burden. Barnes comments that in her role she uses the information provided regarding Beigene's support in the zanubrutinib PQI. The supplemental information section gives all of the details for the **myBeiGene Patient Support** program.

The program can help in multiple ways including co-pay assistance, a bridge supply for insurance coverage delays, and free product for uninsured and underinsured patients. Both practices assist in finding support for patients whether the MID site is able to fill the medication or if it is mandated to go to an outside mail-order pharmacy. Olson comments that their MID staff tries to secure funding whether it stays in the practice or goes out because "in our experience the financial aspect of things can delay the starting, well actually even the acquiring, of the medication by at least a week" if the medication is filled on the outside.

A FINANCIAL BENEFIT: MINIMIZING WASTE

The MID model not only assists patients in financial coverage for their medications, it also minimizes waste to the health care system. Olson shares, "I think that MID really helps with getting medications started, keeping patients on therapy, and minimizing waste." She explains that her MID "saves patients and insurance money by not refilling medication and waiting if a patient still has two weeks of medication" in their procession for reasons such as a therapy hold, hospitalization, etc. She utilizes NCODA's Cost Avoidance and Waste Tracker (CAWT) tool when possible (www.ncoda.org/cawt/).

The CAWT is an innovative platform available to NCODA members to track cost and waste of prescribed drug therapies. Cost avoidance includes interventions made before

the drug being dispensed to the patient that preclude an unnecessary Rx from being filled and dispensed to the patient and waste refers to drugs that have been processed or prescriptions filled and then for any reason, the drug is not used by the patient. Practices can use the CAWT to easily share individual and compiled data to help make the case for MID. The CAWT has many benefits including quantifying cost avoidance and waste at the practice, demonstrating benefit of MID to third-party payers, offering CAWT data for insurance input, and demonstrating the benefit of MID institutions. Effectively using the PQI resource provided information on interactions and monitoring can aid the MID institution with ensuring necessary, correct refills thereby cutting down on waste.

"I THINK THAT MID REALLY HELPS WITH GETTING MEDICATIONS STARTED, KEEPING PATIENTS ON THERAPY, AND MINIMIZING WASTE."

Natasha Olson, PharmD



Summit Cancer Centers in Spokane, Washington

MID AND THE PQI: BRINGING VALUE TO ALL STAKEHOLDERS

For the many reasons listed in this PQI in Action the MID and the PQI bring value to all stakeholders. Most importantly it brings value to patients. AON nurse Tamara Weinburg, RN, OCN says the biggest value of MID is “patient safety, you know that the patient is getting the right drug at the right time.” She believes when patients are required to use outside mail order pharmacies there can be problems for patients. She elaborates that it is a “huge dysfunction for patients if it goes outside of the practice because dealing with the outside mail order pharmacy is not a closed circuit of care.” She adds that patient education from the MID pharmacy regarding the medication and patient follow-up on side effects are two other concerns with patient safety if required to be filled outside of the practice. “I feel like the patient could get really confused and these are drugs that potentially can be very harmful if not taken the correct way. I have been in oncology for 20 years now and I can’t imagine as a patient coming on board, with a new cancer diagnosis, trying to figure out these oral regimens without having a pharmacy that is attached to a practice.” Dr. Andrei adds that their practice has a large population of elderly

patients who do not live close to the clinic and she feels it is a very helpful to have the MID checking in on patients. She also appreciates that her pharmacist follows up on the patient education.

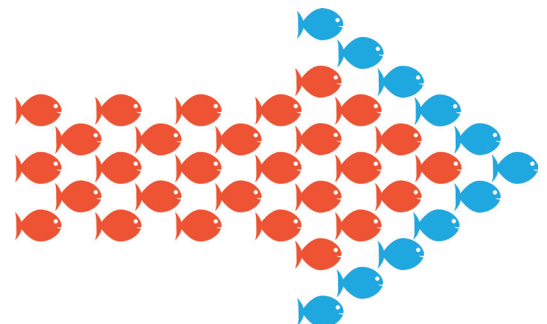
MID paired with the PQI also brings value to practices. MID helps establish communication and procedures within the Medically Integrated Team to make sure everyone is on the same page. At SCC the MID site has put processes into place such as a google calendar to keep track of refills and “new start” email groups. Olson explains that when a provider is starting a patient on an oral oncolytic like zanubrutinib they can select the new start email group within company email and send a communication to the key people in the practice who will facilitate the patient obtaining the medication in one easy step. AON Pharmacy has also put procedures in place that lighten the load of prescribers such as the technicians like Ali Grant, CPhT, RPhT, who are performing intake processing, verifying benefits and scheduling patient fills.

CONCLUSION: PQI PRINCIPLES BUILD THE BRIDGE TO FUTURE SUCCESS

PQI principles promote quality care and create an environment in which the patient feels safe with regular check-ins on their health status. Surrounded by one team of expert professionals with each individual cohesively contributing to the overall journey, these MCL patients are in a position to maintain health and quality of life throughout the treatment process. That’s a comforting feeling for everyone involved. Individuals within cancer treatment organizations are the builders who provide the bridge to success with zanubrutinib therapy. Employers, payers, providers, pharmacists and patients are continuing to recognize the value of this delivery model. NCODA exists to advance the value of dispensing practices for oncology physicians through the provision of innovative and effective resources like the Positive Quality Intervention (PQI). These tools reduce physician burden and instill confidence in health care professionals to achieve optimal outcomes for their patients. But the work is far from over.

All organizations, and more importantly, individuals, should challenge themselves to simply do more. The updated adage is true: it takes a team to care for a cancer patient. NCODA has provided a foundation, but only the individuals within an empowered MID team can take the necessary steps to successfully build the bridge to optimal patient care. Once these tools are properly operationalized, professionals can enable patients to climb up and over the waters and find success on the other side. We are all in this together; let us move forward confidently.

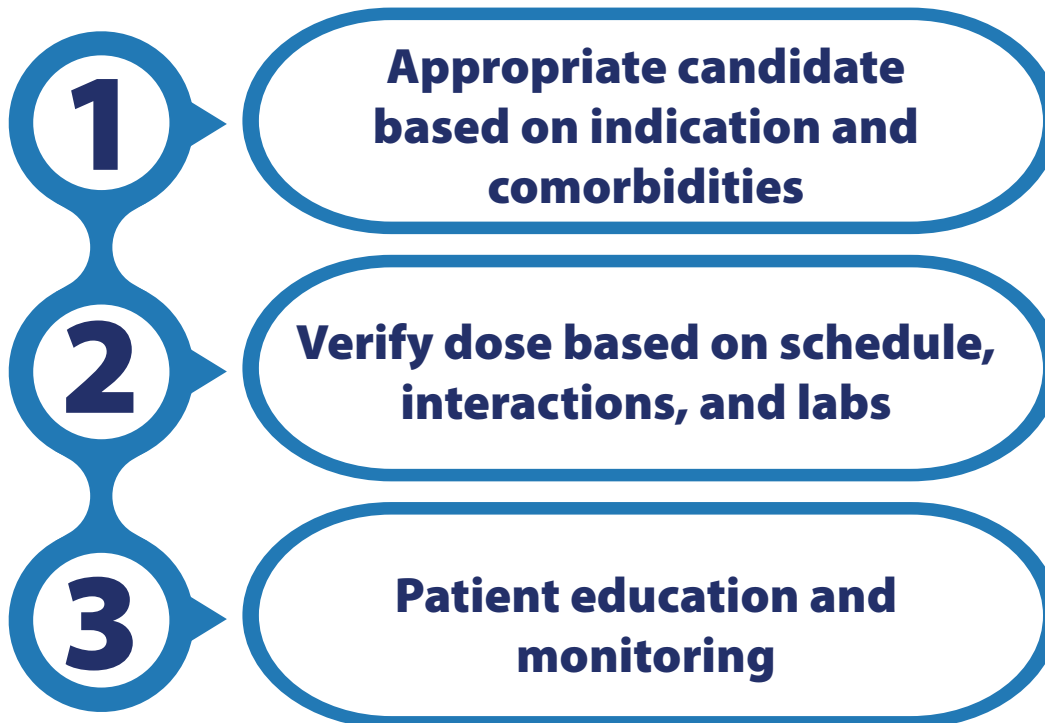
**WORKING TOGETHER,
WE BECOME STRONGER**



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ZANUBRUTINIB PQI PRINCIPLES:





Helpful Online Resources

- www.ncoda.org
- www.ncoda.org/pqi
- www.oralchemoedsheets.com
- www.ncoda.org/zanubrutinib-patient-selection-and-management-in-mantle-cell-lymphoma

ON THE COVER *(from left):*

- Brukinsa (zanubrutinib) 80mg capsules.
- SCC Pharmacist Natasha Olson, PharmD counsels a patient.
- AON Pharmacy Technician Ali Grant, CPhT, RPhT fills a prescription for a patient.

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 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.

