

# PQI IN ACTION



**ZANUBRUTINIB (BRUKINSA®)**  
**PATIENT SELECTION AND**  
**MANAGEMENT PQI**



**NCODA'S POSITIVE QUALITY**  
**INTERVENTION IN ACTION**

# INTRODUCTION

In an effort to promote higher quality patient care, NCODA created the NCODA Positive Quality Intervention (PQI) as a peer-reviewed clinical guidance resource for healthcare providers. By providing Quality Standards and effective practices around a specific aspect of cancer care, PQIs equip the entire multidisciplinary care team with a sophisticated yet concise resource for managing patients receiving oral or IV oncolytics. This PQI in Action is a follow up to the **Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI** and explores how the Medically Integrated Teams at Maryland Oncology Hematology (MOH) and American Oncology Network (AON) incorporate PQIs as part of their daily workflow. This article will discuss how utilizing the **Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI** elevates patient care.

The American Oncology Network (AON) is an alliance of physicians and seasoned healthcare leaders partnering to ensure the long-term success of community oncology. Launched in 2018, the rapidly growing network represents over 220 providers which consists of physicians, nurse practitioners and physician assistants at multiple care sites within 20 states. AON offers a unique model of physician-led, community-based oncology management. With services such as a centralized specialty pharmacy, diagnostics, pathology, fully integrated electronic medical records, a care management team and a variety of financial assistance programs. An alliance with AON ensures that patients' experiences will be at the very pinnacle of cancer care today.

Maryland Oncology Hematology was founded in 1996 and is the largest independent Medical Oncology and Hematology group in Maryland. MOH has over 52 Oncologists/Hematologists, 6 surgeons and 3 radiation oncology physicians practicing in 15 locations across central Maryland. Their state of the art infusion centers offer a full range of chemotherapy services, laboratory testing, clinical trials and support service. MOH is united in healing with The US Oncology Network, one of the nation's largest community-based cancer treatment and research networks focused on advancing cancer care in America. Maryland Oncology Hematology participates in clinical trials through US Oncology Research, which has helped to develop FDA approved cancer therapies.

## THE PARTICIPANTS

### **American Oncology Network** **United States of America**



**Sreekanth Reddy, MD**  
Medical Oncologist



**Sarah Stull, PharmD, MPH, BCACP**  
Oncology Pharmacist



**Mohit Narang, MD**  
Medical Oncologist and Managing Partner



**Courtney Horn, PharmD**  
Oncology Pharmacist



**Michele Walsh CPhT, RPhT**  
Pharmacy Liaison



**Heather Finneyfrock, RN, BSN, OCN**  
Clinical Nurse Manager



**Brandon Sutherland, CPhT**  
Lead Pharmacy Technician

# DEFINING MEDICALLY INTEGRATED PHARMACY AND THE POSITIVE QUALITY INTERVENTION

**N**CODA defines a Medically Integrated Pharmacy (MIP) as a dispensing pharmacy strategically embedded within an oncology center of excellence, championing a patient-centric, multidisciplinary team approach. This innovative model, known as Medically Integrated Dispensing (MID), is a collaborative and comprehensive endeavor that engages oncology healthcare professionals and stakeholders. Together, they prioritize the continuity of high-quality care and therapies for cancer patients, ensuring a seamless and coordinated approach to their well-being. The significance of this approach becomes evident when considering the potential pitfalls associated with filling prescriptions at remote pharmacies—fragmentation of care, inadequate follow-up and monitoring, and a missed opportunity for exploring financial assistance options for patients.<sup>1</sup> The MID model, however, overcomes these limitations by processing and dispensing prescriptions through a pharmacy situated within the oncology clinic.

To empower Medically Integrated Pharmacies, NCODA provides a suite of tools designed to enable all healthcare professionals within the MIP to deliver patient-centered and transformative cancer care. These tools include the financial assistance tool, oral chemotherapy sheets (OCEs), and Positive Quality Interventions (PQIs). Highly regarded by leading oncology organizations, PQIs offer concise clinical guidance



AON pharmacy provides excellent clinical service with each fill of BRUKINSA®.

to elevate the standard of care across all professional disciplines. They serve as invaluable resources that pinpoint critical aspects of drug therapy often overlooked, providing an accessible reference to reinforce clinical principles for each therapy. Throughout this article, we delve into the utility of these resources at AON and MOH, shedding light on their impact in enhancing the overall patient experience and outcomes.

## ZANUBRUTINIB (BRUKINSA®) PATIENT SELECTION AND MANAGEMENT PQI

**C**hronic lymphocytic leukemia (CLL) stands as the most prevalent leukemia among adults, originating in cells that mature into specific white blood cells, known as lymphocytes, within the bone marrow. While the cancerous cells initiate their growth in the bone marrow, they subsequently infiltrate the bloodstream.<sup>2</sup> Accounting for approximately one-quarter of new leukemia cases, CLL predominantly affects the elderly population.<sup>3</sup> In January 2023, the Food and Drug Administration (FDA) granted approval to zanubrutinib for the treatment of CLL or small lymphocytic lymphoma (SLL).<sup>4</sup> Zanubrutinib distinguishes itself as a potent, highly specific, and irreversible

inhibitor of Bruton's tyrosine kinase (BTK). Clinical trials demonstrated remarkable efficacy, achieving 100% inhibition with both twice-daily and once-daily dosing regimens. Notably, beyond its approval for CLL, zanubrutinib has garnered approval for mantle cell lymphoma, marginal zone lymphoma, and Waldenström macroglobulinemia, underscoring its versatility in addressing various B-cell malignancies.<sup>5</sup>

The **Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI** has emerged as a resource in light of the novel indications for zanubrutinib, particularly in optimizing outcomes for patients with CLL. NCODA PQIs, renowned for their precision and conciseness as peer-reviewed clinical

guidance resources, play a vital role in empowering the entire multidisciplinary care team. Designed to be both sophisticated and user-friendly, these PQIs effectively support the management of patients undergoing oral or intravenous oncolytics. Michele Walsh, CPhT, RPhT serving as the Pharmacy Liaison at AON, leads in bridging communication between the pharmacy and clinics. Responsible for keeping clinics abreast of pharmacy processes and changes, Michele states, “I think all information shared in the PQI is important even if it doesn’t play a part in your role. Having that information just helps with the process and you now know how important it is to push through to get those prescriptions processed. Knowing diagnosis and side effects may not be pertinent to my position but it’s definitely good access and good knowledge to have when it comes to medications.” At AON, Sarah Stull, PharmD, MPH transitioning from a non-oncology pharmacist background, expresses her enthusiasm for the tools provided, including PQIs and OCEs. She emphasizes the PQI’s role as a comprehensive guide, aiding in the learning process and facilitating a deeper understanding of oncology. Sarah particularly values the PQI’s “breakdown of

information when handling new orders, especially during new pharmacist training sessions.” This collaborative appreciation for the PQI underscores its pivotal role in fostering informed and adept practices within the oncology care landscape.

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Michele Walsh, CPhT, RPhT

## THE MIP: “A GOOD RETURN ON INVESTMENT”

**A**ON and MOH take great pride in their patient-centric approach, utilizing a multidisciplinary methodology to deliver comprehensive care. The integrated pharmacy system platform stands as a testament to their commitment, reducing administrative inefficiencies and enhancing patient access to care. Medically Integrated Pharmacies, in particular, excel in providing personalized follow-up, fostering heightened adherence rates among patients. Dr. Sreekanth Reddy, MD, Medical Oncologist at AON emphasizes the substantial benefits of a medically integrated pharmacy, noting its “full-service” nature and the profound understanding the pharmacy team develops with patients. Dr. Reddy states, “The MIP has a high degree of expertise with oncology patients and the oncology drugs. They are very adept at patient assistance for the oral therapeutics which makes it very convenient for the ordering physician because they take care of the logistics of getting the drug to the patient.” Additionally, the team plays a crucial role in patient education, toxicity management, and ensuring compliance – elements deemed vital by Dr. Reddy.

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Sreekanth Reddy, MD

Similarly, Dr. Mohit Narang, MD, Medical Oncologist and Managing Partner of MOH shares a decade-long personal experience with a medically integrated pharmacy, describing it as a “phenomenal experience” that initially faced resistance



from physicians due to concerns about costs. However, the return on investment became evident with enhanced safety measures, notably in the vigilant monitoring of drug interactions for both IV and oral chemotherapy products. Dr. Narang underscores that “having a pharmacist not only increased nursing engagement with the pharmacy team but also fostered stronger collaboration between the pharmacy team and physicians, ultimately leading to improved outcomes.” Additionally, he notes a significant increase in order dispensing, attributing this to having a pharmacist, resulting in better economic and safety outcomes. The multifaceted advantages, as outlined by both Dr. Reddy and Dr. Narang, underscore the pivotal role of medically integrated pharmacies in elevating patient care and overall clinical outcomes.

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Mohit Narang, MD

## THE PQI DESCRIPTION AND BACKGROUND

The initial segment of the **Zanubrutinib (BRUKINSA®) Patient Selection and Management Practice Quality Improvement PQI** encompasses the Description and Background. The Description section articulates the PQI's objective, focusing on zanubrutinib's application in the management of diverse indications. In tandem, the Background section furnishes an overview, delving into its indications and clinical trial particulars. Zanubrutinib garnered FDA approval for Chronic Lymphocytic Leukemia (CLL) following extensive evaluation in two pivotal clinical trials—SEQUOIA and ALPINE. The SEQUOIA study demonstrated zanubrutinib's efficacy as a first-line treatment, showcasing prolonged progression-free survival compared to rituximab plus bendamustine in patients with treatment-naïve CLL/SLL.<sup>4</sup> In the ALPINE trial, zanubrutinib outperformed the standard CLL treatment, ibrutinib, as a second-line therapy, with over 78% of patients alive without cancer growth at 2 years.<sup>4</sup> Dr. Reddy, shares his preference for zanubrutinib utilization in CLL is patients with high-risk cytogenetic features, such as the del(17p) mutation, and those who have relapsed after prior therapy. His rationale aligns with the clinical trial outcomes, where zanubrutinib demonstrated superior efficacy with fewer side effects, particularly in cases with genetic mutations associated with a poorer prognosis.<sup>5</sup>

In its clinical trials, zanubrutinib demonstrated a notably lower incidence of potential grade 3-4 adverse effects such as atrial fibrillation and major hemorrhage, contrasting with other Bruton's tyrosine kinase (BTK) inhibitors.<sup>5</sup> Dr. Narang articulates a distinct preference for zanubrutinib as his preferred



**Medically Integrated Pharmacy leads to optimal outcomes for patients.**

red BTK inhibitor for patients in need, citing its second-generation status and markedly enhanced safety profile. Beyond the clinical realm, Dr. Narang strategically promotes the adoption of a single drug per class approach within his practice. In his role as head of P&T at MOH, he underscores the practical advantages, streamlining operations for the entire practice—from simplified oversight for the pharmacy team to facilitating cost-effectiveness approval and easing the process for social workers managing patient assistance programs. Additionally, he emphasizes the benefits for advanced practice providers (APPs) and nursing, noting the simplicity of focusing on one drug per class and its associated side effects, a strategic move that simplifies learning and enhances overall operational efficiency.

# THE PQI PROCESS

The subsequent section of the **Zanubrutinib (BRUKINSA®) Patient Selection and Management Practice Quality Improvement PQI** delves into the PQI Process, offering a structured, step-by-step clinical guidance on the actions to be taken upon receiving a new prescription of zanubrutinib. The PQI mandates a confirmation of the appropriateness of zanubrutinib for a given candidate based on indication. It underscores that certain patient comorbidities, such as a history of atrial fibrillation (Afib), recent hemorrhage, hypertension, or concomitant use of proton pump inhibitors (PPI's) or Histamine Type-2 receptor antagonists (H2RAs), might render zanubrutinib a safer option. Dr. Reddy, drawing on his experience, notes the relatively low incidence of Afib and patients' overall good tolerability, but emphasizes the importance of patient self-monitoring and vigilance for symptoms associated with major depression. Additionally, Dr. Reddy leans towards once-daily dosing for improved compliance, a strategy discussed in the next step of the PQI Process. This step elucidates that the 320 mg dose can be administered either once or twice daily, offering flexibility to tailor the schedule to individual patient needs. The once daily formulation entails taking four 80 mg capsules at the same time whereas the twice daily formulation involves taking two 80 mg capsules in the morning and two 80 mg capsules in the evening. Stull remarks on the patients' preference, with a balanced split between once-daily and twice-daily dosing, citing patient convenience as a key factor. She also mentions that during patient adherence checks they have encountered patients having "too many capsules left over and it tends to happen with patients on twice a day dosing. So then we'll talk and make the recommendation of switching the patient to once a day dosing to ensure good adherence with the medication." Stull anticipates enhanced ease in the future with the availability of alternative strengths beyond the current 80-milligram capsules.

Moving forward, the third step in the PQI Process underscores the necessity to adjust zanubrutinib dose in the presence of strong or moderate CYP3A inhibitors and to avoid concomitant use with moderate or strong CYP3A inducers. The fourth step involves dose reduction for severe hepatic impairment, coupled with a directive for providers to consider prophylaxis against infections such as HSV and PJP due to increased infection risk in patients. Courtney Horn, PharmD, Clinical Pharmacist at MOH provides a pharmacy perspective, details the ongoing monitoring of patients on zanubrutinib, considering blood counts, past medical history of re-

ted infections, and assessing the need for prophylaxis. She extols the **Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI** by saying "it is really helpful in serving as a quick read for how to dose reduce patients if there is a drug interaction and it even reminds about prophylaxis considerations for PJP and HSV, which is something that our new providers and pharmacist probably weren't thinking about before."

Concluding the PQI Process, the final step encourages providers to refer to the full prescribing information for dose modifications in the presence of Grade 3 or worse adverse effects, which are shown in the table below. Among the notable adverse effects is a decreased platelet count with significant bleeding.<sup>5</sup> Stull sheds light on patient concerns related to bruising, noting an influx of calls to AON from patients with past negative experiences with BTK inhibitors. This presents an opportune moment for the pharmacy team to intervene, collaborating with the doctor's office if necessary, while concurrently providing counseling and reassessment for the concerned patient. The PQI Process, as outlined, serves as a robust framework for ensuring the optimal administration and management of zanubrutinib, encompassing clinical considerations, dosing strategies, and proactive measures against potential adverse effects.

**THE ZANUBRITINIB PQI " IS REALLY HELPFUL IN SERVING AS A QUICK READ FOR HOW TO DOSE REDUCE PATIENTS IF THERE IS A DRUG INTERACTION AND IT EVEN REMINDS ABOUT PROPHYLAXIS CONSIDERATIONS FOR PJP AND HSV."**

Courtney Horn, PharmD

### ≥GRADE 3 EVENTS REQUIRING DOSE MODIFICATIONS<sup>6</sup>

- Grade 3 or Grade 4 febrile neutropenia
- Platelet count decreased to 25,000-50,000/mm<sup>3</sup> with significant bleeding
- Neutrophil count decreased to <500/mm<sup>3</sup>\*
- Platelet count decreased to <25,000/mm<sup>3</sup>\*
- Severe or life-threatening non-hematological toxicities†

\*Lasting more than 10 consecutive days.

†Evaluate the benefit-risk before resuming treatment at the same dosage for Grade 4 non-hematological toxicity.

STARTING DOSE <sup>6</sup>	1 <sup>ST</sup> OCCURRENCE	2 <sup>ND</sup> OCCURRENCE	3 <sup>RD</sup> OCCURRENCE	4 <sup>TH</sup> OCCURRENCE
• Start at 320 mg total dose (160 mg twice daily or 320 mg once daily once daily)	• No dose change	• Reduce to 160 mg total dose	• Reduce to 80 mg total dose	• Discontinue

\*Resume treatment once toxicity has resolved to <Grade 1 or baseline<sup>6</sup>

## PATIENT-CENTERED ACTIVITIES: ENHANCING THE PATIENT EXPERIENCE

The Patient-Centered Activities segment stands as the concluding section within the **Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI**, providing invaluable patient-centered guidance for the healthcare team. This pivotal PQI section emphasizes the team's responsibility to counsel patients comprehensively on various aspects, including zanubrutinib dosing, administration techniques, and recognition of signs and symptoms. Both Dr. Narang and Dr. Reddy adopt a collaborative three-step approach to patient counseling, initiating the process themselves, followed by pharmacy counseling during medication dispensing, and ultimately culminating in

counseling by APPs during follow-up visits.

Heather Finneyfrock, RN, BSN, OCN, the nursing supervisor at MOH, sheds light on the clinic's patient counseling process, which involves three MD providers and two APPs. Heather states that she prioritizes counseling BRUKINSA® patients on two significant aspects such as the heightened risk of infections and the importance of monitoring for abnormal symptoms, like heart palpitations. She also mentions she provides each patient an oral chemotherapy education sheet to review, such as NCODA's OCE sheets.

MOH's Clinical Pharmacist, Horn, further elaborates on the

comprehensive approach taken post-prescription. Following the prescription, a thorough medication reconciliation is conducted to ensure patient safety regarding potential drug interactions. The pharmacist team then guides the patient on proper storage and handling of the medication, outlines the frequency of office visits for lab monitoring, and ensures a detailed understanding of the prescribed regimen. Moreover, Horn emphasizes the commitment to patient well-being, describing a structured follow-up process wherein patients are contacted 10 to 14 days after the initial dispensing to assess their progress and address any emerging concerns. This me-

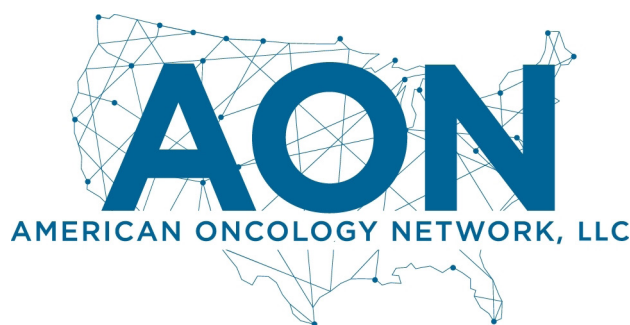
ticulous and multi-faceted approach underscores the team's dedication to delivering patient-centered care throughout the entire treatment journey. Horn concludes by saying, "mail order specialty pharmacies miss out on the personal aspect. We really get to develop those relationships with patients and follow them through therapy. It's exciting but also sad sometimes when a patient finishes therapy because we don't get to call every month for their refill and hear how they're doing."

## MIP FINANCIAL ASSISTANCE

A study conducted in 2018 identified prior authorization and patient assistance as the primary culprits behind delays in patients receiving their oncolytic therapies. However, a compelling counterpoint reveals that medically integrated pharmacies play a pivotal role in overcoming these challenges by ensuring timely access, offering copay assistance, and actively monitoring and managing side effects.<sup>7</sup> This holistic approach not only contributes to heightened adherence to therapy but also results in an overall enhancement of quality and patient satisfaction. Michele Walsh, CPhT, RPhT a key contributor to what she fondly calls the "AON Magic", underscores the efficiency gained from a dedicated team diligently managing prior authorizations. She commends the manufacturer for their patient assistance initiatives, especially beneficial for BRUKINSA® patients under Medicare Part D who may not qualify for certain grants. In addition she commends the MIP for allowing them to get medications to the patient quicker, she states the

"real time access to the EMR systems helps streamline the prescription process and also helps decrease unnecessary fills."

Brandon Sutherland, CPhT, the Lead Pharmacy Technician at MOH, sheds light on his role, which involves processing prior authorizations and facilitating financial assistance. With zanubrutinib ranking among their popular drugs, he highlights the influx of approximately two new zanubrutinib patients daily. Given the financial constraints often faced by Medicare patients, Brandon notes that around "80% of their patients on zanubrutinib require financial assistance from the manufacturer". He acknowledges occasional delays in obtaining prior authorizations, which can impede therapy initiation. However, he highlights the manufacturer's proactive solution—a voucher for a one-month fill provided while awaiting insurance approval, underscoring the commitment to minimizing disruptions in patient access to essential therapies.



MARYLAND  
ONCOLOGY  
HEMATOLOGY

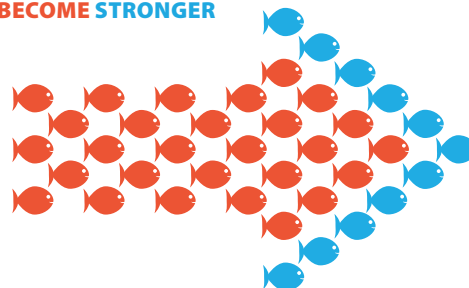


# CONCLUSION: NCODA, THE MIP AND THE BRUKINSA® PQI

The Medically Integrated Team provides value to patients. Dr. Narang sums up the value of a MIP by highlighting the unique patient-pharmacy-physician triangle, emphasizing the personal touch that often diminishes in insurance Pharmacy Benefit Manager (PBM) setups, where communication is less robust. Similarly Heather Finneyfrock states the biggest value of MIP is “the turnaround time for patients, it's nice that patients can get their medications dispensed at our clinics. Patients don't have to plan for when they can be home to get the medication delivered or when to drive to go pick it up. It is just convenient that they can get their medication with their appointments.” The **Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI** provides the Medically Integrated Team with an easy to use, compact clinical resource guide when treating these patients. It helps the team

ensure they are providing patients with the tools and education to improve clinical outcomes. Pairing the Medically Integrated Team with the **Zanubrutinib (BRUKINSA®) Patient Selection and Management PQI** meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.

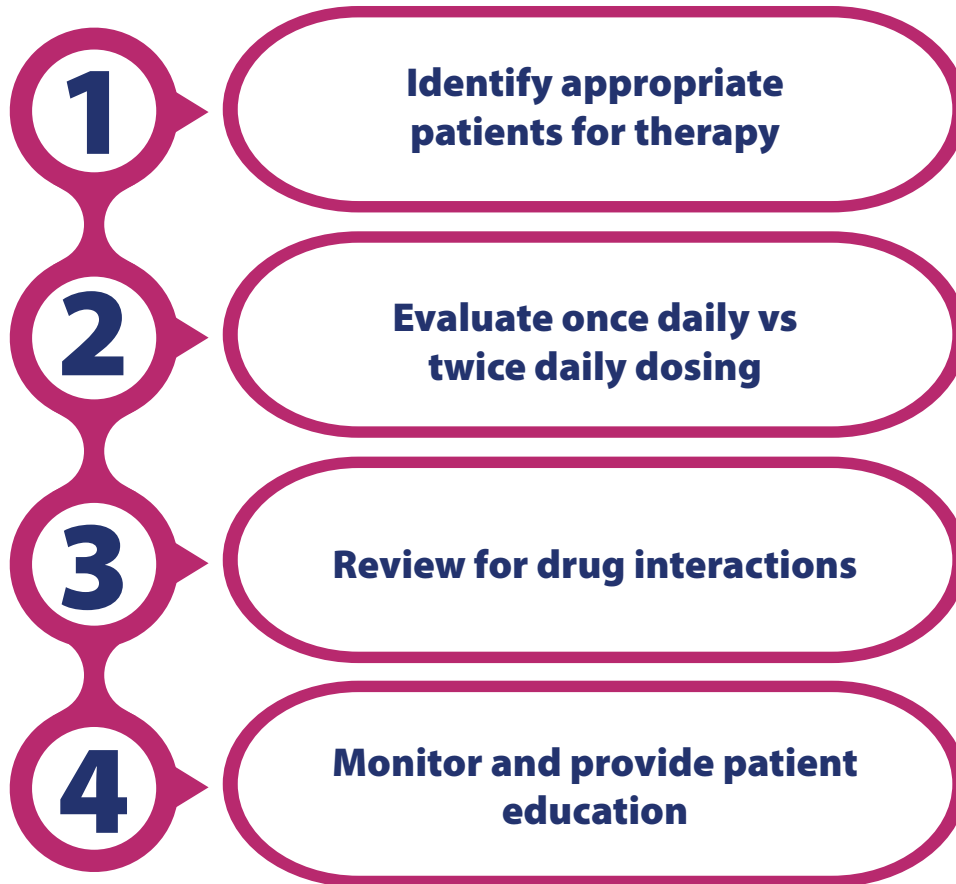
WORKING TOGETHER,  
WE BECOME STRONGER



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# PQI PRINCIPLES:



## ON THE COVER:

- Maryland Oncology and Hematology provides top-notch patient care.

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

Important notice: NCODA has developed this Positive Quality Intervention in Action platform. This platform represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and does not provide individual medical advice and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.



## **NCODA'S POSITIVE QUALITY INTERVENTION IN ACTION**

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