

PQI IN ACTION



**AVAPRITINIB (AYVAKIT®) MANAGEMENT FOR
ADVANCED SYSTEMIC MASTOCYTOSIS**



**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 **Avapritinib (AYVAKIT®) Management for Advanced Systemic Mastocytosis** PQI and explores how the medically integrated teams at Cancer Specialists of North Florida (CSNF) and O'Neal Comprehensive Cancer Center at The University of Alabama at Birmingham (UAB) incorporate PQIs as part of their daily workflow. This article will discuss how utilizing the **Avapritinib Management for Advanced Systemic Mastocytosis** PQI elevates patient care.

Cancer Specialists of North Florida (CSNF) is a physician-owned practice consisting of 34 physicians and offers 13 convenient locations throughout northeast Florida to treat cancer patients. Florida Specialty Pharmacy serves as the medically-integrated dispensing pharmacy of CSNF and is dual accredited to provide the highest quality care to patients within the practice.

The O'Neal Comprehensive Cancer Center at The University of Alabama (UAB) is a nationally recognized cancer center that serves patients in Alabama by providing personalized, patient-centered care with a team based approach. O'Neal Comprehensive Cancer Center is the only NCI-designated center in the four state region of Alabama, Mississippi, Louisiana and Arkansas.

THE PARTICIPANTS

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Margo Lang, RN
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MID, THE PQI, AND AVAPRITINIB: A CLOSE LOOK AT MANAGEMENT FOR ADVANCED SYSTEMIC MASTOCYTOSIS

Advanced Systemic Mastocytosis (AdvSM) is a rare hematologic neoplasm which causes increased proliferation and accumulation of mast cells and has a high rate of KIT D816V expression (90-95%). The presence of the KIT D816V mutation is part of the WHO diagnostic criteria that defines patients with systemic mastocytosis.¹ Mutation analysis for KIT D816V is preferably done using a bone marrow sample since the yield from peripheral blood is low.¹ Avapritinib is an oral type 1 multikinase inhibitor with highly selective and potent activity against KIT and PDGFRA A-loop mutants, including D816V.² Prior to its 2021 approval for use in advanced systemic mastocytosis, avapritinib was primarily used to treat unresectable and metastatic gastrointestinal stromal tumor (GIST) harboring PDGFRA mutations. The phase 1 EXPLORER trial and the phase 2 PATHFINDER trial led to avapritinib's approval for adult patients with AdvSM (including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematologic neoplasm (SM-AHN), and mast cell leukemia (MCL)).^{3,4} The results of the EXPLORER trial determined maximum tolerated dose of avapritinib (200mg Daily) and showed deep and durable response rates (ORR 75%), including molecular remission of KIT D816V in patients with AdvSM.³ In the PATHFINDER study, avapritinib demonstrated a high rate of efficacy with greater than or equal to 50% reductions from baseline in serum tryptase (93%), reduction in bone marrow mast cells (88%) and reductions in KIT D816V variant allele fraction (60%).⁴

Satish Shanbhag, MD of Cancer Specialists of North Florida describes the unique features of avapritinib. "AYVAKIT® is what we call a designer drug – it was developed specifically to target the KIT D816V mutation that is characteristic to Advanced Systemic Mastocytosis. It is highly targeted and highly effective." Avapritinib can be dispensed by the Medically Integrated Team, and thus offers patients more comprehensive care.

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 healthcare professionals and other stakeholders who focus on the continuity of coordinated, quality care and therapies for cancer patients.⁵ The MID model can improve management of patients on therapies

like avapritinib in several ways including improved communication issues, measuring adherence, managing regimen changes, quicker therapy initiation, increased patient satisfaction, financial assistance, cost avoidance, and producing less waste.⁶

Retail Authorization Specialist KeeAnna DeVaughn believes the Medically Integrated System that Cancer Specialists of North Florida offers allows for easy access to information which further leads to a greater overall experience for the patient. "The benefit of a shared EMR system allows the value of not having to request medical records. The information we need is at our fingertips and pharmacists and providers are readily available by email or phone if I have additional questions about something in the EMR system. The integrated system, with easy access to email, messaging tools and the PioneerRx system, also allows us to easily pinpoint where the prescription is in processing if a patient calls and has a question."

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

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KeeAnna DeVaughn,
Retail Authorization Specialist

THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

Dr. Satish Shanbhag of Cancer Specialists of North Florida comments on the PQI. “The PQI serves as a valuable tool for clinicians, as it is a one stop reference. For example, dose adjustments and the monitoring schedule are all built in and it is ideal to have this in one place in the PQI.” Margo Lang, RN, also of CSNF adds, “The PQI is great for a quick breakdown of managing patients on avapritinib. I like that it characterizes the grades of reactions and how to manage these. We had patients on this study prior to the drug’s approval and it was hard to know how to manage prior to having a PQI to go along with it.”

**CLICK HERE
TO VIEW
PQI**

This article will explore the benefits of PQI utilization as a core standard of the MID and how adoption can benefit any practice. Cancer Specialists of North Florida and O’Neal Comprehensive Cancer Center at the UAB each found successful ways to incorporate the PQI clinical resource. Both practices position their Medically Integrated Teams in a way to ensure appropriate treatment, increase compliance, and

maximize clinical outcomes. We will explore their practice settings, how implementing the **Avapritinib Management for Advanced Systemic Mastocytosis** PQI benefits their staff and patients, and how they advance patient care on a daily basis.

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Satish Shanbhag, MD

MEDICALLY INTEGRATED DISPENSING: ELEVATING CARE

As cancer treatment continually grows in complexity containing IV, oral and combination regimens, MID continues 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.

Margo Lang, RN, Triage Oncology Nurse at Cancer Specialists of North Florida comments on the benefit of filling within a MID system. “I really think there is a lack of personal touch on the prescription process when it is sent out and we

are not able to fill on site. The team effort and communication within our pharmacy allows the prescription to be in the hands of the patient in 24 hours or less.” Shanbhag further comments on the benefits of communication being key within the medically integrated space. “When we have outside pharmacies filling the medications, we often find that the communication is not nearly as good as when we fill it as a team on site. Dose adjustments, holding medications, all these communications are much easier done in close coordination. Within our practice, I love that I can send an email about a dose change or holding a medication and the pharmacist can immediately react. I don’t have the luxury of that when dealing with an outside mail-order pharmacy.”

Sharon Perley, RN, BSN, OCN, at O’Neal Comprehensive

ve Cancer Center at UAB truly sees the benefit of having pharmacists on their MID team. She recognizes her pharmacist, Sarah Worth, PharmD, BCOP, BCPS, by stating “It is very helpful having Sarah here. She does extensive education with the patients about the drugs. She makes sure that the drugs are ready for pick up here or informs the team and the patient which pharmacy will be filling the medication. She also performs follow up calls on the patients who receive oral chemotherapy. Educating the patients on oral oncolytics and providing the follow up monitoring is so important, especially with drugs like avapritinib.” Sarah Worth, PharmD, BCOP, BCPS, comments on the importance of early preparation prior to patient appointments. “Because we are physically located in the clinic, we all become aware of when the physician is prescribing the medication. We can often have things ready ahead of time for the patient to streamline the process – clinic visit, baseline labs, go to pharmacy and pick up meds. All of these preparation steps help to bridge the gap between when the patient sees us and when they start therapy.”

“IT IS VERY HELPFUL HAVING SARAH HERE. SHE DOES EXTENSIVE EDUCATION WITH THE PATIENTS ABOUT THE DRUGS. SHE MAKES SURE THAT THE DRUGS ARE READY FOR PICK UP HERE OR INFORMS THE TEAM AND THE PATIENT WHICH PHARMACY WILL BE FILLING THE MEDICATION. SHE ALSO PERFORMS FOLLOW UP CALLS ON THE PATIENTS WHO RECEIVE ORAL CHEMOTHERAPY. EDUCATING THE PATIENTS ON ORAL ONCOLYTICS AND PROVIDING THE FOLLOW UP MONITORING IS SO IMPORTANT, ESPECIALLY WITH DRUGS LIKE AVAPRITINIB.”

Sharon Perley, RN, BSN, OCN

PUTTING THE AVAPRITINIB MANAGEMENT FOR ADVANCED SYSTEMIC MASTOCYTOSIS PQI INTO ACTION

The PQI is a peer-reviewed clinical guidance document 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 **Avapritinib (AYVAKIT®) Management for Advanced Systemic Mastocytosis** PQI is written in sections beginning with a Description and ending with Patient-Centered Activities and References.

Following the Description, the Background section gives pertinent historical data and information, clinical trial experience and the main focus of the intervention. Regarding avapritinib, the Background discusses the approval, indication and published data leading to approval. Again, it discusses the PATHFINDER and EXPLORER trials, specifically avapritinib's approval for Advanced Systemic Mastocytosis, platelet monitoring for these patients and the other common toxicities observed (anemia, neutropenia, cognitive effects).⁷

Worth comments on the trial information included in the PQI. “The trial data summary and percentages included in the PQI are extremely important. These patients who have been diagnosed with advanced systemic mastocytosis are usually very well educated, many already a part of online support groups. They knew immediately when avapritinib was approved and were calling the clinic asking to be placed on the medication.”

“THE TRIAL DATA SUMMARY AND PERCENTAGES INCLUDED IN THE PQI ARE EXTREMELY IMPORTANT. THESE PATIENTS WHO HAVE BEEN DIAGNOSED WITH ADVANCED SYSTEMIC MASTOCYTOSIS ARE USUALLY VERY WELL EDUCATED, MANY ALREADY A PART OF ONLINE SUPPORT GROUPS. THEY KNEW IMMEDIATELY WHEN AVAPRITINIB WAS APPROVED AND WERE CALLING THE CLINIC ASKING TO BE PLACED ON THE MEDICATION.”

Sarah Worth, PharmD, BCOP, BCPS

THE PQI PROCESS: A TEAM EFFORT

The next section of the **Avapritinib (AYVAKIT®) Management for Advanced Systemic Mastocytosis 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.

**CLICK HERE
TO VIEW
ALGORITHM
TOOL**

The first step of the **Avapritinib (AYVAKIT®) Management for Advanced Systemic Mastocytosis PQI** Process states to confirm correct diagnosis for Advanced Systemic Mastocytosis. Pankit Vachhani, MD from UAB confirms this by stating “when it comes to this drug, it is crucial to get the dosing

right. Ensuring correct diagnosis is the first step, then subtyping their Systemic Mastocytosis, then dosing of avapritinib.”

The PQI process continues with steps when receiving a prescription for avapritinib and focuses on platelet count monitoring, dosing, dose modifications and drug-drug interactions. Shanbhag discusses dose reductions in his patients. “Most patients we place on avapritinib will need a dose reduction, usually 2/3 of patients end up needing this. The dose reduction table located in the PQI is relatively straight forward for this drug and its dose reductions.”

RECOMMENDED DOSE REDUCTIONS	
First dose reduction	100 mg once daily
Second dose reduction	50 mg once daily
Third dose reduction	25 mg once daily
Fourth Dose Reduction	Permanently discontinue

Regarding avapritinib, platelet monitoring and close observation of cognitive side effects are essential and are discussed in the last piece of the PQI Process section. Platelets should be checked initially upon beginning treatment, every 2 weeks for the first 8 weeks, then frequency is based on 8 week platelet count level.⁷ For specific grade level reductions, the PQI includes a table for recommendations on holding of the drug or reducing the dose. Following all of these essential monitoring and dose modification steps will assist in allowing patients to remain on avapritinib therapy for longer if warranted. Shanbhag points to this “patients can remain on therapy for a long time. For these patients, compliance may become a challenge down the road. It is important that we educate on this and that we try to keep them on treatment by minimizing toxicity and the side effect profile by adopting methods such as dose holds, dose reductions, assessing frequently, and addressing any potential

problems related to compliance to keep these patients on drug.” Cognitive changes are often hard to assess in these patients and healthcare providers need to continually involve other family members or those helping to care for the patients in accessing for these side effects. Vachhani discusses further on neurocognitive effects. “Neurocognitive changes can be hard to define. Headaches, nausea and visual changes may be minor things that the patients may not be thoroughly aware are things to watch out for. These events, flickering of lights or a slight change in vision, can present very minor and be ignored by some. We need to ensure they are recording these things and alerting us.” Worth, who works alongside Vachhani continues, “Cognitive changes, impairment and brain fog are often hard to distinguish in these patients because they already have a level of impairment at baseline. We often educate the patients or their advocates to be aware if these changes are becoming more frequent or changing from baseline.”

RECOMMENDED DOSE MODIFICATIONS FOR ADVERSE REACTIONS		
Adverse Effect	Grade	Recommendation
Intracranial Hemorrhage	Any Grade	Permanently discontinue
Central Nervous System Effects	Grade 1	Continue avapritinib, reduce dose or hold treatment until improvement to baseline or resolution of symptoms and resume at same/reduced dose
	Grade 2/3	Hold avapritinib until improvement to baseline / Grade 1 / resolution Resume at same or reduced dose
	Grade 4	Permanently discontinue
Thrombocytopenia (platelet < 50,000/mm3)		Hold avapritinib until resolution (platelet > 50,000/mm3) Resume avapritinib at reduced dose Consider platelet support if platelet counts do not recover
Other Adverse Reactions	Grade 3/4	Hold until improvement to > Grade 2 Resume at same or reduced dose as clinically appropriate

PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

The Patient-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. The **Avapritinib (AYVAKIT®) Management for Advanced Systemic Mastocytosis** 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. In 2019 the Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards were published to provide standards for medically integrated dispensing of oral anti-cancer drugs and supportive care medications.⁸ Standard 1.2 of the ASCO/NCODA Standards reads:

**CLICK HERE
TO VIEW
OCE SHEET**

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.⁸

The first patient centered activity on the **Avapritinib (AYVAKIT®) Management for Advanced Systemic Mastocytosis** PQI is to provide patient education and reiterate dosing parameters and specifics on administration. Perley comments “having the PQI in a synopsis form is very beneficial. I like not having to dig and search for important key takeaways. The patient education sheet is very helpful. I am a big believer of giving the patient something that they can physically take with them.”

The Patient-Centered Activities section also discusses avapritinib administration, stressing the importance of taking this medication on an empty stomach. Parker comments on the importance of accessing the PQI during counseling for side effects. “I like to be very specific and detailed when counseling patients on administration of oral oncolytics. For avapritinib, taking the medication on an empty stomach is important to relay. Some providers might write exact instructions for this such as ‘the definition of an empty stomach means 1



Pankit Vachhani, MD and Sarah Worth, PharmD, BCOP, BCPS discuss drug side effects with a patient.

hour prior or 2 hours after a meal.’ Those instructions sometimes confuse patients so we as pharmacists can help them understand by assigning times to their day based on how they want to take it.” Lang comments on counseling and patient responses. “I can ask a question and the patient may not quite understand what I am asking so they will respond that they are fine or not having any side effects. Then the next person

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Kaetlyn Parker, PharmD

who communicates with the patient (pharmacist/technician) will ask the question in a different way or say ‘Are you having any of these issues?’, specifying the side effects. When everyone asks the questions in different ways, I think it helps the patient realize that yes, I do have that, let me tell you about it. Especially with the elderly, having multiple people on the job of asking questions can be very beneficial.”

Counseling patients on drug-drug and drug-food interactions and monitoring patients for the most common adverse effects are noted next. For avapritinib, it is important to consider other drugs that can affect platelets or bleeding in patients, also considering herbals and avoiding grapefruit juice due to the CYP3A4 interactions.⁷ Patients should also avoid drugs that further depress the central nervous system. Patients should be encouraged to report any cognitive side effects, even those that are minor in nature, to their healthcare team immediately. Worth expresses the importance of initial counseling and the patient. “I will usually counsel the patient on the first visit when it is decided they are going on the medication. The patients really appreciate the coordination

of our team and that we see and treat this specialty condition and they appreciate that we understand and know the process. Sometimes before they see us, they have seen so many physicians trying to nail down diagnosis that they appreciate our collaborative team effort.” Lang states “in my new role as triage nurse, I am able to be the middleman between the patient and the physician/providers in most cases. This allows for providers to have more time to focus on other things while I handle patient calls and triage importance. I also realize the value of a quick turnaround time on calls. Patients are often waiting on something and worried, so when you quickly return a call to discuss what they are waiting on, they are truly appreciative.”

FINANCIAL ASSISTANCE: A BENEFIT OF MID AND THE MULTIDISCIPLINARY TEAM

In addition to close follow up and detailed education, MID renders the practice the ability to provide excellent customer service, unmatched patient care, and help with finding funding so the patient can afford to take the medication. With Advanced Systemic Mastocytosis being such a rare and incurable disease, patients often rely heavily on support groups and the team providing their treatment. Perley comments, “This population is a unique subset of patients who have an unusual disease, which many times requires a fair amount of emotional support. They have had all these symptoms for so long before coming to us and they often share that people thought they were crazy before they received their diagnosis. By the time they get to us, they are at their wits end, so any emotional and financial support we can provide is always helpful to the patient.”

The final piece of the Patient-Centered Activities for the **Avapritinib (AYVAKIT®) Management for Advanced Systemic Mastocytosis PQI** contains a Financial Assistance section. The impact of cancer treatment on patient financial well-being is a topic of major concern in the

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FINANCIAL
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“THE PATIENT ASSISTANCE INFORMATION LOCATED IN THE PQI IS THE KEY TO HELPING PATIENTS GAIN ACCESS TO THERAPY. WHICH IN TURN ENSURES COMPLIANCE AND POSITIVE OUTCOMES FOR ALL PATIENTS INVOLVED.”

Brittani L Caddell, CPhT

oncology community.⁹ Financial toxicity has been linked to an increased patient risk of medical noncompliance.⁹ Parker is well aware how this can affect her patients. “Financial toxicity is a concern with our patients. For some patients, their entire life savings can be eliminated by their cancer treatments. Because more patients are being diagnosed with cancer and living longer due to the newer therapies, financial toxicity can be a concern. We work collaboratively with social workers, financial counselors and with the drug manufacturers to help assist patients with financial burdens.” Brittani L. Caddell, CPhT at UAB adds, “The Patient Assistance information located in the PQI is the key to helping patients gain access to therapy. Which in turn ensures compliance and positive outcomes for all patients involved.”

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

All team members from both practices 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 life of patients. Kaetlyn Parker, PharmD, utilizes the PQI when dispensing new oral therapies. “Whenever we get prescriptions for first start chemotherapy, we immediately pull up the PQI and we go through the steps. It is helpful because everything we need as pharmacists is right there. We know right away if an indication is not lining up, what labs to monitor, can look at drug-drug interactions and then what the dose suggestions are for adjusting if needed. Overall, it is a great guideline to help us timely and efficiently address the steps we need to take before the drug gets to the patient. In a sense, it wraps up the whole treatment plan for us to review with the patient to ensure nothing is forgotten.”

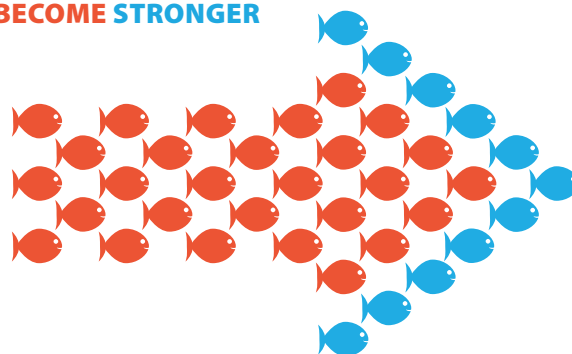
Parker also shares her passion for patients on working within a MID team. “The Pharmacy component of the MID team is essentially the extra arm to the body that is CSNF. We strive to work collaboratively to assist our patients and ensure that they get the most optimal care that they can possibly receive in terms of seeing that their cancer care is as good as it can be.”

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. DeVaughn comments, “I like the layout of

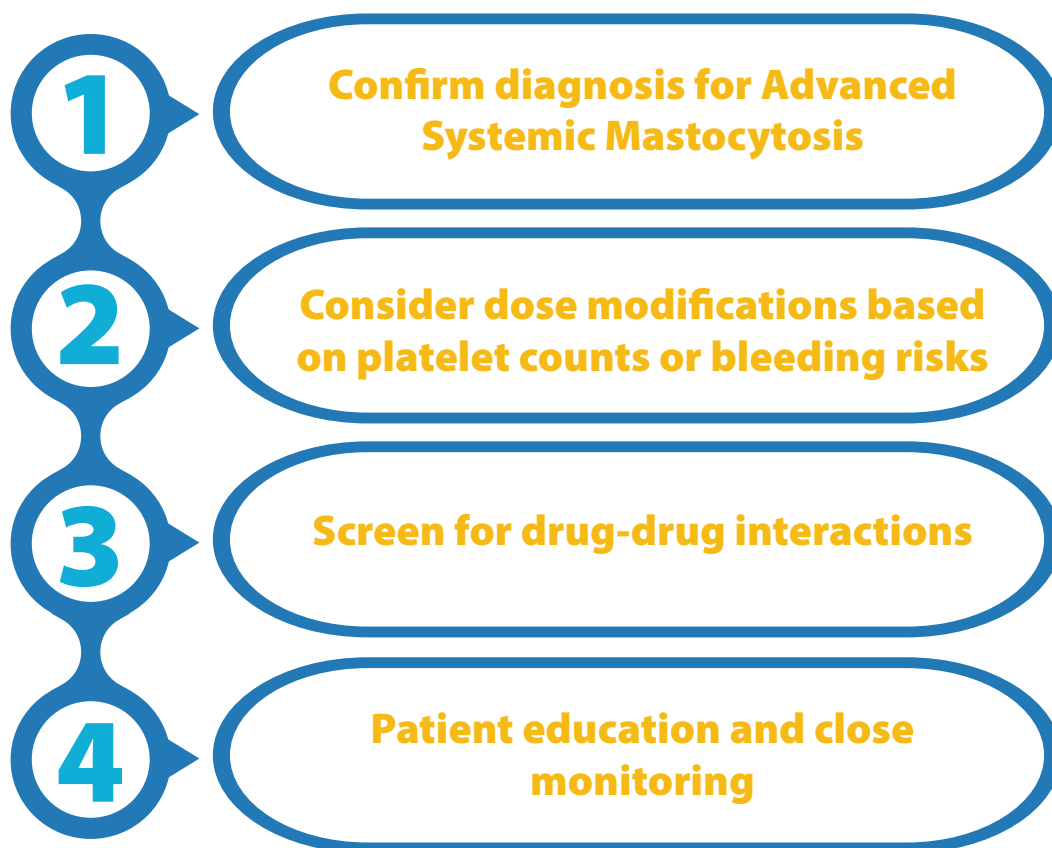
the PQI because it is easy to read and everything you need is right at your fingertips. I like that the dosing information is clearly listed and that everything you would need for a prior auth is right there in one spot.”

Avapritinib gives patients with advanced systemic mastocytosis a new and targeted treatment option. The PQI provides the MID program with an easy to use, compact clinical resource guide when discovering the right patient and dispensing AYYAKIT®. It helps the team ensure they are providing patients with the tools and education to improve clinical outcomes. Pairing Medically Integrated Dispensing with the **Avapritinib (AYYAKIT®) Management for Advanced Systemic Mastocytosis** PQI meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.

**WORKING TOGETHER,
WE BECOME STRONGER**



PQI PRINCIPLES:



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Helpful Online Resources

- [Avapritinib Management for Advanced Systemic Mastocytosis PQI](#)
- [Positive Quality Interventions](#)
- [Oral Chemotherapy Education Sheets](#)
- [NCODA Website](#)

ON THE COVER:

- Kaetlyn Parker, PharmD and KeeAnna DeVaughn discuss the recent prior authorization of a prescription at Florida Specialty Pharmacy.
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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.



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