RIPRETINIB (QINLOCK®) FOR TREATMENT OF ADULTS WITH ADVANCED GASTROINTESTINAL STROMAL TUMORS
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 Ripretinib (QINLOCK®) for Treatment of Adults with Advanced Gastrointestinal Stromal Tumors PQI and explores how the medically integrated teams at Oncology Consultants, Oregon Health & Science University, and New York Oncology and Hematology incorporate the information found in the PQIs as part of their daily workflow. This article will discuss how utilizing the Ripretinib (QINLOCK®) for Treatment of Adults with Advanced Gastrointestinal Stromal Tumors PQI elevates patient care.

Oncology Consultants (OC) is a private physician practice based in Houston, Texas. They are a community-based healthcare team committed to providing state of the art care to adult hematology and oncology patients in a caring environment. Services include on-site radiation treatment, state of the art imaging facilities, and medically integrated pharmacies to ensure that prescriptions are filled quickly and efficiently. The highly qualified pharmacy staff collaborate with the medical team to manage complex therapies, minimize drug interactions, and make the dispensing process safe and easy.

Oregon Health & Science University (OHSU) Knight Cancer Institute is a frontrunner in cancer research, education, and training. This Portland, Oregon-based facility has earned a national reputation for excellence including the National Cancer Institute designation as a Comprehensive Cancer Center. OHSU Knight Cancer Institute’s mission is to give patients excellent care, find better ways to treat patients, find better ways to detect cancer, and to train and inspire the next generation of doctors and scientists. As evidenced by its numerous accolades and affiliations, OHSU Knight Cancer Institute houses some of the most distinguished providers and scientists in the world.

New York Oncology and Hematology (NYOH) has six convenient locations including Albany, Albany Medical Center, Amsterdam, Hudson, Troy, and Clifton Park in upstate New York. Their focus is solely on the treatment of cancer and blood disorders. This allows NYOH to provide their patients with personalized, expert care, advanced treatment options, and specialized support programs. Their team includes 34 physicians and 350 cancer care specialists and is the largest in the area; with expertise in medical oncology, radiation oncology, hematology and neuro-oncology. NYOH is affiliated with every major hospital in the area, and through their participation in The US Oncology Network, NYOH physicians and patients have played a vital role in the research and development of 39 FDA approved cancer drugs.

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NCODA’S POSITIVE QUALITY INTERVENTION IN ACTION
Gastrointestinal stromal tumors (GISTs) are soft tissue sarcomas that occur throughout the gastrointestinal tract, most commonly in the stomach or small intestine. GISTs typically involve mutations in genes that encode for the receptor tyrosine kinases KIT and platelet-derived growth factor receptor A (PDGFRA). The majority (~80%) of GISTs have a KIT mutation, while 5%-10% have a PDGFRA mutation.

The standard treatment for unresectable or metastatic GIST is a tyrosine kinase inhibitor (TKI) that inhibits KIT and PDGFRA. Imatinib is typically used first-line and results in response or tumor control in about 80% of patients. However, many patients with advanced GIST will experience progression within 24 months of starting imatinib. This is due to secondary mutations in the ATP-binding domain or activation loop of KIT. As a result, resistance to imatinib occurs.

Ripretinib is a switch-control TKI that utilizes a dual mechanism of action to broadly inhibit KIT and PDGFRA kinase signaling. Ripretinib binds both the switch pocket and activation loop of the kinase, which locks the kinase in an inactive state. This prevents downstream signaling and cell proliferation. The efficacy and safety of ripretinib in advanced GIST after three prior TKIs was demonstrated in the INVICTUS trial. Ripretinib significantly improved progression-free survival compared to placebo (6.3 months vs 1 month, hazard ratio 0.15, 95% CI 0.09-0.25; p <0.0001). Ripretinib represents a treatment option for patients who have received three or more prior therapies in advanced, unresectable GIST.

Ripretinib 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.

The MID model can improve management of patients on therapies like ripretinib 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.

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.

Oncolytic nurse navigator for Oncology Consultants, Monica Martinez, LVN believes in the value of MID in streamlining patient care. “One of the biggest benefits is that patients can get started on treatments a lot faster than if they have to go through a specialty pharmacy outside of our practice. It’s a huge benefit for patients. When we collaborate as a team, if there’s an adverse reaction, a medication is placed on hold, or a dose is changed, that can be communicated a lot quicker to the pharmacy rather than having to go outside to a specialty pharmacy. Those are huge benefits. The fact that I reach out to patients and I’m able to communicate directly with the clinical team, provide updates, and let them know what’s going on, that’s also a huge benefit.”
THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

OC Pharmacist Jenny Pearson, PharmD finds the PQIs a useful resource as a refresher. “In general, the PQIs are a really nice review of the medication. Especially for a pharmacist, if it’s been a little while since you’ve dispensed the medication it gives you a nice overview of what class it falls into, which triggers you to remember some of the class effects of a TKI. That’s mostly what I use PQIs for, just a nice refresher. And also, the dosage modification part is really helpful if you just want to have a quick glance. If the patient is experiencing a side effect, then what would be the dose modification for that? It gives a nicely laid out table for what you should look for.”

OC nurse practitioner Jenny Morrow, MSN, RN, FNP-C, OCN finds the PQIs useful as part of her every day practice in managing patient side effects. “I really like the adverse reaction and dose modification table. It shows what I need to do. It is convenient and easy.”

Click here to view PQI

“I REALLY LIKE THE ADVERSE REACTION AND DOSE MODIFICATION TABLE. IT SHOWS WHAT I NEED TO DO. IT IS CONVENIENT AND EASY.”

Jenny Morrow, MSN, RN, FNP-C, OCN

This article will explore the benefits of PQI utilization as a core standard of the MID and how adoption can benefit any practice. OC, OHSU and NYOH each found successful ways to incorporate the PQI clinical resource. All three 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 steps found in the PQIs benefit their staff and patients, and how they advance patient care on a daily basis.

MEDICALLY INTEGRATED DISPENSING: ELEVATING CARE

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

OC, OHSU and NYOH all have multidisciplinary MID workflows in place to ensure that the patient is fully supported throughout the whole process. Clinical pharmacists make sure that the ripretinib prescriptions are clinically appropriate by checking for drug interactions, indication, and dose. The prescription then moves to the authorization phase, where both institutions have teams in place to secure any necessary financial assistance in the event of a high copay. The patient is then educated on medication side effects and the medication is dispensed to the patient from their in-house pharmacy. But the support doesn’t stop there. OC utilizes their nurse navigator to capture any side effects that have an early onset. Depending on the risk level of the medication, the patient may receive up to three follow-up calls to ensure medication tolerance. The OC team also has a dedicated adherence pharmacist to ensure that patients are receiving their refills ahead of time.

Clinical oncology pharmacist at OHSU, Stephanie Giangiuli, PharmD, BCOP also sees the value in a MID for simplifying the process for patients. “The major benefit is it improves patient care. It makes it so that you can get everything in one place. Having a pharmacist there is like a one stop shop. We
can get the nurses, labs, and provider input, so I think it’s helpful for patients to get that all in one place.”

Stephanie Giangiuli, PharmD, BCOP

PUTTING THE RIPRETINIB (QINLOCK®) FOR TREATMENT OF ADULTS WITH ADVANCED GASTROINTESTINAL STROMAL TUMORS 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 Ripretinib (QINLOCK®) for Treatment of Adults with Advanced Gastrointestinal Stromal Tumors PQI is written in sections beginning with a Description and ending with Patient-Centered Activities, References and a Supplemental Adverse Reaction and Dose Modification Table. It was developed to provide guidance for management of patients treated with ripretinib.

Following the Description, the Background section gives pertinent historical data and information, clinical trial experience, and the main focus of the intervention. Regarding ripretinib, the Background discusses the approval, indication, and published data leading to approval. Again, it discusses the INVICTUS trial, specifically ripretinib’s approval for advanced gastrointestinal stromal tumors after treatment with three prior TKIs.

OHSU Clinical Oncology Pharmacy Supervisor Jillian Paxton, PharmD, BCOP notes that the PQI is particularly useful for those that might not work in the same clinic setting every day. “It’s great for me clinically because I don’t work as often in the clinic setting due to my role as a supervisor. I staff in all different areas. It’s quick for me to pull up and read through and now I know all the highlights to be able to do the things I need to do. These are great for new drugs that come out to find out what the highlights are and look at it really quickly.”
THE PQI PROCESS: A TEAM EFFORT

The next section of the Ripretinib (QINLOCK®) for Treatment of Adults with Advanced Gastrointestinal Stromal Tumors 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 Ripretinib (QINLOCK®) for Treatment of Adults with Advanced Gastrointestinal Stromal Tumors PQI Process is to identify patients with advanced, unresectable metastatic GIST in the fourth line setting. Ripretinib has a Category 1 recommendation by the NCCN Guidelines as a preferred fourth-line option after treatment with imatinib, sunitinib, and regorafenib. However, ripretinib can be considered in the second-line setting if patients cannot tolerate second-line sunitinib and need to switch to a different TKI.9

The next step in the Ripretinib (QINLOCK®) for Treatment of Adults with Advanced Gastrointestinal Stromal Tumors PQI Process includes what to do after receiving a ripretinib prescription. The first section includes ensuring that the ripretinib dose is correct. The initial dose of ripretinib is 150 mg once daily — this can be increased to twice daily if the patient progresses. The next section goes on to list important drug interaction concerns and any baseline cardiac tests that need to be completed before starting treatment.

Patel mentions that their physicians frequently escalate the ripretinib dose. But checking the dosage on the prescription is just a small piece of the puzzle for the clinical pharmacists at OC. “First things first, we look for drug interactions. We also make sure there is a baseline blood pressure in the patient’s chart. And we make sure that any cardiac tests like the ejection fraction are in the notes.”

Dr. Lal outlined some of the side effects to monitor. “Side effects reported in clinical trials include hair loss and hypertension which are very common, along with anemia and abdominal discomfort. Due to the potential for heart failure, ECG and MUGA scans are recommended before initiating treatment.”

The following steps list out what side effects need to be monitored for throughout treatment. The OC, OHSU and NYOH teams find this part of the PQI very useful, especially because it includes a Supplemental Table to assist with appropriate dose modifications when adverse reactions arise. Martinez, who is intimately involved with patient monitoring at OC, can use the PQI to assist her providers in quickly managing ripretinib side effects that patients mention during her follow-ups. “The part of the PQI that I find most useful is the adverse reactions that are listed by grade and the dose modifications. That’s very useful. I forward that information to the clinical team and let them make a decision on how to move forward.”

The last step provides guidance on what to do with ripretinib prior to elective and major surgeries. In addition to ripretinib’s KIT and PDGFRA inhibition, it’s also a vascular endothelial growth factor (VEGF) inhibitor.10 This results in impaired wound healing, so ripretinib should be held 1 week prior to elective surgeries and 2 weeks after major surgery. Healing should be adequate prior to restarting ripretinib.6,10

“THE PART OF THE PQI THAT I FIND MOST USEFUL IS THE ADVERSE REACTIONS THAT ARE LISTED BY GRADE AND THE DOSE MODIFICATIONS. THAT’S VERY USEFUL. I FORWARD THAT INFORMATION TO THE CLINICAL TEAM AND LET THEM MAKE A DECISION ON HOW TO MOVE FORWARD.”

Monica Martinez, LVN
### SUPPLEMENTAL INFORMATION: ADVERSE REACTION AND DOSE MODIFICATION

Dose reduction for adverse reactions: 100 mg orally once daily; permanently discontinue in patients who are unable to tolerate 100 mg orally once daily.

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<tr>
<th>Adverse Reaction</th>
<th>Severity</th>
<th>Dose Modification</th>
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| Palmar-Plantar Erythrodysesthesia     | Grade 2  | Hold until Grade ≤1 or baseline. If recovered within 7 days, resume at same dose; otherwise resume at reduced dose.  
Consider re-escalating if maintained at Grade ≤1 or baseline for at least 28 days.  
If PPE recurs, hold until Grade ≤1 or baseline and then resume at a reduced dose regardless of time to improvement. |
|                                       | Grade 3  | Hold for at least 7 days or until Grade ≤1 or baseline (max 28 days). Resume at a reduced dose.  
Consider re-escalating if maintained at Grade ≤1 or baseline for at least 28 days. |
| Hypertension                          | Grade 3  | If symptomatic, hold until symptoms have resolved and BP is controlled.  
If BP is controlled to Grade ≤1 or baseline, resume at the same dose; otherwise, resume at reduced dose.  
If Grade 3 hypertension recurs, hold until symptoms have resolved and BP is controlled. Resume at a reduced dose. |
|                                       | Grade 4  | Permanently discontinue.                                                           |
| Left Ventricular Systolic Dysfunction | Grade 3/4| Permanently discontinue.                                                           |
| Arthralgia/Myalgia                    | Grade 2  | Hold until Grade ≤1 or baseline. If recovered within 7 days, resume at same dose; otherwise resume at reduced dose.  
Consider re-escalating if maintained at Grade ≤1 or baseline for at least 28 days.  
If arthralgia or myalgia recurs, hold until Grade ≤1 or baseline and then resume at a reduced dose regardless of time to improvement. |
|                                       | Grade 3  | Hold for at least 7 days or until Grade ≤1 or baseline (max of 28 days). Resume at a reduced dose.  
Consider re-escalating if maintained at Grade ≤1 or baseline for at least 28 days. |
| Other                                 | Grade 3/4| Hold until Grade ≤1 or baseline (maximum 28 days), and then resume at a reduced dose; otherwise permanently discontinue.  
Consider re-escalating if no recurrence of the adverse reaction for at least 28 days.  
If Grade 3 or 4 recurs, permanently discontinue. |

### PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

The Patent-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. The Ripretinib (QINLOCK®) for Treatment of Adults with Advanced Gastrointestinal Stromal Tumors 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 chemothera-
In 2019 the Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards were published to provide standards for medically integrated dispensing of oral anticancer drugs and supportive care medications. 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.

The first patient-centered activity in the Ripretinib (QIN-LOCK®) for Treatment of Adults with Advanced Gastrointestinal Stromal Tumors PQI is to provide the patient with a ripretinib oral chemotherapy education (OCE) sheet and an OCE supplemental sheet. The OCE supplemental sheet includes additional information on management of hand-foot syndrome, a common side effect of ripretinib.

At OC, the dispensing pharmacists depend on the NCODA chemotherapy education sheets. Patel says that they are “given to each and every patient with new treatments. Any time we have a new treatment, there is a checklist that the dispensing pharmacist has to check off on — has the starter kit been dispensed and has the patient been counseled with an NCODA education sheet?”

Jigna Patel, PharmD

The pharmacists at NYOH utilize NCODA Resources to enhance patient-centered care.

The pharmacists at OHSU also frequently use the OCE sheets to talk to their patients about side effects. Paxton says “Our pharmacists use a lot of the education like the OCE and managing hand foot syndrome supplemental sheet. These are things we use to do our education with patients.”

The next Patient-Centered Activity discusses the importance of how to take ripretinib. This medication is only available as 50 mg tablets, so it’s important that the patient knows they need to take three of them to make up the 150 mg dose. Giangiuli stresses the importance of starting a patient teaching session with how they are going to take the medication. This not only includes mentioning both the brand and generic names so the patient is familiar with both, but also whether it should be taken with food, how many tablets to take, and finding the right time to take it to improve adherence. This PQI step specifically mentions that ripretinib can be taken with or without food, and what to do if a dose is missed or vomited up.

Giangiuli also notes that pregnancy concerns sometimes fall on the pharmacists at OHSU. Ripretinib can cause harm to an unborn baby, so the next step of the Patient Centered Activity provides guidance on how to prevent pregnancy while taking ripretinib.
FINANCIAL ASSISTANCE: A BENEFIT OF MID AND THE MULTIDISCIPLINARY TEAM

In addition to close follow up and detailed education, MID renders the practice able to provide excellent customer service, unmatched patient care, and help with finding funding so the patient can afford to take the medication.

The final piece of the Patient-Centered Activities for the Ripretinib (QINLOCK®) for Treatment of Adults with Advanced Gastrointestinal Stromal Tumors PQI contains a financial assistance section. OHSU, OC and NYOH incorporate incorporate financial assistance into their workflows so that delays in care are minimized. Pearson mentions that after ripretinib has been approved by insurance, the patient may have a high copay they cannot afford. OC’s team reaches out to the patient to help them with financial assistance. “If the patient does need financial assistance, we’ll collect the necessary documents and take care of getting them either grants through foundations or if they need to go through a patient assistance program or copay card, we’ll help them with that.”

OHSU has a similar process, but they have a unique perspective on ripretinib financial assistance since they were involved with clinical trials that led to its approval. OHSU Knight Cancer Institute is heavily involved in GIST research and houses one of the largest GIST programs in the U.S. Paxton speaks to the unique challenges in transitioning patients from clinical study to standard of care. After the clinical trial was closed, patients that were receiving benefit from ripretinib were allowed to continue to receive free medication from the manufacturer. But the process for how that is done isn’t always clear. She mentions that manufacturers that provide ripretinib as a research medication may not fully understand the clinical workflows that need to be put in place to ensure that patients get their medications safely and are documented appropriately.

“We had a lot of conversations with the manufacturing team. Our research team provided us a list of patients on ripretinib, and they worked through trying to make it as streamlined and electronically easy as possible because one of the things that the manufacturers forget is it’s great they have a form and that form turns into a prescription. But that form isn’t in the electronic medical record (EMR) system. So, finding ways to allow for the prescription to be in your EMR and fill out the forms correctly to ensure that the right patients are getting the right assistance programs is also key. Partner with those manufacturing teams to have those conversations early.”

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 life of patients. Morrow realizes the value of having pharmacists within the Oncology Consultants practice. “Having pharmacists on site that work in the clinic help us in multiple ways. They help make sure that all of the treatment plans get arranged, they help with prior authorizations, they provide extra safety checks. They do a lot for us. We are lucky.”

Pearson also notes that the MID benefits both staff and patients. “There’s definitely a lot of benefits to the patients in particular. I would say that they receive more of a white glove treatment with our pharmacy compared to an outside pharmacy or mail order pharmacy. One thing that is definitely better is that we have access to the chart. We can assess a lot of different things that a regular pharmacy would not be able...
to do. And having access to the doctors also helps. We can use each other as resources and that’s a benefit to the patient because there are fewer delays in therapy. There’s also a lot less wastage of drug because we are constantly in communication with the patients and doctors. The benefit to the patient is pretty great, not only financially, but also patients with a cancer diagnosis have a lot going on. We are assisting them in connecting the dots between pharmacy and physician.”

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.

Paxton highlights how pharmacist integration in the clinic has improved patient safety. “I think we work as a team really well. Even if a nurse or physician could find the interaction quickly, it might be easier for them to ask the pharmacist to help understand it because we might call that patient and they might have additional questions or follow up related to the medication or the drug interaction. So, I think there is a component of quality we provide from that side of things that is just part of the team working together for the better of the patient. With us being involved, we’ve made great strides in making sure the appropriate follow-up and safety checks are in place.”

Ripretinib gives patients with advanced, unresectable GIST another treatment option in the subsequent line setting. The PQIs provide the MID program with an easy to use, compact clinical resource guide when discovering the right patient and dispensing ripretinib. 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 Ripretinib (QINLOCK®) for Treatment of Adults with Advanced Gastrointestinal Stromal Tumors PQI meets NCODA’s Guiding Values of being Patient-Centered and Always Collaborative.
REFERENCES


Helpful Online Resources

- NCODA Website
- Oral Chemotherapy Education Sheets
- Positive Quality Interventions
- Ripretinib (QINLOCK®) for Treatment of Adults with Advanced Gastrointestinal Stromal Tumors PQI

ON THE COVER:
- MIP staff at NYOH provide excellent patient care enhanced by access to the EHR.
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.