PQI IN ACTION

SELPERCATINIB (RETEVMO®) GENOMIC TESTING AND MANAGEMENT

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 Selpercatinib (RETEVMO®) Genomic Testing Management PQI and the Selpercatinib (RETEVMO®) Management PQI, and explores how the medically integrated teams at Moffitt Cancer Center, Smilow Cancer Center at Yale New Haven Health, and Texas Oncology incorporate the information found in the PQIs as part of their daily workflow. This article will discuss how utilizing the Selpercatinib (RETEVMO®) Genomic Testing Management PQI and the Selpercatinib (RETEVMO®) Management PQI elevates patient care.

Moffitt Cancer Center is Florida’s only National Cancer Institute-Designated Comprehensive Cancer Center. In addition to medical oncology services, Moffitt also offers a 36-bed blood and marrow transplant unit; 14 operating rooms; a diagnostic radiology department with MRI, PET/CT, digital mammography and all other imaging capabilities; and a radiation therapy department with seven linear accelerators. Clinical pharmacists are part of their team and they have their own medically integrated specialty pharmacy.

Smilow Cancer Center at Yale New Haven Health includes a main campus center, Smilow Cancer Hospital, and ambulatory centers across the state of Connecticut and Rhode Island. Smilow Cancer Hospital is recognized by the American Society of Clinical Oncology with QOPI® certification. Smilow Cancer Hospital has more than a dozen multidisciplinary cancer teams to serve patients.

Texas Oncology is an independent, physician-led practice delivering cutting edge technology and treatment options and conducting innovative research. Texas Oncology has more than 500 physicians in 210 locations across the state of Texas. The practice offers many services including medical and radiation oncology, surgery services, bone marrow transplant, research and the medically integrated pharmacy.

We would like to thank Lilly for their support of this initiative.
A ctivating receptor tyrosine kinase RET (rear-ranged during transfection) gene alterations have been identified as oncogenic drivers in multiple malignancies. RET-altered cancers include both RET fusions and RET mutations. Both alterations involve activating RET signaling pathways that promote unwanted cell proliferation in cancers. In recent years, selective RET inhibitors have been developed to achieve higher potency and less toxicity previous multikinase inhibitors (MKIs). Selpercatinib is one of these selective RET inhibitors that is now indicated for the treatment of:

- Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC)
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy
- *Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

*S This indication is approved under accelerated approval based on overall response rate and duration of response.

Selpercatinib 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 selpercatinib 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 oncology. This toolbox contains a Patient 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 resource documents. Moffitt Cancer Center Retail Services Pharmacy Manager Sophia Alfonso, PharmD, BCACP believes in Medically Integrated Dispensing. She comments, “we have really been able to grow the business the way that we wanted to practice and take care of our patients, which has been such a blessing. Not only professionally to the pharmacists who do this but for the patients for sure. I feel we get better outcomes because we are integrated here at Moffitt.”
THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

Texas Oncology VP of Precision Medicine, Lori Brisbin, MS discusses the value of the PQIs to her oncologists and care team. She shares “the PQI speaks their language to them on how this can help them improve the outcomes for their patient. It really is a quick reference guide that speaks towards our audience.”

Moffitt Ambulatory Pharmacist Specialist Meghan Driggs, PharmD, BCPS, CSP also finds value in the PQI and comments, “I think it is very helpful anytime you can have a reference that is succinct, to the point and highlights the major educational points, as well as information you are needing to get a medication approved, and also to counsel your patients.”

This article will explore the benefits of PQI utilization as a core standard of the MID and how adoption can benefit any practice. Moffitt, Yale and Texas Oncology 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.

“THE PQI SPEAKS THEIR LANGUAGE TO THEM ON HOW THIS CAN HELP THEM IMPROVE THE OUTCOMES FOR THEIR PATIENT. IT REALLY IS A QUICK REFERENCE GUIDE THAT SPEAKS TOWARDS OUR AUDIENCE.”

Lori Brisbin, MS

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.

Yale Specialty Liason Krystal Zoock, CPhT sees the value in MID and shares, “it is nice that we just get the direct line to the patient and if there are ever any issues the patients will give us a call and we will handle it immediately.” She adds, “we can track their deliveries, we know exactly when they receive the medication and if there are any issues. MID makes it easy to submit prior authorizations because anything we need is in the same system and we do not have to call the physician and ask for anything.” Pharmacy is a vital part of the Yale system.

Anne Chiang, MD, PhD is the Deputy Chief Medical Officer and Chief Integration Officer for Smilow Cancer Hospital. She shares, “pharmacy is a huge part of what we do and it is a huge key pillar of the comprehensive cancer center. We built this network over the past ten years and a key part of that was putting pharmacists in all of our locations. The feedback has been tremendous. They serve as resources for our clinical staff, our medical oncologists, our nurses, advance practice providers, and for our patients. Embedding
Moffitt Cancer Center and Texas Oncology also believe in the MID and multidisciplinary team model. Alfonso comments on the benefits of patients filling their prescriptions at Moffitt versus an insurance mandated mail-order pharmacy and says, “I want to really distinguish us in the sense that we can get our patients on their medications faster because we are here on the ground. We have access to the medical record and there are things that do not get delayed here that are delayed when they have to go through an outside mail-order pharmacy. Our communication here can happen instantaneously because we are with the clinicians.” At Texas Oncology Pharmacy Manager Payam Etebari, PharmD says MID is beneficial to patients for a number of reasons, “first and foremost it is a matter of convenience.” He also shares that timing is ideal and patients can receive a refill of their medication while waiting on labs to be drawn or other appointments.

“PHARMACY IS A HUGE PART OF WHAT WE DO AND IT IS A HUGE KEY PILLAR OF THE COMPREHENSIVE CANCER CENTER. WE BUILT THIS NETWORK OVER THE PAST TEN YEARS AND A KEY PART OF THAT WAS PUTTING PHARMACISTS IN ALL OF OUR LOCATIONS. THE FEEDBACK HAS BEEN TREMENDOUS. THEY SERVE AS RESOURCES FOR OUR CLINICAL STAFF, OUR MEDICAL ONCOLOGISTS, OUR NURSES, ADVANCE PRACTICE PROVIDERS, AND FOR OUR PATIENTS. EMBEDDING THEM IN THE CLINICS ALLOWS THEM TO INTERACT AND TALK TO OUR PATIENTS AND I THINK THEY ARE JUST INVALUABLE RESOURCES.”

Anne Chiang, MD, PhD

PUTTING THE 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 Selpercatinib (RETEVMO®) Genomic Testing Management PQI provides guidance to genomic testing with respect to selpercatinib. The Selpercatinib (RETEVMO®) Management PQI is written in sections beginning with the Description and ending with Patient-Centered Activities and was developed to provide guidance for management of patients treated with selpercatinib.
GENOMIC TESTING MANAGEMENT

A cancer contains billions of genomic alterations. Driver mutations are somatic mutations that confer a selective growth advantage to malignancies. Targeted therapy is based on the identification of these driver mutations. The RET (rearranged during transfection) gene was discovered in 1985 and encodes the RET transmembrane receptor kinase. This kinase is needed for normal neuronal and genitourinary development.

Sporadic RET point-mutations and fusions are common in medullary and papillary thyroid cancers and RET fusions were discovered by four independent research groups in lung cancer back in 2012.

The Background section of the Selpercatinib (RETEVMO®) Genomic Testing Management PQI provides information on RET testing found in NCCN guidelines. According to the PQI, NCCN guidelines for NSCLC include a Category 2A recommendation for RET testing as part of broad molecular profiling in routine clinical practice. RET testing should also be considered within the medullary thyroid cancer (MTC) space according to American Thyroid Association, NCCN, and ESMO guidelines. The PQI goes on to explain that there are multiple testing methods for RET that will help determine patient eligibility for selpercatinib.

<table>
<thead>
<tr>
<th>RET ALTERATION TO TEST</th>
<th>ASSOCIATED TUMOR TYPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>RET-fusion</td>
<td>NSCLC, Thyroid</td>
</tr>
<tr>
<td>RET-mutation</td>
<td>MTC</td>
</tr>
</tbody>
</table>

Moffitt, Yale and Texas Oncology all have genomic testing programs for patients that vary in specifics. Brisbin’s role at Texas Oncology is “primarily to establish precision medicine tools and capabilities within the Texas Oncology organization as a whole and to create a database with our patients—not only genomic information—but matched to all of the other clinical information from their patient record.” This database allows Texas Oncology to participate in both internal and external research collaborations. Brisbin shares that Texas Oncology works closely with manufacturers when their molecules are in late stage and close to a PDUFA date to try and understand what genetic testing requirements may be. She adds that due to selpercatinib’s indications across multiple tumor types, it was something that was a bit more sophisticated, “so we wanted to put the information into our diagnostic pathways tool in such a way that it could really guide the physician on which test to order dependent upon the tumor type.”

Brisbin also shares Texas oncology uses a diagnostic tool that they were able to create and customize. The tool has daily updated information as per ASCO guidelines and the FDA, and physicians can simply click on the tool in their EHR. She explains, “it then takes them through a series of questions regarding the clinical status of the patient—some of that information can be pulled directly from the EHR or other data sources. When that information is entered the algorithm will run and the recommended genetic testing will be displayed. The physician is then given the choice of laboratories that offer the proper testing and the type of test that is required. The tool then aides them in placing the order directly to the performing laboratory and that order is placed electronically in such a way that the result can come back electronically. The value of this tool is that it automatically updates with those guidelines.” She adds the tool makes a big difference for the practice “not only in getting these patients tested but in getting the right patient tested with the right test.”

Moffitt Cancer Center has a pharmacogenomics department. Clinical Pharmacy Coordinator Sal Bottiglieri, PharmD, BCOP elaborates, “there are three pharmacists in that group and sometimes a fellow as well. They have a robust program with a pharmacogenomics tumor board. Our providers are ordering the NGS testing. If the testing finds something that is targetable the pharmacogenomics department really steps up and reviews all of the results. They place a note on all of the patients with recommendations based on the different sequences and provide references as well. It is nice to have this service—it is very transparent for us in the clinic when we are taking care of these patients.”

Dr. Chiang shares that Yale has reflex testing at this point. “All of our biopsies for NSCLC are essentially sent for what is called our oncomine panel, which is a little over 200 genes. If we see a targeted driver mutation we know up front which patients have it and how to get them the therapeutics they need in a timely fashion.” Pharmacogenomic testing is making a difference for cancer patients.

“WE WANTED TO PUT THE INFORMATION INTO OUR DIAGNOSTIC PATHWAYS TOOL IN SUCH A WAY THAT IT COULD REALLY GUIDE THE PHYSICIAN ON WHICH TEST TO ORDER DEPENDENT UPON THE TUMOR TYPE.”

Lori Brisbin, MS
MANAGING PATIENTS ON SELPERCATINIB THERAPY

The Selpercatinib (RETEVMO®) Management PQI Background Section identifies all approved indications of selpercatinib as stated earlier. It also provides clinical trial information for the team including various objective response rates (ORR) in NSCLC and MTC. It also provides statistics from the trials concerning adverse reactions.

The next section of the Selpercatinib (RETEVMO®) Management PQI is the PQI Process. This section lays out the intervention in step by step points, contains clinician directed guidance and critical clinical criteria that can benefit the entire team. At Moffitt, much of this process is handled by the clinic pharmacists. Bottiglieri explains, “we are right there with the nurses and the providers so there is transparency and drug information we can provide to the team and updates on new data when it comes out. We follow the patients just like the providers do and we are able to stay on top of a lot of things as they come through.”

The first step of the Selpercatinib (RETEVMO®) Management PQI Process states to determine if a patient is eligible for selpercatinib and references the Selpercatinib (RETEVMO®) Genomic Testing Management PQI. This is critical for patient care but also vitally important to ensure the medication is covered by a patient’s insurance. At Texas Oncology Lindsey Scott, CPhT manages the team responsible for obtaining prior authorizations. According to Scott, access to the proper pathology report with a result showing the indicated genomic mutation is crucial for drug approval with insurance companies. She also mentions this is one area where MID is so valuable her team has access to the EHR and can easily pull the reports, saving time and preventing delays for the patient.

Driggs shares a similar sentiment at Moffitt and says she submits the mutation analysis and explains “that is what insurance companies are looking for whenever we are trying to submit these prior authorizations. The mutation analysis shows that the therapies are appropriate and indicated for our patients.” She does also mention that in addition to insurance coverage she assists with helping patients get relevant copay assistance through grants or the RETEVMO® Savings Card when applicable. She comments “having someone there to be a resource and advocate for the patient has been very helpful.”

The next step in the Selpercatinib (RETEVMO®) Management PQI is to confirm correct dosing upon receiving a selpercatinib prescription. The recommended dosage in adults and pediatric patients 12 years of age or older is based on weight. If the patient is less than 50 kg the recommended dose is 120mg orally twice daily and if the patient is 50 kg or greater the recommended dose is 160mg twice daily. The PQI also includes tables that contain recommended dose reductions for adverse reactions, drug interactions, and hepatic impairment.

### RECOMMENDED SELPERCATINIB DOSE REDUCTIONS FOR ADVERSE REACTIONS

<table>
<thead>
<tr>
<th>Dose Reduction</th>
<th>Patients Weighing Less Than 50 kg</th>
<th>Patients Weighing 50 kg or Greater</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td>80 mg orally twice daily</td>
<td>120 mg orally twice daily</td>
</tr>
<tr>
<td>Second</td>
<td>40 mg orally twice daily</td>
<td>80 mg orally twice daily</td>
</tr>
<tr>
<td>Third</td>
<td>40 mg orally once daily</td>
<td>40 mg orally twice daily</td>
</tr>
<tr>
<td></td>
<td>Permanently discontinue if patient is unable to tolerate three dose reductions</td>
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</tbody>
</table>
Pharmacists at all three practices are helping ensure correct dosages for patients and monitoring for interactions. It is truly a team effort. Dr Chiang comments, “it is important to make sure you are doing a concomitant medication evaluation because there are CYP3A inhibitors that may affect the dose.” Regarding the tables in the PQI she adds, “this is the LFT dose reduction but again, you have to look at all of the baseline labs and make sure everything is fine.”

### RECOMMENDED SELPERCATINIB DOSE REDUCTIONS FOR ADVERSE REACTIONS

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Severity</th>
<th>Dosage Modification</th>
</tr>
</thead>
</table>
| Hepatotoxicity          | Grade 3/4| Hold selpercatinib and monitor AST/ALT once weekly until resolution to Grade 1 or baseline  
Resume at reduced dose by 2 dose levels and monitor AST/ALT once weekly until 4 weeks after reaching dose taken prior to the onset of Grade 3/4 increased AST/ALT  
Increase dose by 1 dose level after a minimum of 2 weeks without recurrence and then increase to dose taken prior to the onset of Grade 3/4 increased AST or ALT after a minimum of 4 weeks without recurrence |
| Hypertension            | Grade 3  | Hold selpercatinib for Grade 3 hypertension that persists despite optimal antihypertensive therapy; resume at a reduced dose when hypertension is controlled |
|                         | Grade 4  | Discontinue selpercatinib                                                          |
| QT Interval Prolongation| Grade 3  | Hold selpercatinib until recovery to baseline or Grade 0/1; resume at a reduced dose |
|                         | Grade 4  | Discontinue selpercatinib                                                          |
| Hemorrhagic Events      | Grade 3/4| Hold selpercatinib until recovery to baseline or Grade 0/1  
Discontinue selpercatinib for severe or life-threatening hemorrhagic events |
| Hypersensitivity        | All Grades| Hold selpercatinib until resolution of the event and initiate corticosteroids  
Resume at a reduced dose by 3 dose levels while continuing corticosteroids  
Increase dose by 1 dose level each week until the dose taken prior to the onset of hypersensitivity is reached, then taper corticosteroids |
| Other Adverse Reactions | Grade 3/4| Hold selpercatinib until recovery to baseline or Grade 0/1  
Resume at a reduced dose |

### RECOMMENDED DOSAGE FOR CONCOMITANT USE OF STRONG AND MODERATE CYP3A INHIBITORS

<table>
<thead>
<tr>
<th>Current Dosage</th>
<th>Recommended Dosage</th>
</tr>
</thead>
</table>
| 120 mg orally twice daily       | Moderate CYP3A Inhibitor: 80 mg orally twice daily  
Strong CYP3A Inhibitor: 40 mg orally twice daily |
| 160 mg orally twice daily       | Moderate CYP3A Inhibitor: 120 mg orally twice daily  
Strong CYP3A Inhibitor: 80 mg orally twice daily |

### RECOMMENDED DOSAGE FOR SEVERE HEPATIC IMPAIRMENT

<table>
<thead>
<tr>
<th>Current Dosage</th>
<th>Recommended Dosage</th>
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<tbody>
<tr>
<td>120 mg orally twice daily</td>
<td>80 mg orally twice daily</td>
</tr>
<tr>
<td>160 mg orally twice daily</td>
<td>80 mg orally twice daily</td>
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</tbody>
</table>
The Patent-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. The **Selpercatinib (RETEVMO®) Management PQI**

Patient-Centered Activities suggests providing the patient with an Oral Chemotherapy Education (OCE) sheet. OCE sheets are an NCO-DA-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 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.

Moffitt Cancer Center uses the OCE sheets to assist in educating their patients. Bottiglieri explains that he uses the OCE sheet to guide his conversations with patients, “I usually highlight the areas to go through with the patient – the handouts are really well organized for the oral chemotherapy drugs.” He also shares Moffitt sends a handout to the patients via the patient portal. He explains that Moffitt pharmacists are performing comprehensive education with their patients. Moffitt is currently participating in a lot of virtual health. He shares a pilot started in December of 2020 and has gone really well in his clinic because they do have a lot of patients that are not in the Tampa area. He thinks the telehealth consults are “here to stay for pharmacy because it is a really good use of our discipline since we do not have to do a physical exam. It is a great way to fit us into the patient’s schedule.”

The Patient-Centered Activities section also discusses selpercatinib administration. Selpercatinib capsules should be swallowed whole with or without food and patients should be counseled not to crush or chew the capsules. At Yale, both nurses and pharmacists are taking an active role in patient education. Luon shares “it is important to review the dosing, the weight based dosing twice a day. He says “we do our best to help educate patients on these complicated medications – making sure they are taking it at the right time, able to communicate with us for any concerning side effects and knowing when to call either a member of their treatment team or the pharmacy staff.” Evanica Rosselli, BSN, MSN, OCN is the nurse educator at Yale and is in charge of maintaining competencies and coming out with new information for staff. She explains Yale has practice nurses that work directly with physicians and manage all of the oral chemotherapy of their specific patients. The nurses will either perform a face to face education session or call the patient with instructions. She says, “the expectation is that each practice nurse does make verbal contact with a patient to describe what they need.”

The next Patient-Centered Activity is to review the pa-
tient medication list to avoid concomitant use of strong and moderate CYP3A inhibitors. Bottiglieri explains that when Moffitt pharmacists hold virtual education sessions with patients, “we basically have a brown bag session. They have their medicines lined up for us, or if they are not sure what they are taking I ask them to go get the bottle and let me look at it because I have a video screen and can see it. That is really a benefit—we are catching a lot of drug interactions.” He says that there is an order in Moffitt’s EHR system to consult pharmacy and a report that pharmacists run once every Monday. The report shows all of the TKIs prescribed in the last week for the entire center. He is then able to filter down based on the drug and the provider and flag all of his patients on selpercatinib, “because we will talk to all of them.” He also shares that educating on medication timing is often vital for these patients. “A lot of these patients are also on levothyroxine and PPIs and the timing of all of this is important. Sometimes we type out a handout for them with times of the day to take their medications, because it can get confusing.”

At Texas Oncology, Etebari also shares that talking to patients about drug interactions is important. “I always make sure to tell them that we have to know if they start taking a medication from a different doctor. We educate them to be sure to tell their medical assistant or the pharmacy so it can be added to their profile, because there are a lot of drug interactions.” He also uses the OCE sheets and discusses safe handling, where to store the medication, and helps the patient plan for missed doses. He says counseling on the dosing schedule and “making sure they understand it is twice a day” is one of the most important points.

**ADVERSE EVENTS: PATIENT-CENTERED MEDICATION MANAGEMENT**

Another step in the Patient-Centered Activities is to counsel the patient to report adverse events related to high blood pressure, liver problems, heart rhythm changes, signs of bleeding, allergic reactions, and lack of wound healing. Dr. Kirtane shares, “I think the biggest side effect we have had to deal with clinically is high blood pressure. I would say there are two ways to strategically manage the hypertension. If the patient has a primary care doctor with a good working relationship we cooperate with them on close monitoring and follow up on blood pressures. I do that because a lot of our patients are not from Tampa so it makes it easier to logistically manage. If they do not have that in place I try to manage it with the pharmacy team. I also add nursing staff and that helps—they usually call the patients two weeks after they start and follow up on all symptoms of high blood pressure.”

**“I THINK THE BIGGEST SIDE EFFECT WE HAVE HAD TO DEAL WITH CLINICALLY IS HIGH BLOOD PRESSURE.”**

Kedar Kirtane, MD

Dr. Chittoor agrees that one of the most important adverse events is hypertension and that warrants monitoring the blood pressure. He also shares, “all of these patients end up having blood counts and blood chemistry that we are paying attention to for toxicity monitoring. Another thing is QT prolongation. Before I start at some point I want to get a baseline EKG.” Dr Chiang also points out the importance of monitoring QTc and says the team and patients need to
remember that “even though it is an oral it still can be toxic and still needs to be monitored.” She also monitors labs and often a baseline EKG to evaluate cardiac function and changes.

Luon educates patients on knowing the signs of potential hepatotoxicity, “informing the patient that we will be looking at their liver labs and also the need to inform us of any sort of unusual signs of hepatic impairment such as jaundice and yellowing of the skin.” He says another major side effect reinforced by Yale physicians, nurses and pharmacists is “looking out for any risk of bleeding – knowing the specific signs of bleeding – so blood in the urine or stool, bruises appearing and getting worse are reasons to contact the staff.”

Rosselli agrees and shares the Yale nurses review bleeding risk with the patients “and what that means, so if they are going to have a procedure they need to let someone know. Our patients get a lot of tests, procedures, and surgeries so bleeding risk is a huge area of importance.” She also adds “a huge part of their teaching is making sure the patient understands who they call and when. We have someone available all days, times, holidays, weekends, nights everything. We make sure the patient knows the number to contact for 24/7 assistance with things.”

Tumor Lysis Syndrome (TLS) occurred in 1% of patients with MTC receiving selpercatinib so the final Patient-Centered Activity is to counsel the patient to report signs and symptoms of TLS. These signs and symptoms may include: nausea, vomiting, lack of appetite, fatigue, dark urine, flank pain, reduced urine output, numbness, seizures, hallucinations, muscle cramps and heart palpitations.

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. Dr. Chittoor shares, “it is very important to keep in mind it is a team. Oncology is unlike other specialties – this is complete teamwork. There are so many components that are involved, not only physical but emotional and family support. You need all players taking a personal interest in the patient.” Luon also comments, “there is a reason I work at Yale and it is because it is very, very collaborative. I can text Dr. Chiang whenever I have a question about one of her patients, whereas in other places I might be nervous to text the doctor.”

Zoock adds she feels the MID model benefits patients because “there is always a pharmacist available so anytime a patient has a question they are going to get an immediate answer. I think that is the best possible outcome for the patient.” Alfonso points out “our patients are so overwhelmingly positive and appreciative of everything we do and we call it the positive feedback loop–because we are able to

CONCLUSION: NCODA, THE MID AND PQI: OPTIMIZING PATIENT OUTCOMES
make an impact for them, they are so appreciative and because they are so appreciative we are always trying to go that extra mile for them. Everything I have learned in this space – business, workflow and process wise is to be able to make that impact. Our cancer patients are so much in need of that education and to not only be the safety net for them and our clinics but also to be able to follow up with them and make sure they are not struggling with any issues has been a really great journey.”

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 Medical-ly Integrated Teams. Etebari values the PQI for “all around education with regards to RET altered cancers.” Bottiglieri appreciates the PQI in looking up needed information because “it makes it a little bit faster for me and I can find exactly what I need quickly.”

Selpercatinib gives patients with certain types of NCSLC and thyroid cancer another treatment option. The PQIs provide the MID program with an easy to use, compact clinical resource guide when discovering the right patient and dispensing RETEVMO®. The PQIs help the team ensure they are providing patients with the tools and education to improve genomic testing and clinical outcomes. Pairing Medically Integrated Dispensing with the Selpercatinib (RETEVMO®) Genomic Testing Management PQI and the Selpercatinib (RETEVMO®) Management PQI meets NCODA’s Guiding Values of being Patient-Centered and Always Collaborative.

“IT IS VERY IMPORTANT TO KEEP IN MIND IT IS A TEAM. ONCOLOGY IS UNLIKE OTHER SPECIALTIES–THIS IS COMPLETE TEAMWORK. THERE ARE SO MANY COMPONENTS THAT ARE INVOLVED, NOT ONLY PHYSICAL BUT EMOTIONAL AND FAMILY SUPPORT. YOU NEED ALL PLAYERS TAKING A PERSONAL INTEREST IN THE PATIENT.”

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PQI PRINCIPLES:

1. Appropriate identification of RET gene fusions or mutations is crucial
2. Confirm correct dosing and dose adjustment when necessary
3. Screen for drug interactions and adverse events
4. Provide thorough patient education

REFERENCES

ON THE COVER:

- Yale Pharmacist Darren Luon, PharmD, BCOP provides patient-centered care.
Practice panelist’s comments reflect their experiences and opinions and should not be used as a substitute for medical judgment.

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