

PQI IN ACTION

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



**MEDICALLY INTEGRATED DISPENSING OF IXAZOMIB IN THE
TREATMENT OF MULTIPLE MYELOMA**



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INTRODUCTION

In an effort to promote higher quality patient care the National Community Oncology Dispensing Association, Inc (NCODA), created the NCODA Positive Quality Intervention (PQI) as a peer-reviewed clinical guidance document 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 simple-to-use resource for managing patients receiving oral or IV oncolytics. This PQI in Action is a follow up to the Ninlaro (ixazomib) PQI and explores how the medically integrated teams at Cancer Specialists of North Florida (CSNF) and Mitchell Cancer Institute (MCI) incorporate the PQI as part of their daily workflow. It will discuss how utilizing the ixazomib PQI elevates patient care.

Cancer Specialists of North Florida has been providing cancer treatment to their community for over three decades. They are a physician-owned practice located in Northeast Florida. CSNF owns Florida Specialty Pharmacy, which serves as their central hub for prescriptions. Their pharmacists work as a team with CSNF physicians to ensure that complicated medications are taken in the most effective way.

Mitchell Cancer Institute (MCI) is a comprehensive cancer center and part of the University of South Alabama Health System, the only academic medical center in the Gulf Coast. MCI has three locations and employs 34 physicians ranging in oncology specialties from medical and radiation oncology, the only GYN-Oncologists in the region, fellowship trained surgical oncologists and other specialists such as urology and pulmonary. The MCI pharmacy team plays an integral role with the center's specialists. Their focus is to provide the latest and most effective oral medications to not only achieve the best outcome but also to prevent or manage side effects and assist with financial toxicities.

THE PARTICIPANTS

Cancer Specialists of North Florida Jacksonville, FL



Mehdi Moezi, MD, FACP
*Medical Oncologist and Medical
Director of Clinical Research*



Michelle Eaves, RN,BSN,OCN
Nurse Supervisor



Ernestine Wigelsworth, PharmD
Pharmacy Manager



Jessica Simmons, CPhT
Pharmacy Team Lead

Mitchell Cancer Institute Mobile, AL



Thomas W. Butler, MD
*Senior Staff Medical Oncologist & Associate
Professor, Interdisciplinary Clinical Oncology*



Blair Pringle, CRNP
Clinical Nurse Practitioner



Brittney Carden, PharmD
Specialty Pharmacy Manager



Carolyn DeMouy, RPhT
Specialty Pharmacy Coordinator

MEDICALLY INTEGRATED DISPENSING PAIRED WITH NCODA TOOLS

NCODA defines Medically Integrated Dispensing (MID) as a dispensing pharmacy within an oncology center of excellence that promotes a patient-centered, multidisciplinary team approach. The MID is an outcome-based collaborative and comprehensive model that involves oncology health care professionals and other stakeholders who focus on the continuity of coordinated, quality care and therapies for cancer patients.¹ The need for Medically Integrated Dispensing continues to grow as more and more oral oncology agents are approved. In 2018, over half of the new oncology therapeutics launched were oral formulations.²

The MID model can improve management of patients on these therapies in several ways including communication issues, measuring adherence, managing regimen changes, speed to therapy, increased patient satisfaction, financial assistance, cost avoidance and producing less waste.³ NCODA offers multiple tools to aid the MID practice in managing oral formulations. The lineup continues to grow and now contains Patient Surveys, a Cost Avoidance and Waste Tracker tool, a Financial Assistance tool, Treatment Support Kits, Oral Chemotherapy Education sheets and of course the Positive Quality Intervention clinical resource.

Mitchell Cancer Institute Pharmacy Manager Brittney Carden, PharmD, values the PQI (<https://www.ncoda.org/ixazomib-in-the-treatment-of-multiple-myeloma/>) because it helps her team become more uniform in monitoring parameters and side effect management. Her pharmacy is their site's hub for oral drugs and the PQI ensures "we are all on the same page." MCI Medical Oncologist and Associate Professor of Interdisciplinary Oncology at the University of South Alabama, Dr. Thomas Butler feels there is no question in the value of the PQI. "I think this is essential" says Dr. Butler. He says, "I like succinct guidelines that help you know what to look for, what not to omit, and I think that is the way you elevate patient care."

CSNF's Florida Specialty Pharmacy Manager Ernestine Wigelsworth, PharmD echoes the same sentiment. She expresses that the PQI helps staff of the MID and clinic all to be on the same page. She likes that the PQI is "consistent and concise." CSNF's Pharmacy Team Lead Jessica Simmons,



Carolyn DeMouy, MCI Specialty Pharmacy Coordinator, works to get Prior Authorizations approved and helps patients find financial assistance when needed.

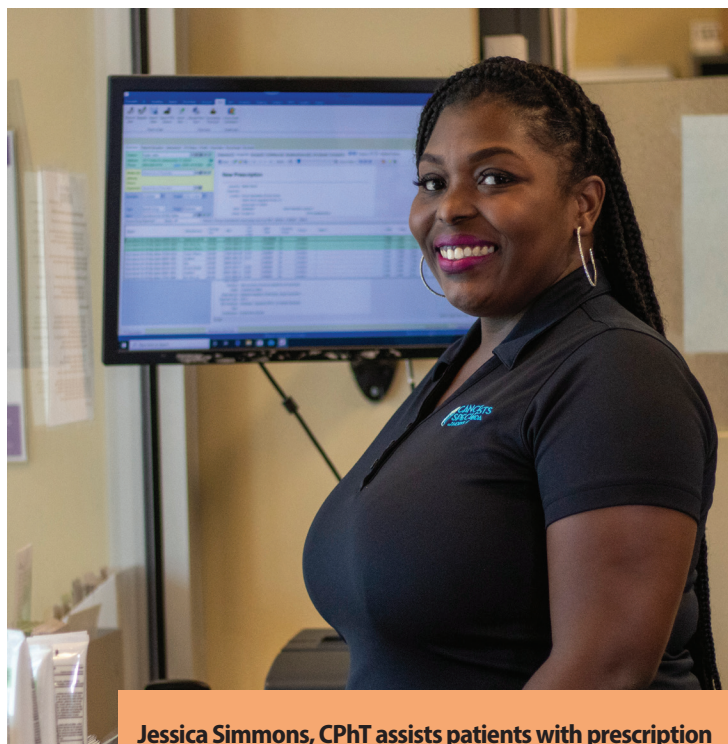
CPhT values the PQI "especially with being new to oncology" because it helps her have a quick guide with background information on each drug. As Pharmacy Team Lead, it also helps her easily disseminate that information to her team.

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 Mitchell Cancer Institute differ in clinical setting type but have both found successful ways to incorporate the PQI resource tool. Both practices share in NCODA's Guiding Values of being Patient-Centered and Always Collaborative. We will take a look specifically at their MID settings, how implementing the Ixazomib in the Treatment of Multiple Myeloma PQI benefits their staff and patients, and hurdles and challenges they face on a daily basis.

MEDICALLY INTEGRATED DISPENSING: CONTINUING TO PROVIDE COLLABORATION AND VALUE

As the number of oral oncolytics continues to rise, so does the need for Medically Integrated Dispensing. Offering Medically Integrated Dispensing is a better care model for patients as it offers an additional level of support at the practice; leading to improved continuity of care and overall management of therapy.⁴

Cancer Specialists of North Florida Medical Oncologist and Medical Director of Clinical Research Mehdi Moezi, MD, FACP explains the biggest benefit of MID is patient convenience and comfort. CSNF started their pharmacy around 15 years ago to optimize patient care as well as to create an additional revenue source for the practice. Dr. Moezi sees the benefit of the pharmacy helping provide continuity of care; the patients can have an office visit, labs, scans, and prescriptions services all under one roof. He says this “minimizes aggravation and confusion for the patient.” CSNF nursing supervisor Michelle Eaves, RN, BSN, OCN agrees. “We are dealing with patients who have cancer. That is hard enough as it is. The more we can do personally with them the better they will be long term.”



Jessica Simmons, CPhT assists patients with prescription pick up at CSNF's Florida Specialty Pharmacy.

**“[THE PQI IS] ADDING TO OUR EFFICIENCY,
ADDING TO OUR PATIENT SATISFACTION AND IT
IS ADDING TO OUR EDUCATIONAL LEVEL.”**

Thomas Butler, MD

MID helps fill a need in a patient's cancer treatment and decreases fragmentation of care. Using tools like the PQI and following the Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards helps set the stage for better team alignment and patient management. Medicine is relying on an increasing number of people to provide patient care yet opportunities to collaborate can still be rare.⁵ Dr. Butler is an advocate for the team effort. “I strongly believe in interdisciplinary management” he says. He also believes that patients like the team concept and that MID is “adding to our efficiency, adding to our patient satisfaction and it is adding to our educational level.”

MCI's pharmacy just celebrated its two-year anniversary. Carden and Carolyn DeMouy, RPhT, started the MID program and feel their most rewarding opportunity was gaining the trust of their nurses. They explain that they gained this trust after the nurses saw all of the services the pharmacy was able to provide. Carden elaborates, things changed “when they saw we are completing prior authorizations and financial assistance, providing the counseling, keeping up with refills, and providing a 1-2 day turnaround instead of a 7-10 day turnaround.” Carolyn really believes the financial assistance piece helped gain this trust. She follows up on her applications daily and updates notes in the practice's EMR system. “I keep in contact with the patient, I keep them updated” she states and believes this helps relieve phone burden from nurses to allow them to focus more directly on patient care. According to Carden now “we are a team. We are all working together for each patient.”

POSITIVE QUALITY INTERVENTIONS: PROVIDING UNIFORMITY AND MEETING STANDARDS

In 2018 an expert panel was formed and they used the NCODA patient-centered standards as the basis for “Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards.” According to publication, adoption of standards can help MID practices obtain optimal adherence and persistence rates, minimize the risk of toxicity with therapy, and positively affect patient health outcomes.⁶ The PQI can assist in meeting many of these standards in multiple categories including patient relationships, education, adherence and persistence, safety, and refilling of prescriptions.⁶ Both of the participating practices touch on ways the ixazomib PQI helps reach these goals.

Wigelsworth shares that when her pharmacy is filling a prescription they must remember that “it is more than just a prescription coming through. We are helping patients.” It is therefore important to incorporate the PQI. “It is important to have a concise, 1-2 page tool that tells you what the drug is about, what you can expect from it, possible clinical interventions, and where you can find helpful resources.” The PQI does just that; it lays a foundation with a description and background of the drug and disease state, pulls out a process

**“WE ARE A TEAM. WE ARE
ALL WORKING TOGETHER
FOR EACH PATIENT.”**

Brittney Carden, PharmD

for filling the medication, lists patient-centered activities, and includes supplemental information if applicable. Most importantly it provides a resource for clinical interventions.

Dr. Moezi expresses that MID is an integral part of the practice and that the pharmacists can see via the EMR that he has a plan. The pharmacist has the PQI tool and then “reads my note, looks at the prescription, looks at the labs, looks at everything else that is going on. It gives them a lot more information.” Dr. Butler comments the PQI “has helped dosing, it has helped monitoring toxicity, and knowing how to change dosing on the toxicity.”

IXAZOMIB IN THE TREATMENT OF MULTIPLE MYELOMA

Multiple Myeloma outcomes have improved substantially in the last 15 years.⁷ Dr. Moezi has been treating patients with myeloma for over 25 years and has seen an increase in life expectancy of patients over his tenure, he says patients are “living much longer” now and “the number of existing patients on some sort of treatment and follow up is fortunately continuously increasing.” He believes that five years from now there will be many more myeloma patients that are 5, 10, and 15 years on therapy if managed correctly. He has “had patients up to 20-21 years on treatment.”

Proteasome inhibitors and immunomodulatory (IMiD) drugs now form the backbone of myeloma treatment.⁷ Triplet regimens have increased in use and there is also a shift towards extended treatment. With the shift in extended treatment comes the need for agents with tolerable side effects as well as ease of use for patients.

Ixazomib is a proteasome inhibitor indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.⁸ At time of publication, ixazomib is the only oral proteasome inhibitor on the market and is available as 2.3mg, 3mg, and 4mg capsules. It should be taken on days 1, 8, and 15 of a 28-day cycle.⁸ It may be used in the relapsed / refractory (r/r) setting in combination with lenalidomide and dexamethasone as well as in various off label settings as discussed in the PQI. The most common side effects associated with ixazomib include diarrhea, constipation, thrombocytopenia, peripheral neuropathy, nausea, peripheral edema, vomiting, and back pain.⁸



THE PQI: BETTER PATIENT MANAGEMENT ON NINLARO (IXAZOMIB)

The ixazomib PQI is an advantageous resource regarding labs and dosing. Both CSNF and MCI appreciate and utilize the dosing table provided. Carden explains “the PQI has great tables so it is easy to find dose reductions and dose recommendations.” MCI Nurse Practitioner Blair Pringle agrees, the PQI “helps us determine toxicities and if a patient is on a correct dose.” According to Dr. Butler the ixazomib PQI “is pretty clear on holding drug and on which drug to change dose and this is pretty important, particularly if you are not seeing all multiple myeloma patients.”

ALTERNATING DOSE REDUCTIONS WITH LENALIDOMIDE

Reaction	Platelets	Neutrophils	Rash
Parameter	< 30,000/mm ³	< 500/mm ³	Grade 2 or 3
First Occurrence	<ul style="list-style-type: none">Withhold ixazomib and lenalidomideUpon recovery, resume both but reduce lenalidomide at next lower dose and continue ixazomib at most recent dose		
Subsequent Occurrence	<ul style="list-style-type: none">Withhold ixazomib and lenalidomideUpon recovery, resume both but reduce ixazomib at next lower dose and continue lenalidomide at most recent dose		

Both practices are checking baseline labs and pertinent labs at least once monthly for patients started on ixazomib (more frequently in the beginning). Both MID programs have access to the clinic’s EMR system and pharmacists are checking labs with each prescription of ixazomib. The pharmacists agree that it is not hard to communicate dosing recommendations to their respective prescribers. They have direct access through the phone, email, and even face to face and believe this access leads to quick dose modifications. DeMouy stays in constant contact with patient’s insurance companies and knows the ins and outs when a new prior authorization is required for a dose modification.

Part of the Ninlaro PQI is ensuring that patients receiving PI therapies are also receiving antiviral therapies to prevent against herpes zoster reactivation. It also involves checking that patients on IMiD (Revlimid or Pomalyst) therapies are also taking aspirin for DVT/PE prophylaxis or therapeutic anticoagulation. The pharmacists of both practices review the patient’s profile to make sure these medications have been prescribed, and make the request to the prescriber if they have not. Wigelsworth adds that this is not hard to request to the physician or nursing staff, the pharmacist typically sends an email request and can attach the PQI as a reference. The PQI attachment is something the prescriber or staff can look over quickly in the middle of their busy day. Dr. Moezi agrees and mentions it “helps to have a second set of eyes.” Of note, both practices have fellowship programs, Dr. Moezi feels there is particular value in the PQI as a reference tool for newer physicians.

The ixazomib PQI also recommends that a therapy calendar be utilized for all patients with Multiple Myeloma. A treatment calendar is a recommendation of the ASCO/ NCODA standards as well. The standard states:

*Calendars or other scheduling communications are helpful. If a patient calendar is provided, the calendar should include refill dates and medication schedules, clearly outlining specific dates to take medication. Include documentation of calendar information in the patient record.*⁵

Both practices follow this recommendation. Carden creates a calendar for all MCI pharmacy patients on ixazomib and will also create one for patients that are required to fill prescriptions outside of the practice. Pringle finds the calendar example to be one of the most helpful parts of the ixazomib PQI. One of the patient centered activities listed on the PQI is to ensure patients understand the dosing schedule. Ixazomib is administered on days 1,8, and 15 every 28 days and the IMiDs and steroids have different dosing schedules. The calendar is particularly useful with medications like ixazomib that are part of triplet therapy since each drug has a unique dosing schedule.

EDUCATION IS KEY FOR STAFF AND PATIENTS



MCI Pharmacy Manager Brittney Carden provides patient education and counseling on Ninlaro.

As cancer treatment continues to become more complex, with an increase in combination therapies, varied dosing schedules, and more, the need for patient and staff education is vital. Research has shown that patients who are satisfied, who experience fewer information barriers, and have fulfilled information needs, generally have a better Health-Related Quality of Life and lower levels of depression and anxiety.⁹ In one study when asked about which ways patients preferred to receive information on their chemotherapy drugs, most indicated they would like a combination (oral, written, calendar, etc.).¹⁰ The ASCO/NCODA Standards state that 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's assistant and give more detailed information about what this education should contain.⁵ The PQI for ixazomib recommends an Oral Chemotherapy

Education (OCE) (<http://www.oralchemoedsheets.com>) sheet for all patients as well as various other educational components. Both practices utilize the OCE sheets and find them to be an incredibly valuable resource for patients. CSNF gives the patient a copy with each new fill of an oral oncolytic and also uses the sheet as a guide for pharmacist counseling as part of the chemo teach. Wigelsworth particularly likes the OCE sheet as a patient education tool because it is “laid out in a way that makes it easy for them to read and not be so overwhelmed.” Carden also utilizes the sheets at MCI and sends out to her physicians so they can have a quick educational guide when speaking with patients. She appreciates having something in writing that is easy to understand to send home with patients. She directs her patients to the side effect management section so they can refer back if they have a side effect. She finds this helpful since patients are often “bombarded with counseling” at the start of therapy and may forget many points.

The practices also find merit in the education the PQI provides for staff. Staff education is essential for a successful MID program. Staff education benefits the practice in many ways including employee retention, staff morale, practice efficiency, job competency, and even patient satisfaction.¹¹ From the nursing perspective Eaves says implementing the MID program has helped improve “education for the nurses, staff and physicians. It has helped everyone become more aware of what we have to offer our patients, the latest and greatest.”

CSNF uses the PQI as an educational tool for all new pharmacy staff members. Wigelsworth finds inherent value “particularly for pharmacists that may be new to oncology and pharmacy interns.” Simmons says that the PQI helps her to know what things to look for to make sure the patient is getting everything they need. She feels that they are particularly helpful to members of the team who are new to oncology, “it definitely educates us”. CSNF began having a staff member present the PQI to other staff as part of quarterly education. They rotate the presenter each quarter and this gives multiple employees the opportunity for growth. Dr. Butler believes everyone on their team has equal ability to try and take care of the patient, and the PQI helps with edu-

cation of the team. He believes in clinical pathways and keeps a book of references and source documents for staff-where the ixazomib PQI will be housed. He believes it is a good clinical guide for staff in this respect.



Cancer Specialists of North Florida in Jacksonville, FL.

FINANCIAL RESOURCES: ADDING TO THE LIST OF MID BENEFITS

Cancer is one of the most expensive medical conditions to treat in the United States and co-payments and co-insurance can cause financial toxicity even in the insured.¹² One of the biggest benefits of the MID model is the assistance with finding coverage for patients with high co-pays on oral medications. Both practices have employees dedicated to completing prior authorizations and obtaining financial assistance. At MCI, technician DeMouy finds assistance for all patients. Carden says “if there is a co-pay card available, we are using it” and goes on to share that patients may not receive that same benefit from outside mail-order pharmacies.

DeMouy has spent her time calling outside pharmacies multiple times for one claim because the mail-order pharmacy does not process the card correctly or does not carry it over from one fill to the next. Dr. Butler finds the financial resource link in the ixazomib PQI useful. He has personally spent hours of his time working for insurance coverage for patients via phone and completing paperwork. He has the

most difficult time when medications are sent to outside mail-order pharmacies. He works with many patients from an underserved population and states “a lot of these folks do not know they have rights with the healthcare system, so they need advocates to go to bat for them. I just believe we need to advocate.”

CSNF pharmacy technicians find and apply co-pay cards when available and also work with practice social workers if patients require assistance or free drug. Their pharmacy staff uses the PQI to point them in the right direction of where to find the financial resources for each drug. Simmons says the PQI “lets us know where we can get financial help for the drug for the patient.” It helps the technicians “see what financial resources are out there.” Their pharmacy uses the Takeda link provided in the PQI: (www.ninlaro.com/cost) when researching help for ixazomib patients- this group often needs assistance as they are filling multiple medications and therefore have multiple co-pays.

MID AND THE PQI: RAISING THE BAR



CSNF Pharmacy Manager Ernestine Wigelsworth checks prescriptions for accuracy.

A common theme with every team member interviewed is that the MID program paired with the PQI is a winning and ideal scenario for patients. Pringle believes this combination leads to “timely administration of antineoplastics.” She goes on to say that filling medications through the MID leads to quick communication with the prescriber, an outside pharmacy is required to leave a message and wait for a nurse or medical assistant to return the phone call. She says her pharmacy is a crucial part of the clinical evaluation team and contacts them right away to clarify a dose or ask a question about labs. Filling the medication through MID can lead to faster coordination of triplet therapy. Both practices have cases of patients filling medications with their pharmacy and an outside mail order pharmacy and these can be particularly hard to coordinate. A delay in one medication of the therapy can cause the team

**“WHEN THEY FILL HERE WITH US THEY ARE NOT
JUST THE PRESCRIPTION THEY ARE THE PATIENT.”**

Ernestine Wigelsworth, PharmD

to have a difficult conversation with the patient and lack of continuity of care.

Dr. Butler finds difficulty sometimes in receiving part of the triplet therapy from outside mail order pharmacies and has been amazed by length of delay from these outside pharmacies. Dr. Moezi also often finds difficulty in communicating with the outside mail order pharmacies. He comments that while the practice tries to be proactive and call the other pharmacies, sometimes he cannot get an answer or a person on the phone. Involving the external stakeholder adds an extra level of complexity to care coordination in these cases.

When patients are required to fill medications outside of the MID program they miss out on personalized attention they get from the practice. “When they fill here with us they are not just the prescription they are the patient” Wigelsworth says. Simmons agrees. Patients miss out on “face to face interactions and knowing who is giving them the medication” when they cannot fill through the MID. When patients are counseled by the MID team “education is alive” says Eaves. “You can verbally have buy-in and tell if patients are comprehending.”

Carden adds the patients truly benefit because “they know us by name” which is not the case at an outside mail order pharmacy. This means patients have a personal relationship with her team that they do not build with the external pharmacy. She also explains her pharmacy can deliver the medication to the patient next day for no delivery cost if needed, at least one pharmacy they work with often charges the patients extra for this service.



Mitchell Cancer Institute in Mobile, Alabama.

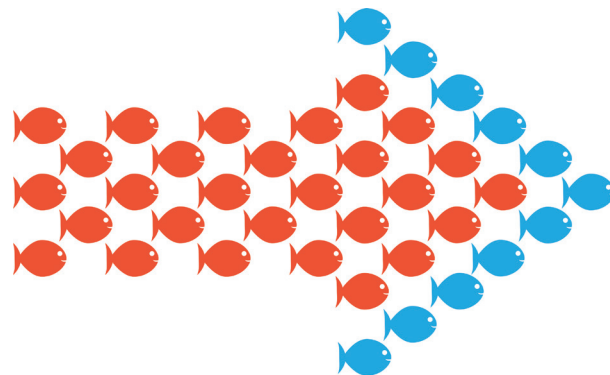
CONCLUSION: NCODA THE MID, AND PQI- LEADING THE WAY TO BETTER PATIENT CARE

As the quest for optimal patient care and improved outcomes continues, NCODA is providing tools to allow the MID program to lead the way. MID continues to bring value to the dispensing of oral oncolytics. DeMouy knows there is no substitute for the integrated team who KNOWS the patient. “They can call the pharmacy and speak to someone.” As an oncology nurse, Eaves is constantly in tune with and aware of patient needs. “You might find an interaction just by having a conversation with the patient. They sometimes don’t know what questions to ask. They are already scared, they are already so overwhelmed. If they have a moment to share their fears or share their understanding with a team-member they may be more compliant.”

MID elevates patient care and the PQI becomes one more tool in the box to raise the bar even higher. The PQI fosters better care for patients 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. Ixazomib

gives multiple myeloma patients the option of an all oral regimen that they can take from the comfort of their own home. The ixazomib PQI gives the MID program an easy to use, compact clinical resource guide when dispensing ixazomib. It ensures that a patient is receiving the correct dose, necessary supporting medication and standard education. Pairing Medically Integrated Dispensing with the ixazomib PQI is truly patient-centered and collaborative.

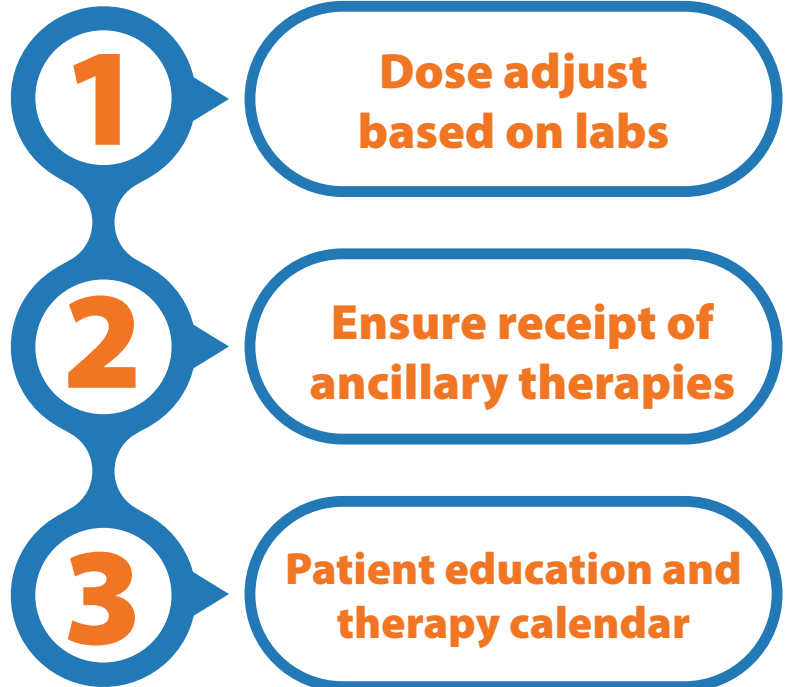
**WORKING TOGETHER,
WE BECOME STRONGER**



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IXAZOMIB PQI PRINCIPLES:



Helpful Online Resources

- www.ncoda.org
- www.ncoda.org/pqi
- www.oralchemoedsheets.com
- www.ncoda.org/ixazomib-in-the-treatment-of-multiple-myeloma

ON THE COVER *(from left):*

- Katrina Butler, Pharmacy Technician at CSNF;
- Dr. Thomas Butler, Medical Oncologist and Blair Pringle, CNPN, Nurse Practitioner at MCI;
- Michelle Eaves, Nurse Supervisor at CSNF

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

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

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

