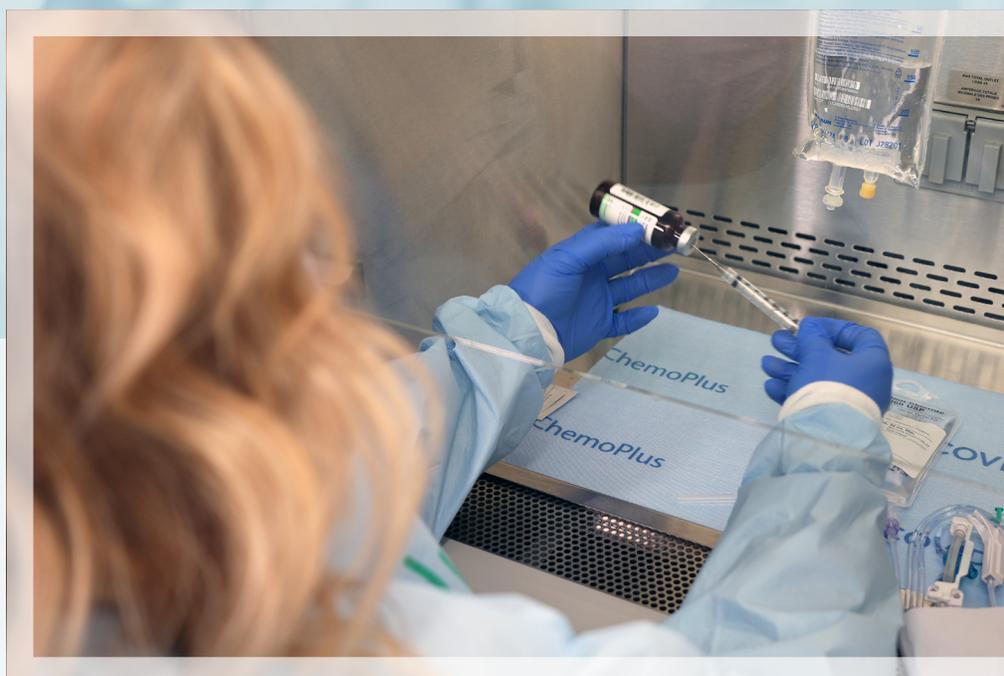


PQI IN ACTION



**LURBINECTEDIN (ZEPZELCA™)
FOR SMALL CELL LUNG CANCER**



**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 document for the oncology healthcare team. 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. The PQI library also contains PQIs on supportive care and various diseases states. The PQI fosters better care for patients through appropriate patient identification, treatment selection, increased speed to therapy, reduced cost and hospitalization, and by improved adherence techniques for the patient and their medically integrated teams. The treatment and management of oncology patients on hematology and oncology drug therapy is continually evolving, and becoming ever more complex. The growing complexity creates a need for healthcare professionals to have a quick resource to turn to for drug therapy management information. The medically integrated pharmacy team is in a unique position to ensure appropriate treatment, increase compliance, and maximize outcomes. PQIs, an NCODA Quality Standard, are designed to operationalize and standardize those practices to achieve these positive clinical outcomes. PQIs are created, written, and updated biannually by NCODA members with expertise on the topic, making this a go-to for an up-to-date, relevant, patient-centered resource. Andrea Ketcham, PharmD of the McFarland Clinic shares, “the PQIs are very helpful. They give condensed, concise guidelines to work off.” This is echoed by Lawrence Garbo, MD of New York Oncology and Hematology, “PQIs provide an excellent overview that is easy to access and follow.” This PQI in Action will delve into Small Cell Lung Cancer (SCLC), the **Lurbinectedin (ZEPZELCA™) for Small Cell Lung Cancer** PQI, and three centers of excellence who have a passion for patients and excel at optimizing the patient experience.

The McFarland Clinic is Iowa's largest physician-owned multi-specialty clinic. The McFarland Clinic's network of healthcare providers serves residents in 12 Iowa communities with additional communities served by physician outreach clinics. More than one million patient visits are made at McFarland Clinic annually, offered by more than 280 providers and 1,000 staff members. Their caring professionals demonstrate their values of quality care, extraordinary service, trusting relationships, and an exceptional workplace.

Texas Oncology is an independent, physician-led practice delivering leading edge technology and treatment options and conducting innovative research. Founders of the practice pioneered community-based care to enable more cancer patients to receive high-quality care while staying close to the critical support of family and friends. With more than 500 physicians caring for patients in 210 locations across the state, Texas Oncology's mission, vision, and core values reflect the practice's commitment to providing high-quality, evidence-based, patient-centered care to cancer patients.

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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THE MEDICALLY INTEGRATED TEAM: BENEFICIAL FOR PRACTICES AND SMALL CELL LUNG CANCER PATIENTS

In 2021, lung cancer was the second most diagnosed cancer in the United States and was the leading cause of cancer deaths in both men and women.¹ The majority of lung cancer cases are classified as non-small cell lung cancer, with a small portion of cases classified as small cell lung cancer. Small cell lung cancer (SCLC) accounts for around 15% of all lung cancer diagnoses and is typically highly aggressive with poor survival outcomes.¹ SCLC is fast growing, with symptoms beginning only 8-12 weeks prior to presentation, and has usually metastasized outside of the lung (extensive stage/disease) by the time diagnosis is made.¹ Smoking is associated with all types of lung cancer and many other cancer types, however, the strongest associations are with SCLC and squamous cell lung cancer.¹ There appears to be a dose-dependent relationship between the degree of smoke exposure (type of cigarette, duration of inhalation, and use of a filter) and the relative risk of lung cancer.^{2,3} Katie Good, PA-C with Texas Oncology shares, "SCLC patients are difficult to manage due to the fact that long-term survival is rare and that most patients relapse after initial treatment." The recommended first-line treatment in SCLC is a platinum-based chemotherapy regimen.⁴ This first-line treatment has remained relatively the same for decades.³ Few options exist for treatment of patients with SCLC after failure of this first-line platinum-based treatment.

The excitement surrounding lurbinectedin, obviously, is there has not been a real development in small cell lung cancer for twenty plus years. This makes the discovery of lurbinectedin quite exciting. Katie Good, PA-C shares this feeling, stating "It is very exciting to have ZEPZELCA(TM) come to market in the SCLC space due to the potential benefit for patients. SCLC is characterized by being an aggressive cancer that is associated with rapid doubling time and early development of widespread metastatic disease. Although SCLC is initially highly sensitive to chemotherapy most patients relapse and eventually die from metastatic recurrent disease. It is very exciting to have a second-line therapy option." Lurbinectedin (ZEPZELCA™) is an alkylating agent that inhibits oncogenic transcription. It is approved as second-line therapy in patients with metastatic SCLC. The United States Food & Drug Administration's accelerated approval of lurbinectedin in this setting is based on a single-arm, open-label, phase 2, multi-centered basket trial in Europe and the United States.⁵ Patients enrolled in the trial were adults (aged ≥18 years) with a pathologically proven diagnosis of SCLC, ECOG performance status less than or equal to 2, measurable disease, absence of

brain metastasis, adequate organ function, and pre-treated with only one previous chemotherapy-containing line of treatment. The primary outcome was overall response (ORR) as assessed by the investigators according to RECIST 1.1. In the 105 patients who were enrolled and treated with lurbinectedin, ORR was demonstrated in 37 patients (35.2%; 95% CI 26.2-45.2). The most common grade 3-4 adverse events included hematological abnormalities such as anemia (9%), leukopenia (29%), neutropenia (46%), and thrombocytopenia (7%). Serious treatment-related adverse events occurred in 10% of the patients, of which neutropenia and febrile neutropenia were the most common (5% patients for each). No treatment-related deaths were reported.^{5,6} The fact that we have a novel drug that is effective and tolerable in this space is exciting and long overdue. This approval brings hope in a treatment space with so little options. The National Comprehensive Cancer Network (NCCN) SCLC Panel recommends lurbinectedin as a preferred regimen designation for relapse after 6 months or less and as category 2A designation for relapse occurring after more than 6 months.⁴ The **Lurbinectedin (ZEPZELCA™) for Small Cell Lung Cancer PQI** was developed to aid all members of the medically integrated team in the treatment of those patients who are a good candidate for lurbinectedin (ZEPZELCA™). This helps oncologists and clinical pharmacists to manage adverse effects, to aide nurses in their varying roles, to assist technicians in product preparation, and to help the whole medically integrated team provide value to the patient. Andrea Ketcham, PharmD shares, "I think that sometimes we can get scared of new products, but it helps to have backup with the PQI. The PQI has really helped us provide the best patient care that we can, especially with new medications."

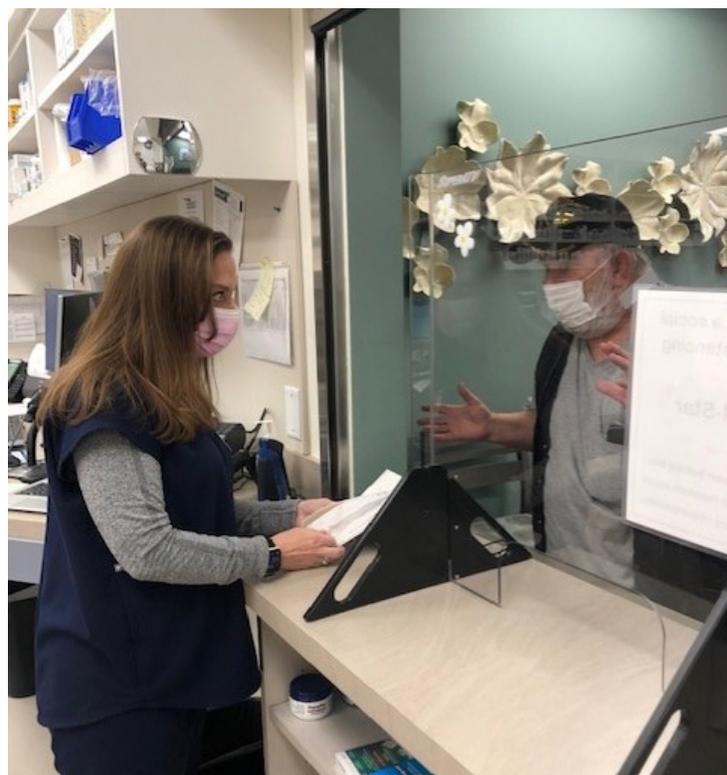
"THE PQI HAS REALLY HELPED US PROVIDE THE BEST PATIENT CARE THAT WE CAN, ESPECIALLY WITH NEW MEDICATIONS."

Andrea Ketcham, PharmD

THE PQI: DISPENSING POSITIVE PATIENT-CENTERED OUTCOMES

All PQIs begin with a brief synopsis, the description section, of the document. This gives the reader a solid idea at a glance what the PQI will cover. In the **Lurbinectedin (ZEPZELCA™) for Small Cell Lung Cancer** PQI, we see that the purpose of this PQI is to evaluate the use of lurbinectedin for the treatment of adult patients with metastatic small cell lung cancer with disease progression on or after platinum-based chemotherapy. Dr. Garbo shares, “I use lurbinectedin as second-line therapy in patients with SCLC who have progressed after or did not respond to initial platinum-based therapy. Usually this is for a progression within 6 months of initial treatment. The performance status should be at least an ECOG 2 and there should be adequate preservation of renal and hepatic function and blood counts acceptable for treatment.” As previously addressed, failure of treatment in the first line setting historically has left patients with very few options. The approval of ZEPZELCA™ (lurbinectedin) is a very encouraging option for metastatic SCLC patients. The description section is followed by the background section, which delves into the details of clinical studies and relevant information regarding the medication or the disease state covered in the PQI; giving the reader of the document a full picture of lurbinectedin’s background. Many of the details covered in the background section have already been addressed in this article, again giving the reader an appropriate look at all they need to know.

The PQI process then goes into a step-by-step guide for oncology professionals to follow for the best practices around lurbinectedin. As always, it is important to screen for drug-drug interactions with all patients prior to the start of treatment. With lurbinectedin it is important to avoid coadministration with strong/moderate CYP3A inhibitors/inducers, which can change concentrations/exposure to lurbinectedin. Astrid Slaughter, PharmD, PhD, BCSCP of Texas Oncology shares that the pharmacist checking for drug-drug interactions is of major importance at her practice. Not only do pharmacists identify potential interactions, but they also provide recommendations on dose adjustments and clean up the treatment plan. She says, “it makes for a much cleaner process and helps us to avoid issues coming up later on in the process.” It is also important to note that treatment should only be initiated if baseline ANC $\geq 1,500$ cells/mm³ and platelet count is $\geq 100,000/$



Diane Renfro, PharmD of Texas Oncology counsels a patient.

mm³. Kinga Faulkner, PharmD and Dr. Garbo also touched on the importance of monitoring creatine phosphokinase (CPK) prior to initiating therapy and periodically during treatment to monitor for rhabdomyolysis. There is no initial dose adjustment recommended for baseline renal or hepatic impairment, however, there is limited data available at this time in this subset of patients. Kinga Faulkner, PharmD and Kaylee Hart, CPhT both from NYOH reiterated their organization’s importance on checking lab values prior to starting treatment. Their workflow, which provides multiple double checks throughout the process, adds extra layers of safety while supporting the entire team. The workflow also strives to prevent medication wastage and can provide cost savings to the practice. The recommended dosage of lurbinectedin is 3.2 mg/m² administered over 60 minutes every 21 days until disease progression or unacceptable toxicity. Pre-medications recommended for antiemetic prophylaxis include a corticosteroid like dexamethasone 8 mg intravenous (or equivalent) and a serotonin antagonist like ondansetron 8 mg intravenous (or equivalent). Andrea Ketcham,

PharmD emphasizes, “it is helpful to have a team approach to treating patients. We address things proactively and work alongside each other to address dose adjustments, side effects, etc.”

Like all medications in this space, there is a mild toxicity, which is comparable or favorable to other medications that we use in second-line. The most common adverse reactions ($\geq 20\%$) affecting laboratory values include: leukopenia, lymphopenia, fatigue, anemia, neutropenia, increased creatinine, increased alanine aminotransferase, increased glucose, increased aspartate aminotransferase, decreased albumin, decreased sodium, and decreased magnesium. Katie Good, PA-C advises, "In general I always advise patients to listen to their bodies and to reach out to their medical provider early if they are having uncontrollable symptoms." It is important to monitor laboratory values prior to each administration and address accordingly. Kinga Faulkner,

PharmD shares that, “I have found that most patients tolerate lurbinedectin pretty well” and this is a result of their medically integrated team. The medically integrated team helps with the management of labs, early identification of adverse events, and provides superb patient education. The supplemental section of this PQI gives the reader guidance on what to do with specific adverse events and also provides information on dose adjustments if this is the appropriate action. For example, with neutropenia, if the patient experiences Grade 4 or any grade of febrile neutropenia it is important to hold until this has resolved to Grade 1. If the neutrophil count is less than 500 cells/mm^3 then granulocyte colony-stimulating factor (G-CSF) should be used to help boost the neutrophil count. This is a key Positive Quality Intervention that can help keep patients on treatment. The tables included cover more adverse events, the recommended action, and information on dose reduction specifics.

ADVERSE EVENT TABLE FROM LURBINECTEDIN (ZEPZELCA™) FOR SMALL CELL LUNG CANCER PQI⁷

ADVERSE EVENT	SEVERITY	RECOMMENDED ACTION
Neutropenia	Grade 4 or any grade febrile neutropenia	<ul style="list-style-type: none"> Hold until \leq Grade 1 Use G-CSF for neutrophil count $< 500 \text{ cells/mm}^3$ Resume at reduced dose
Thrombocytopenia	Grade 3 with bleeding or Grade 4	<ul style="list-style-type: none"> Hold until platelets $\geq 100,000/\text{mm}^3$ Resume at reduced dose
Hepatotoxicity Grade 2/3/4	Hold until \leq Grade 1	<ul style="list-style-type: none"> Resume at reduced dose

DOSE REDUCTION FOR LURBINECTEDIN FOR ADVERSE REACTIONS FROM LURBINECTEDIN (ZEPZELCA™) FOR SMALL CELL LUNG CANCER PQI⁷

EVENT	RECOMMENDED ACTION
1st dose reduction	2.6 mg/m ² every 21 days
2nd dose reduction	2 mg/m ² every 21 days
3rd dose reduction	Permanently discontinue if unable to tolerate 2 mg/m ² or dose delay greater than two weeks

KEEPING THE FOCUS ON THE PATIENT: PATIENT-CENTERED ACTIVITIES

Since one of NCODA's guiding values is to always be patient-centered, it comes as no surprise that every PQI has a patient-centered activities section. Brandon Dyson, PharmD, BCOP, BCPS of Texas Oncology states, "The PQIs are fantastic. They are well laid out and easy to read. They are patient centric (which is the most important thing), but they cover everything without being overwhelming." It is important to counsel each and every lurbinctedin patient verbally, but to also provide written educational material as well, hitting education from many angles with different modalities. Patient education is the first step in the patient-centered activities section. At the McFarland Clinic, the patient receives patient education from multiple members of the medically integrated team at different times. Melissa Miner, RN from the McFarland Clinic says, "from a nursing perspective this medication is pretty straight forward, but the most important things for nurses to do is to prepare yourself by reading up on the most common side effects, mixing, and administration" in order to allow the day of treatment to go smoothly. Her colleague Andrea Ketcham, PharmD shares, "starting any new therapy is overwhelming. We tell the patients to write down any questions they have once they get home from counseling so that when they come back from treatment, they can bring the questions back for answers." She goes on to say, "the PQIs show us the big things we need to educate these patients on." The next step is to ensure that the patient has access to supportive medications, like antiemetics for at home use. It is also important to counsel female and male patients of reproductive potential of the risk of fetal harm while on lurbinctedin. It is important to ensure effective contraception during treatment and 6 months after the last dose.

The most common adverse reactions ($\geq 20\%$) that are important to educate the patient on are fatigue, thrombocytopenia, nausea, decreased appetite, musculoskeletal pain, constipation, dyspnea, vomiting, cough, and diarrhea. A best practice is to not only educate the patient on the side effect, but to also let them know who to call and when to call the office. Jess Kruckenberg, ARNP of the McFarland Clinic went into detail around the specifics for lurbinctedin patient education. She speaks on at home antiemetic and antidiarrheal use, hydration, and knowing when to call the clinic. She says, "it is just a balance of trying to get the patient to understand that they are going to have some side effects, but there are ways that we can manage them effectively." She goes on to share that

"IT IS JUST A BALANCE OF TRYING TO GET THE PATIENT TO UNDERSTAND THAT THEY ARE GOING TO HAVE SOME SIDE EFFECTS, BUT THERE ARE WAYS THAT WE CAN MANAGE THEM EFFECTIVELY."

Jess Kruckenberg, ARNP

there are ways of managing the side effect of fatigue, which many providers often do not thoroughly educate patients on. Kruckenberg says, "I start with talking about nighttime sleep and sleep hygiene; making sure they get eight hours of restful sleep, have a set bedtime and routine." Other sleep hygiene tips include avoiding TV, phones, and technology with screens an hour before bedtime, avoiding caffeinated beverages in the evening, avoiding alcohol, having a comfortable sleep environment (quiet and cool), getting plenty of physical activity during the day, and dimming the lights 30 minutes before bed. Kruckenberg also states, "it is imperative to emphasize the importance of resting when the patient needs rest. This can be a challenge for the patient to give up certain things in their life, but it is important for the patient and their loved ones to understand that some of those things have to change in order to get rest and to make sure they feel their best." She may go on to discuss other medications to treat fatigue, but often starts with addressing the above mentioned points first.

Another patient-centered activity addressed in the PQI is the need for patient assistance. Financial toxicity is a real and important issue to all patients as cancer care in the United States is quite expensive. According to an article published in the Journal of the National Cancer Institute, "a growing body of evidence supports the existence of financial toxicity resulting from cancer treatment, and recent research suggesting a link between financial toxicity and greater risk of mortality is compelling."⁸ Meaning, that financial toxicity should be on the radar of all involved in the care of a cancer patient. The NCODA Financial Assistance Tool is an NCODA initiative that provides up-to-date and comprehensive financial

[CLICK HERE TO VIEW FINANCIAL ASSISTANCE TOOL](#)

resource information about most chemotherapy and cancer care treatment options. Tool information includes industry coupons, discount cards, and free drug applications, as well as foundation support from charitable organizations. This resource is available in the NCODA member portal (also known as NCODA CONNECT) in a convenient online format and also

as a downloadable Excel spreadsheet. All three practices that are a part of this PQI in Action shared that financial assistance is a very important factor in the patient care journey, affecting the time to treatment. All of this making financial assistance a high priority.

THE VALUE OF THE PQI FROM VARIOUS PERSPECTIVES

When asked about the value of the PQI resource, each participant has slightly different views on what they found to be of the most value. Astrid Slaughter, PharmD, PhD, BCSCP states, “we are always trying to get the most updated information. Pharmacists check the NCODA website quite frequently to see if there any tips on how we can better treat a patient” and this is where the PQI comes in. She goes on to share that the PQI process and the side effect section are particularly of importance to her. Her colleague, Brandon Dyson, PharmD, BCOP, BCPS shares, “I like to see those common clinical nuggets that show up that are going to help a pharmacist on the ground to properly clinically evaluate the drug; making sure that it gives the benefit and reduces the risk of harm to a patient. I want them to be able to catch those drug interactions or to find those dose adjustments.”

“I LIKE TO SEE THOSE COMMON CLINICAL NUGGETS THAT SHOW UP THAT ARE GOING TO HELP A PHARMACIST ON THE GROUND TO PROPERLY CLINICALLY EVALUATE THE DRUG; MAKING SURE THAT IT GIVES THE BENEFIT AND REDUCES THE RISK OF HARM TO A PATIENT.”

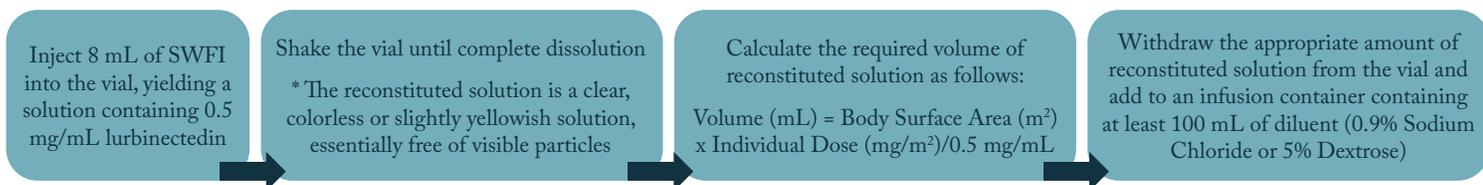
Brandon Dyson, PharmD, BCOP, BCPS

Nurses can play so many different roles in oncology practices; from traditional roles of infusion administration, to education and symptom management, or oral nurse navigators. Nurses are an essential part of the medically integrated team. Melissa Miner, RN of the McFarland Clinic shares that she finds, “the PQIs make it easy to see what pre-medications are needed, what preparation is going to look like, and overall are a good resource.” Kinga Faulkner, PharmD of NYOH shared that nurses at her practice handle a lot of the education of patients, providing a different nursing perspective to the mix. When available, they like to use the Intravenous Cancer Treatment Education (IVE) sheets and the Oral Chemotherapy Education (OCE) sheets for patient education. When speaking about NCODA resources that she finds helpful in practice, Katie Good, PA-C noted, “I always appreciate having patient hand-outs that are both informative and easy to understand. Patients want clear information regarding their diagnosis and treatment options and providing hand-outs is an excellent way to give this education to our patients.”

Kaylee Hart, CPhT of NYOH explained that from a technician’s perspective, “the reconstitution of the medication and the preparation instructions; specifically, the use of sterile water for injection in the reconstitution of the lyophilized powder stands out as the most important part of the lurbinectedin PQI.” Lurbinectedin has a slightly more in-depth preparation process than other products, with many steps; guidance from the PQI can be seen in detail in the graphic.

From the concise length, to the extensive coverage of important information, regardless of the individual’s role on the medically integrated team, it is clear that the PQI fills the needs of all involved. All of which make the PQI a valuable clinical reference document.

MIXING INSTRUCTIONS FOR LURBINECTEDIN.



ALWAYS COLLABORATIVE: NCODA, MEDICALLY INTEGRATED TEAMS, AND THE PQI

The benefits of the Medically Integrated Team for the patient and practices cannot be emphasized enough. By collaboratively working together each member of the team brings a unique perspective to care for the patient, ensuring successful, focused care that keeps the patient at the center. Melissa Miner, RN sums it all up, “my favorite part of my job is the patients! That is what keeps us coming back each day. We have the best patients in the world! They are always so grateful for all that we do for them.” This is just another example of how a medically integrated team goes above and beyond. The focus on the patient

“MY FAVORITE PART OF MY JOB IS THE PATIENTS!”

Melissa Miner, RN

and the relationship is something that can only be found in the Medically Integrated Pharmacy model. Jess Kruckenberg, ARNP states, “seeing these people time and time again is my favorite part of this job. Just building a relationship is great!” Many studies have shown that medically integrated teams lead to superior compliance and patient satisfaction.^{9,10} Just like the goals of the PQI initiative, the medically integrated oncology teams at all three practices involved in this PQI in Action elevate patient care to provide excellent clinical outcomes through positive quality interventions to ultimately help cancer patients.

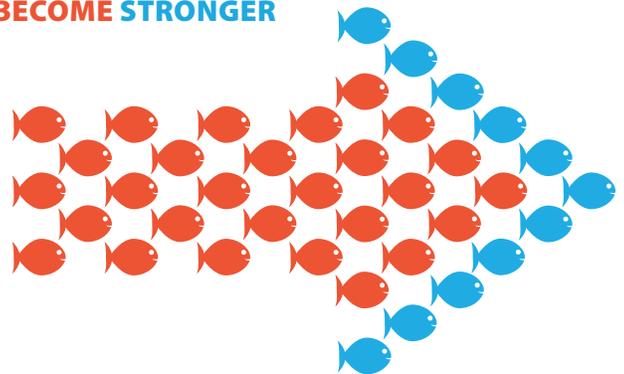
The goal of NCODA is to build a patient-centered medically-integrated community whose focus is to innovate the continuity of cancer care so that every patient receives the maximum benefits from their cancer treatment. Through the



Pharmacy technician Lori Myers, CPhT of Texas Oncology Fort Worth Pharmacy mixing medication for a patient.

use of the **Lurbinectedin (ZEPZELCA™) for Small Cell Lung Cancer PQI** and other NCODA resources members of Texas Oncology, McFarland Clinic, and New York Oncology and Hematology deliver positive, patient-centered outcomes every day.

**WORKING TOGETHER,
WE BECOME STRONGER**



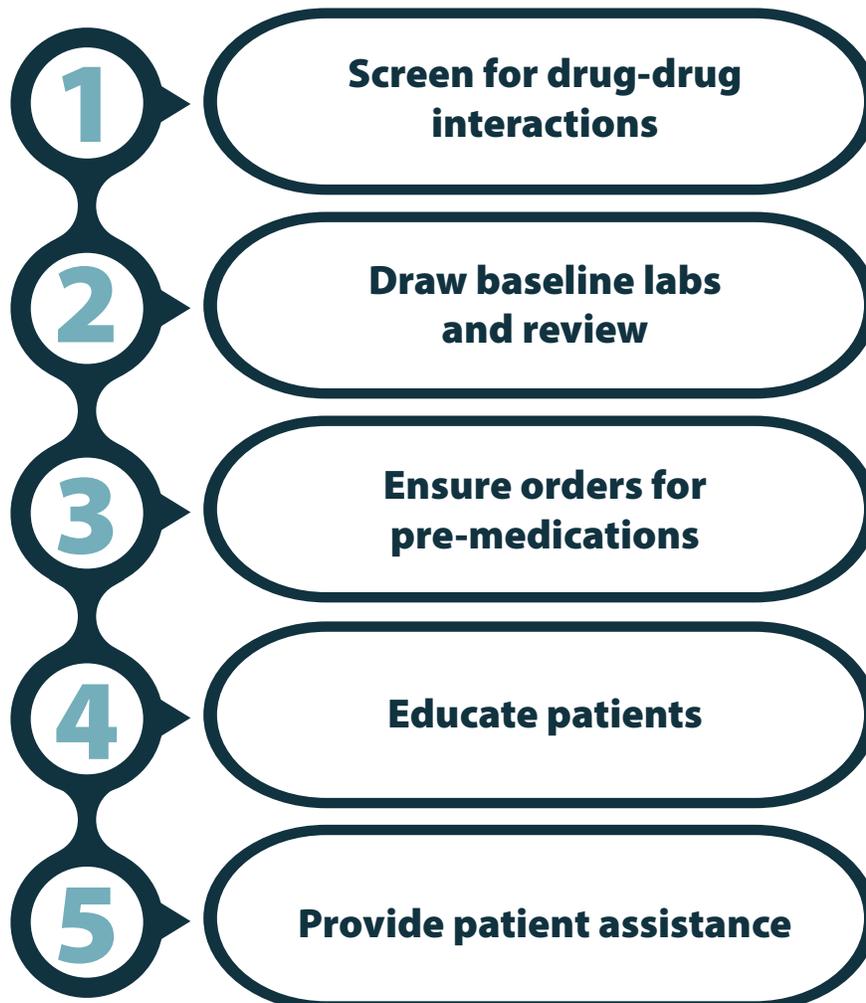
ON THE COVER:

- A McFarland Clinic pharmacy technician mixing medication.

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PQI PRINCIPLES:





Helpful Online Resources

- [Tivozanib \(Fotivda®\) for Relapsed or Refractory Advanced Renal Cell Carcinoma](#)
- [Positive Quality Interventions](#)
- [Intravenous Cancer Treatment Education Sheets](#)
- [Oral Chemotherapy Education Sheets](#)
- [NCODA Website](#)
- [NCODA Financial Assistance Tool](#)

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

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



NCODA'S POSITIVE QUALITY INTERVENTION IN ACTION

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