

PQI IN ACTION



SELINEXOR (XPOVIO®) PATIENT 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 **Selinexor (XPOVIO®) Patient Management PQI** and explores how the medically integrated teams at Rocky Mountain Cancer Centers and Boston Medical Center incorporate PQIs as part of their daily workflow. It will discuss how utilizing the **Selinexor (XPOVIO®) Patient Management PQI** elevates patient care as well as the utilization of NCODA's Selinexor Treatment Support Kit (TSK).

Rocky Mountain Cancer Centers (RMCC) is Colorado's largest and most comprehensive provider of cancer care with 56 physicians, in 18 community-based locations across the state. RMCC is part of The US Oncology Network (USON), one of the nation's largest networks of integrated community-based oncology practices dedicated to advancing high-quality, evidence-based patient care. As part of USON Research, RMCC has played a role in more than 80 FDA approved cancer therapies, nearly one-third of all new cancer therapies approved. RMCC has a medically integrated pharmacy that fills supportive and oncolytic medications for their patients.

Boston Medical Center's (BMC) Cancer Center is part of the main academic medical center serving the community of the New England area. They are Boston's only community-based multidisciplinary oncology practice, comprised of 60+ providers in over 12 specialties. They operate with a comprehensive, multi-specialty team approach to ensure the most up-to-date options and recommendations are offered to patients. Aside from the pharmacy, the center also provides supportive services such as nutrition and genetic counseling.

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POWER OF THE PQI AND MID: PROVIDING PATIENTS NEW OPTIONS FOR TREATING MULTIPLE MYELOMA

Multiple Myeloma (MM) is a fairly uncommon, but ever present cancer risk. The American Cancer Society estimates there will be about 34,920 new cases diagnosed in 2021, with 19,320 in men and 15,600 in women.¹ Relapsed Multiple Myeloma is regarded as a recurrence of the disease after prior response and relapsed/refractory is defined as a disease which becomes non-responsive or progressive on therapy or within 60 days of the last treatment in patients who had achieved a minimal response (MR) or better on prior therapy.²

As the first and currently only FDA-approved XPO1 inhibitor, selinexor's unique mechanism of action mediates transport of the multiple proteins and RNA species within the cells. XPO1 overexpression is a common feature as an oncogenic driver among multiple cancer types. This makes selinexor a hopeful inclusion in the ongoing journey to better the lives of cancer patients.³

In the BOSTON trial, patients with MM who have received 1-3 prior therapies demonstrated an early and sustained progression-free survival benefit with selinexor, bortezomib, and dexamethasone, compared to a regimen of bortezomib and dexamethasone. In the STORM trial, selinexor and dexamethasone demonstrated clinically significant responses in adult patients with Relapsed/Refractory Multiple Myeloma (RRMM) whose disease was refractory to bortezomib, carfilzomib, lenalidomide, pomalidomide, and daratumumab.

In order to maximize the utility of therapy, the **Selinexor (XPOVIO®) Patient Management PQI** Process section goes in depth into proper prophylaxis and dose modification based on prior study data. Based on the studies, the PQI demonstrates the potential need and ability to keep a patient on beneficial therapy while minimizing the adverse events associated.

Selinexor can be dispensed and managed by the practice site's Medically Integrated Team, which provides patients a more comprehensive care experience. NCODA defines Medically Integrated Dispensing (MID) as a dispensing pharmacy within an oncology center of excellence that promotes a patient-centered, multidisciplinary team approach. The MID is an outcome-based collaborative and comprehensive model that involves oncology healthcare professionals and other stakeholders who focus on the continuity of coordinated, quality care and therapies for cancer patients.⁵ The MID

“FOR A LOT OF MEDICATIONS THE PROVIDERS LEAN ON US TO SEE IF WE CAN DIVE DEEP ON EFFICACY DATA BEFORE THEY MAKE A DECISION ON THE BEST TREATMENT OPTION FOR THE PATIENT.”

Ryan Adler, PharmD

model is the evolution of effective patient and medication management which involves enhancements in communication, adherence measurement, regimen management, speed to therapy, and financial assistance, which results in cost avoidance, and less waste produced by the health care system.⁶

NCODA as an organization provides access to multiple tools and educational resources that the MID practice can utilize when managing oncolytics. Resources include a customizable Patient Survey, a Cost Avoidance and Waste Tracker tool for logging expenses saved through proactive practice management, a Financial Assistance database for locating additional funds, Treatment Support Kits, Oral Chemotherapy Education Sheets (OCE) Sheets and IV Chemotherapy Education Sheets (IVE), and of course the Positive Quality Intervention clinical resources. RMCC Oncology Pharmacist Melissa Shimanek, PharmD mentions, “the team utilizes the resources to make sure we have appropriate measures for prepared prescribing and we use the OCE sheets as well for patient education. Both PQIs and OCEs have been beneficial to make sure that you know the proper protocols are being addressed, or you know issues that may not be thought about first are considered.”

THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

This article will help showcase the benefits of PQI utilization as a core standard of the MID and how adoption in any form is beneficial for practices and patients. Rocky Mountain Cancer Centers and Boston Medical Center have both found different yet successful ways to incorporate the PQI clinical resource. Each practice utilizes their Medically Integrated Team to provide optimized treatment management to increase compliance and to attempt to maximize clinical outcomes for the patient. We will take a look specifically at their MID settings, how implementing the **Selinexor (XPOVIO®) Patient Management PQI** benefits their staff and patients, and how they advance patient care on a daily basis.

[CLICK HERE
TO VIEW
THIS PQI](#)

“THE PQI IS A VERY SHARP SUMMARY ABOUT INDICATION AND OF THE MAIN SIDE EFFECTS AND I FIND IT VERY HELPFUL.”

Raphael Szalat, MD, PhD

“THE PQI CONTAINS A LOT OF INFORMATION THAT I LOOK UP DAY-TO-DAY. SOMETIMES FINDING THIS INFORMATION IS LIKE DIGGING THROUGH THE WEEDS, SO HAVING A DOCUMENT WHERE IT IS EASILY AND READILY AVAILABLE IS WONDERFUL.”

Amy Wall, NP-C



RMCC Pharmacist, Melissa Shimanek, PharmD, fills a prescription for a patient.

MEDICALLY INTEGRATED DISPENSING: ELEVATING CARE

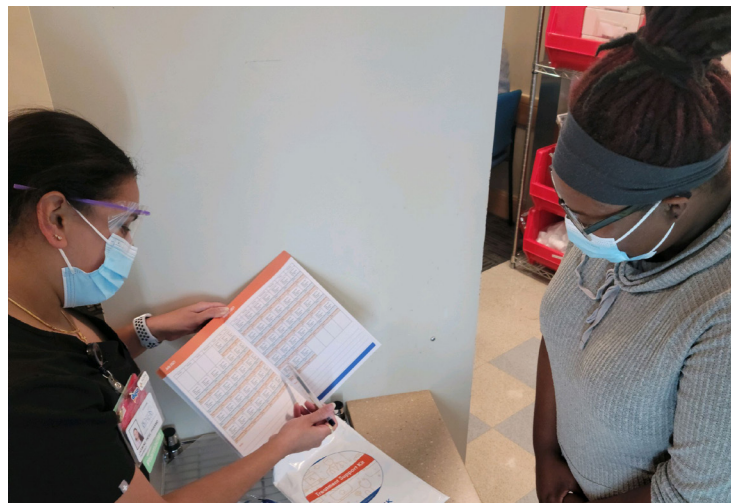
Cancer treatment has rapidly expanded in the last decade with regimens growing in variety and complexity for IV, oral and now combination regimens. The MID provides a successful model to manage this growing deluge of options in the world of cancer care. The MID staff have access to patient information and data,

this coupled with the direct member communication with the rest of the multidisciplinary team, is an incomparable asset when evaluating other patient management alternatives. With direct communication with patients, the MID team can easily record patient reported outcomes back to the clinical staff for triage.

The fragmentation of care is greatly reduced by these improvements. BMC Oncologist-Hematologist and Director of Multiple Myeloma Program Raphael Szalat shares, “in my opinion, and this is our practice here, the pharmacist is very central. As soon as we decide that we need to start a new treatment, we involve a pharmacist in our decision.” BMC physician assistant Frances Blevins, PA-C agrees and says “it has been amazing having pharmacy onsite. Almost all of the providers feel the same way, that we really would not be able to do our job as well without clinical pharmacists around and without having pharmacy around for this extra support.”

On the benefits of MID in direct patient care, RMCC Pharmacy Manager Ryan Adler, PharmD shares, “I have a lot of patients that are nervous starting a medication in general, it doesn't matter which medication. On top of that I am giving the patient information that either they are not 100% comfortable writing down, or they don't want to miss anything so they want to write down every word. So it is really nice to be able to share with them that ‘everything I'm speaking about is going to be sent in writing. I'm going to hit the highlights for you, but feel free to go over anything that's been sent.’” He adds, “they have all the other data at their fingertips and you can almost feel the sigh of relief when I tell them, it's really

nice.” BMC Specialty/Oncology Pharmacy Liason Shefena Gebremeskal, CPhT discusses the many issues their team and patients encounter with mail order pharmacy including lack of follow-up and delays in treatment. She says MID makes it “easier for the patient to receive their medications and start treatment.”



Staff members at Boston Medical Center review the treatment calendar found in NCODA's TSK resource when dispensing selinexor to a patient.

PUTTING THE SELINEXOR (XPOVIO®) PATIENT MANAGEMENT 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, which are an NCODA Quality Standard, are designed to optimize and standardize best practices to achieve positive clinical outcomes. The Selinexor Patient Management PQI is written in sections beginning with a description

and ending with patient-centered activities and references.

Following the description, the background section gives general information to provide context to the main process of the intervention. Regarding selinexor, the background discusses mechanism of action as discussed earlier and the indications of the drug. Dr. Szalat shares that the clinical practice at BMC is of course mainly based on the clinical trials and published data and thus the FDA approved indications.

SELINEXOR IS INDICATED⁴:

- 1 In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy
- 2 In combination with dexamethasone, for the treatment of adult patients with relapsed refractory multiple myeloma (RRMM) who have received at least 4 prior therapies and whose disease is refractory to at least 2 proteasome inhibitors (PI), at least 2 immunomodulatory agents (IMiD), and an anti-CD38 monoclonal antibody (mAb)
- 3 For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy

THE PQI PROCESS: A TEAM EFFORT

The next section of the **Selinexor (XPOVIO®) Patient Management PQI** is the PQI Process. This section is built to be a quick and organized read in step-by-step instructions, containing directed guidance and critical clinical criteria that can benefit the entire team. The first step of the **Selinexor (XPOVIO®) Patient Management PQI** Process states to confirm appropriate dosing of selinexor with the consideration of its many indications and various usages in regimens.

The PQI process continues with ensuring proper dispensing of prophylactic medications to the patient per the specific regimen. Gebremeskal shares this is a part of the PQI she finds very beneficial in her role as pharmacy liaison. In obtaining prior authorizations for medications she says it is helpful to know the other medications that may be part of the patient's regimen. This section of the PQI also discusses the need to maintain adequate fluid and caloric intake throughout treatment and that IV hydration can be a consideration for patients at risk of dehydration. Blevins shares that patients with gastrointestinal toxicities often decrease their oral intake significantly and can require fluid support and electrolytes.

BMC clinical pharmacy specialist Jasmine Patel, PharmD, BCOP shares that her clinic has a referral set in their EMR system for all oral oncolytics. As part of this set, their setup gives the pharmacist collaborative authority to prescribe the oncolytic and any supportive care medications under the provider. Patel goes on to share that as part of the order set for selinexor her clinic is typically giving patients a long acting NK1 receptor antagonist as well as prochlorperazine or ondansetron as needed depending on various patient factors. They also ensure the patients have loperamide for prophylactic use if needed. RMCC Nurse Practitioner Amy Wall, NP-C shares that the RMCC EMR system also has a regimen builder, but she most often consults NCCN guidelines directly for specific antiemetic regimens.

The PQI Process then goes on to list monitoring patients for the following common side effects reported in the various trials. The selinexor side effects that the PQI highlights include cytopenias, nausea, vomiting, diarrhea, fatigue, weight loss, and hyponatremia.⁷ Ryan Adler, PharmD mentions their process for more at risk adverse effects, “we perform a three day follow up on those at risk for adverse effects. The follow up discusses how the patient is taking the medication, ensures they know how to take the medication properly, and that the patient is taking it properly with regard to with or without food.”

Adler also discusses the process that RMCC patient care nurse Carrissa Ross, RN, BSN, OCN has and says “she is also following up with side effect management including asking if patients are experiencing any side effects and what to expect. She is asking if the patient has any questions for a pharmacist so she can transfer the phone call to us or let us know that we need to call a patient back. The patient may need to visit the clinic themselves to see if there is any specific information that the clinic needs to know. She knows what clinicians need to be aware of so is a great liaison there. She follows up two weeks later, on day 21, to see how the patient is doing and to make sure everything is still going smoothly. She also sets up the first refill for the patient at that time if they are ready for it.”

COMMON SIDE EFFECTS REPORTED⁷:

- Cytopenias (thrombocytopenia, anemia, neutropenia)
- GI intolerance (nausea, vomiting, diarrhea)
- Fatigue
- Weight loss
- Hyponatremia
- Potential side effects involved with utilizing bortezomib in combination (peripheral neuropathy, blurred vision)

After the monitoring point in the PQI Process, there is a large table outlining potential dose modifications for adverse reactions and how to adjust the dose for particular regimens. At RMCC, Ross says knowing the potential adverse reactions that may require dose adjustments is valuable. She says knowing what patients may experience helps her determine potential red flags when speaking with patients. This allows her to take the information to the provider to make decisions regarding treatment. Erin Woodard, CPhT is the Senior Pharmacy Technician in the MID at RMCC and finds the dosing information a useful part of the PQI. In her role she helps in many areas including making adherence calls, packing and shipping, inbound prescriptions and inventory. It is helpful in her role to know that selinexor is available in 20 mg, 40 mg, 50 mg and 60 mg tablets.⁴

XD DOSE REDUCTION STEPS FOR RR-MM ADVERSE REACTIONS

Selinexor starting dose	1 st Reduction	2 nd Reduction	3 rd Reduction	
80 mg <u>Days 1 and 3</u> of each week (160 mg total per week)	100 mg ONCE Weekly	80 mg ONCE Weekly	60 mg ONCE Weekly	Discontinue

XVD DOSE REDUCTION STEPS FOR MM ADVERSE REACTIONS

Selinexor starting dose	1 st Reduction	2 nd Reduction	3 rd Reduction	
100 mg <u>ONCE Weekly on Day 1</u> of each week (100 mg total per week)	80 mg ONCE Weekly	60 mg ONCE Weekly	40 mg ONCE Weekly	Discontinue

DOSE REDUCTION STEPS FOR RR-DLBCL ADVERSE REACTIONS⁵

Selinexor starting dose	1 st Reduction	2 nd Reduction	3 rd Reduction	
60 mg <u>Days 1 and 3</u> of each week (120 mg total per week)	40 mg Days 1 and 3 of each week (80 mg total per week)	60 mg ONCE Weekly	40 mg ONCE Weekly	Discontinue

The final point of the PQI Process section discusses additional adverse effects of note to watch out for including gastrointestinal, hyponatremic, and weight loss effects. Both MID pharmacies screen patients for interactions and the potential for side effects. Patel shares that pharmacy is often on the front lines in managing patient adverse events. She says “our patients usually call us first for any toxicity and side effects because they know they can reach someone right away. Having the pharmacy directly in the clinic shortens the time for addressing and managing side effects.”

“OUR PATIENTS USUALLY CALL US FIRST FOR ANY TOXICITY AND SIDE EFFECTS BECAUSE THEY KNOW THEY CAN REACH SOMEONE RIGHT AWAY. HAVING THE PHARMACY DIRECTLY IN THE CLINIC SHORTENS THE TIME FOR ADDRESSING AND MANAGING SIDE EFFECTS.”

Jasmine Patel, PharmD, BCOP

PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

The Patient-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. The **Selinexor (XPOVIO®) Patient Management** PQI Patient-Centered Activities suggests providing the patient with an Oral Chemotherapy Education sheet. OCE sheets are an NCODA-led initiative

[CLICK HERE TO VIEW THIS OCE SHEET](#)

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.⁹ 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.⁹

The Patient-Centered Activities section also discusses selinexor administration. Patients receiving selinexor should be aware if they require any applicable prophylactic medication such as dexamethasone for RR-MM or an anti-emetic as selinexor is classified as moderate to high emetogenicity. Wall shares it is important to educate patients on side effect management and watching for interactions or concerns about bleeding. She also talks to patients about the management of nausea. She says, “most of these patients are pretty experienced in the management of nausea and know how to use antiemetics, but all of that is certainly reinforced as part of the education session.

**“WE ARE AGGRESSIVE IN TERMS
OF PREVENTION WITH SELINEXOR
BECAUSE WE KNOW IT CAUSES
NAUSEA AND VOMITING.”**

Raphael Szalat, MD, PhD

Dr. Szalat shares that since their team knows the treatment can come with a lot of nausea, vomiting or diarrhea they often have pharmacists call the patients to check on them, especially during the first two weeks of therapy, which he shares is most critical. He says BMC has their own protocol with the medication and works closely with pharmacy to enact the protocol. He adds “we are aggressive in terms of prevention with selinexor because we know it causes nausea and vomiting.” For more instruction on chemotherapy induced nausea and vomiting management, there is a PQI that delves more in-depth to manage all cancer medication related side effects (<https://www.ncoda.org/chemotherapy-induced-nausea-and-vomiting/>).

The Patient-Centered Activities also gives guidance on educating patients to take the tablet whole with water, and that the tablet should not be broken, chewed or crushed. It also speaks to the importance of proper monitoring of body weight and blood testing. It is important that the patient is aware of maintaining adequate fluid and caloric intake throughout treatment.

Adler shares that one of the most important points educational points for patients taking selinexor is education on the potential for diarrhea. Diarrhea was reported as a common side effect. Adler shares, “I think the biggest thing I always talk with patients about when starting selinexor is that diarrhea is something that if left untreated can be pretty severe. We want to make sure that diarrhea is covered, so we always talk about having an anti-diarrheal medication on board and making sure the patient is aware of what to do. We do not want the patient to end up excessively dehydrated or to have other issues.”

A Patient-Centered Activity point to note is the recommendation of a selinexor Treatment Support Kit which provides antidiarrheal agents to have on hand when starting selinexor. According to Adler, RMCC pharmacists offer patients starter kits when starting on a new therapy. The pharmacist will review the contents of the starter kit and the potential side effects of the medication with the patient. In the case of selinexor and potential diarrhea the pharmacy team gives the patient instructions on when they would need such as calling the pharmacy or physician if any major changes occur. The practices proactively give the patient an idea of what to anticipate and emphasize the importance of describing the side effects on a patient level.

The National Institutes of Health (NIH) define plain language as grammatically correct language that includes complete sentence structure and accurate word usage.⁹ According to NIH, using plain language avoids creating barriers that set us apart from the people with whom we are communicating.⁹ Patel shares that at BMC the pharmacists are providing the bulk of the patient education on oral oncolytics. She explains that making sure the patient understands the potential side effects of selinexor and when to call the pharmacy or provider is vital. She says by this point in treatment patients often understand the role of the medication and how it is helping the patient keep their malignancy in check. She shares that focusing on side effects and how to manage them helps the patient use the medication as long and as safely as possible.

TREATMENT SUPPORT KITS: A VALUABLE RESOURCE FOR PATIENTS

In addition to close follow up and detailed education, MID's have the ability to provide excellent supportive care in the form of TSKs or Treatment Support Kits. An effective option for practices where unbranded materials and products are welcomed, TSKs are offered as an additional resource full of education and functional materials. Within the selinexor kit, patients receive the following:

- Resealable bag to hold contents
- Treatment booklet (with Oral Chemotherapy Education sheet)
- Treatment calendar
- Loperamide hydrochloride caplets (2 mg x 24 caplets)
- Collapsible water bottle
- Thermometer

The ability to provide these items is unparalleled as they offer another source of information that is fully approved by the practice staff for patient use.

Treatment Support Kit provisions allow for a one-stop resource that educates and assists in the MID's process with regimen and adverse effect management. Following the Patient Centered Activities, the **Selinexor (XPOVIO®) Patient Management PQI** is included with a shipment of these

TSKs so that the practice is given the full complement of educational resources for both the practice and the patient's benefit. MID pharmacies can now have their dedicated staff supported in helping patients remain at ease with their cancer journey. Each kit has been clinically reviewed by MID teams within the vast NCODA community and customized specific to the respective medication in order to provide a tailored patient experience.

Shimanek shares "I think Treatment Support Kits and OCE sheets are vital to provide to the patient. Not everyone is going to remember everything over the telephone or when talking in person so it is important to have information in print form." She adds the treatment support items are helpful to have so the patient does not have to go out and get them prior to starting therapy, it is convenient for them to have the items on hand.

**"I THINK TREATMENT SUPPORT KITS
AND OCE SHEETS ARE VITAL TO
PROVIDE TO THE PATIENT."**

Melissa Shimanek, PharmD

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

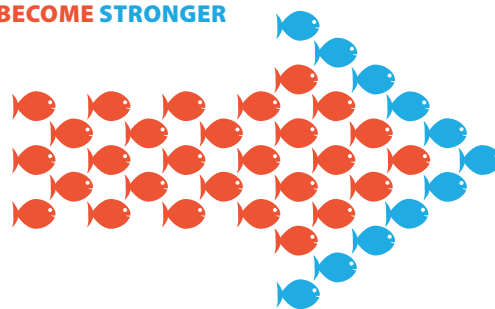
All team members from both BMC and RMCC agree that the MID model and the NCODA PQI and TSKs are valuable clinical resources to the team and to patients. The MID team is the future of cancer care and health care in general, because a proactive change makes for a significant difference in a patient's life. Woodard shares that the MID model is really great for patients. "We have access to their EMR and we are able to have a better, more personal relationship with them. We build a rapport so the patients trust us and it is great all around." With cancer drugs and regimens being approved in

what seems to be on a regular basis, the MID team always has an opportunity to stay up to date on new processes and stocked with resources that can help optimize care. The **Selinexor (XPOVIO®) Patient Management PQI** furthers this proactivity with appropriate clinical considerations to increase adherence and speed to therapy, reduce cost, and reduce hospitalizations in order to improve patient health outcomes.

Selinexor gives patients a new option as an XPO1 inhibitor for MM, RR-MM, and RR-DLBCL treatment regimens. The PQI gives each MID program an accessible, pick-up-

and learn compact clinical resource guide for dispensing and managing patients on selinexor. It reinforces the team's desire to provide their practice with the tools and education they need to succeed at taking care of their patients. Combining Medically Integrated Dispensing with the **Selinexor (XPO-VIO®) Patient Management PQI** and TSK meets NCO-DA's Guiding Values of being Patient-Centered and Always Collaborative.

**WORKING TOGETHER,
WE BECOME STRONGER**



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Helpful Online Resources

 [NCODA Website](#)

 [Oral Chemotherapy Education Sheets](#)

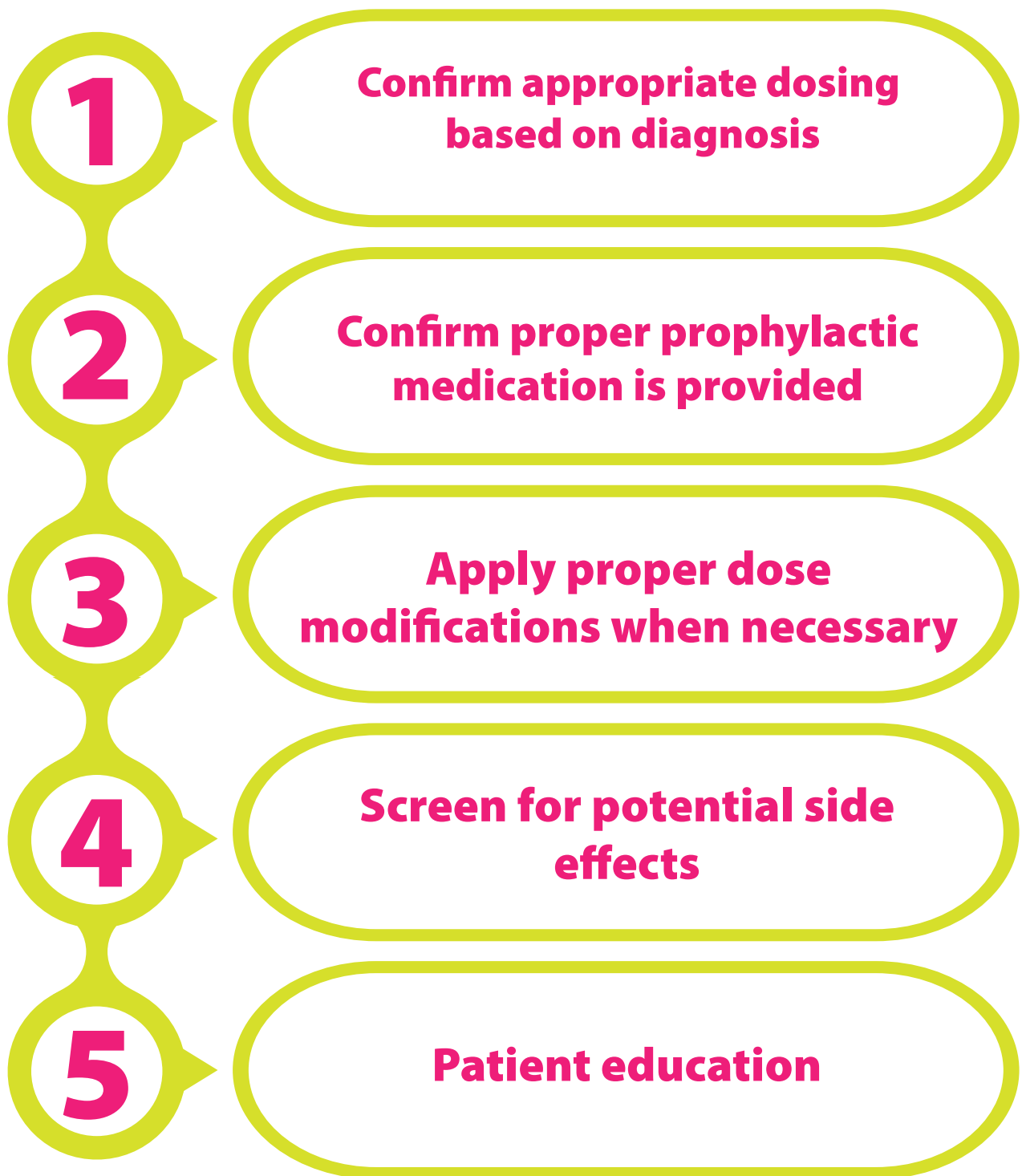
 [Are you interested in authoring a PQI?](#)

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 [Selinexor PQI](#)

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PQI PRINCIPLES:



ON THE COVER:

- Team members at Rocky Mountain Cancer Centers work together to provide exceptional patient care.



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.



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