PQI IN ACTION

ANDROGEN DEPRIVATION THERAPY WITH RELUGOLIX (ORGOVYX®) PQI

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 Androgen Deprivation Therapy with Relugolix (ORGOVYX®) PQI and explores how the medically integrated teams at SUNY Upstate University Medical Center, Vanderbilt University Medical Center, and Los Angeles Cancer Network incorporate the information found in the PQIs as part of their daily workflow. This article will discuss how utilizing the Androgen Deprivation Therapy with Relugolix (ORGOVYX®) PQI elevates patient care.

SUNY Upstate Cancer Center provides outpatient hematology/oncology services in a 17-county radius around Central New York (NY), including Syracuse, Oneida, and Oswego. They are renowned for their exceptional range of services and remarkable achievements in the field of cancer care. Offering comprehensive, state-of-the-art treatments and support, the center provides patients with cutting-edge therapies, personalized care plans, and a multidisciplinary approach that addresses all aspects of cancer management. Their dedication to patient-centered care and collaboration with leading experts in the field have established SUNY Upstate Cancer Center as a beacon of hope and excellence in the battle against cancer.

Vanderbilt-Ingram Cancer Center is a National Cancer Institute (NCI)-designated Comprehensive Cancer Center located in Nashville, Tennessee (TN). Vanderbilt-Ingram is one of only two NCI-designated Comprehensive Cancer Centers in TN and 51 in the country to earn this prestigious distinction. Vanderbilt-Ingram Cancer Center ranks in the top 10 nationwide for cancer research. Their mission is to alleviate cancer death and suffering through pioneering research, innovative, patient-centered care, and evidence-based prevention, education, and community activities. Vanderbilt-Ingram's world-renowned team of experts is committed to providing a personalized, integrated, and patient-centric approach to cancer treatment, research, support, education, and outreach.

Los Angeles Cancer Network is a compassionate care team, serving the greater Los Angeles (LA) area for more than three decades. With more than 13 offices, LA residents can find convenient and thoughtful hematology/oncology care from the most devoted group of medical professionals. Los Angeles Cancer Network's mission is to provide unparalleled care to each patient that walks through their doors. They offer individualized treatment using the latest advancements in cancer care and are committed to educating and supporting patients and families through every step of the cancer journey. Los Angeles Cancer Network is a proud partner of OneOncology, a customizable technology that enables oncology practices to grow, provide services, and incorporate the latest scientific developments.
Prostate cancer is the second most common cancer among men in the United States. This cancer is fueled by male hormones called androgens, which stimulate prostate cancer cells to grow. Androgen deprivation therapy (ADT, or hormone therapy) uses surgery or medicine to lower androgen levels in the body. Types of ADT include orchiectomy (surgical castration), luteinizing hormone-releasing hormone (LHRH) agonists, and LHRH antagonists. ADT is commonly used in prostate cancer and is often one of the first types of hormone therapy that most men with prostate cancer receive.

Relugolix (ORGOVYX®) is an oral LHRH antagonist that decreases prostate cancer cell growth. Also known as a gonadotropin-releasing hormone (GnRH) receptor antagonist, it works by blocking pituitary GnRH receptors, which reduces the release of luteinizing hormone (LH), follicle-stimulating hormone (FSH), and ultimately testosterone. Approved in December 2020, relugolix is the first and only oral GnRH receptor antagonist approved for use in advanced prostate cancer. Degarelix (Firmagon®) is another LHRH antagonist option, but it is only available as a subcutaneous injection.

Relugolix was FDA-approved based on the phase 3, multinational, randomized, prospective HERO trial, comparing relugolix (120 mg orally once daily after a single 360 mg loading dose) to the LHRH agonist leuprolide (22.5 mg every 3 months [11.25 mg in Japan and Taiwan]) for 48 weeks. Relugolix provided sustained castrate-level testosterone suppression (<50 ng/dL) for 48 weeks in 96.7% of patients compared to 88.8% of patients receiving leuprolide. Relugolix was found to be both non-inferior and superior to leuprolide. In addition, relugolix provided more rapid testosterone suppression and a lower risk of major adverse cardiovascular events compared to leuprolide. The National Comprehensive Care Network (NCCN) guidelines include relugolix as an option for ADT in patients with castration-sensitive disease in both the early and advanced setting. It’s important to note the HERO trial did not include patients receiving curative intent therapy. Although NCCN considers relugolix an ADT option in the curative setting, more studies are needed to confirm its effect in this patient population.

Data on long-term adherence to relugolix and the potential effects of non-adherence on optimal ADT is limited. Relugolix adherence in the HERO trial was >99% highlighting the importance of patient monitoring programs to achieve outcomes similar to clinical studies.

Meredith Donahue, ARNP, nurse practitioner with the Urology Department at Vanderbilt regularly prescribes relugolix and hasn’t noticed any adherence issues. “But it would be pretty easy to catch, because we can check testosterone and see. If their testosterone is not low, then we would know to investigate with the patient.”

This might be because Vanderbilt (as well as SUNY Upstate and Los Angeles Cancer Network) have patient monitoring programs in place to ensure adherence. Whether it’s a pharmacy database monitoring system or an institution-created process, all three institutions monitor adherence by making monthly refill calls. Stephanie White, PharmD clinical pharmacist at Vanderbilt says, “I like that we have a very proactive approach. We do rely heavily on our technicians to manage the refills. Our system drops refill renewals at the 14-day mark, and then we’ll start calling seven to ten days before the patient should be out of their medication. There’s also a survey that they are asked with their refill, so we can ensure that we’re constantly checking in with how the patient is doing.”

Relugolix 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.
The MID model can improve management of patients on therapies like relugolix 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. Donahue recognizes the value of having pharmacists integrated within the clinic. “I could not do what we do without our pharmacists. The pharmacists are probably who I talk to the most because they are the experts in these medications. We all know how to use them clinically, but as to how the medications work and side effects and all those things, the pharmacists are the first ones I go to. So I think that is how use them most. But then I think of a hundred different ways I use them. We lean on them.”

NCODA offers multiple tools to aid the MID practice in managing oncology. This toolbox contains a Patient Satisfaction Survey that is practice-customizable, a Cost Avoidance and Waste Tracker tool, a Financial Assistance database, Treatment Support Kits, Oral Chemotherapy Education sheets, and of course the Positive Quality Intervention clinical resource documents.

**THE POSITIVE QUALITY INTERVENTION:**  
**A VALUABLE CLINICAL RESOURCE**

Shaina Ghermezi, PharmD, oncology pharmacist within the IOD Department at Los Angeles Cancer Network comments on the value of the PQI. She says, “I do find it valuable. I appreciate that it is in bullet point formation and that it goes through all the important points of ORGOVYX®. I like that it is more to the point and something you can look through without having to read through pages and pages of education.” The easy-to-read format and concise nature of the PQI is a resounding theme throughout all three institutions. Rachel Bullock, patient care coordinator at SUNY Upstate outpatient specialty pharmacy thinks, “It’s very accessible. It’s pulling out the pieces of information that are pertinent, but it’s just nice to have everything in one place and just more concise.”

This article will explore the benefits of PQI utilization as a core standard of the MID and how adoption can benefit any practice. SUNY Upstate, Vanderbilt, and Los Angeles Cancer Network have each found successful ways to incorporate the PQI clinical resource. All three of these practices position their Medically Integrated Teams in a way to ensure appropriate treatment, increase compliance, and maximize clinical outcomes. We will explore their practice settings, how implementing the Androgen Deprivation Therapy with Relugolix (ORGOVYX®) PQI benefits their staff and patients, and how they advance patient care on a daily basis.

The PQI can be utilized in multiple ways. Abigail Alley, PharmD clinical oncology specialty pharmacist at SUNY Upstate finds them useful in her patient counseling sessions. She says, “I always just do a quick glance through to ensure nothing is forgotten. They are laid out nicely to flow through a conversation. When I was new, these things were the things I was going to every single time to guide my counseling and explanation of the drug to the patients. It just lays it out in a really nice flow.”

PQIs aren’t just valuable for pharmacists, but for all members of the team that take care of patients on relugolix. Vache Sharyan, PharmD, MHA, BCPS, APh, Senior Director of Operations and Pharmacy Services at Los Angeles Cancer Network notes that nurses can also benefit from the PQI. He says, “It is a really good educational piece not only for the pharmacist or physician, but I think it’s a really good educational resource for the nurses. Because these patients come into the clinic and see nurses and other clinical staff more often, and patients always ask nurses questions.”
As cancer treatment continually grows in complexity containing IV, oral and combination regimens, MID continues to offer an invaluable option for patient care. The MID and multidisciplinary staff have 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.

Collin Dempsey, PharmD, BCPS, specialty pharmacist at SUNY Upstate likens medically integrated dispensing to having your own concierge pharmacist. He says, “Regardless of whether they have cancer or not, I wish that every patient, even if they aren’t on a specialty medication, could get 24 hours a day, 7 days a week access to a clinical pharmacist. That’s a very personal relationship.” He goes on to say, “Having that relationship, having the time, the resources and having the charts, progress notes, and all that information at our fingertips being integrated within the medical center really allows a much higher level of care than I could have ever imagined.”

SUNY Upstate, Vanderbilt, and Los Angeles Cancer Network all see decreased prescription turnaround time and accelerated access to relugolix as a huge benefit to MID. The pharmacists at SUNY Upstate make sure to resolve relugolix prescription issues and do a full clinical review while awaiting prior authorization. Alley mentions, “That way, when it’s approved, we’re ready to hit the ground running and get the med to them as soon as possible. We pride ourselves here on turnaround time of how quickly we get the script received and then in the patient’s hands.” Even if the prescription has to be sent to an outside specialty pharmacy due to insurance requirements, the pharmacists at Los Angeles Cancer Network make an effort to decrease turnaround time in other ways. Ghermezi says, “We actually follow through on the prescription until we confirm that the patient has received it or that they’ve set up delivery.”

Assisting the patient throughout the entire prescription approval process is critical in enhancing the patient experience. Jared Crumb, PharmD clinical pharmacist at Vanderbilt says, “We’re doing all the legwork to drastically reduce the burden to the patient from a mental and financial aspect.” He also mentions that another benefit of MID is having access to the electronic medical record and the rest of the healthcare team. “We can reach out to the patient and everything’s transparent there which I think helps with patient outcomes as well as how successful they may be on therapy.”

MEDICALLY INTEGRATED DISPENSING: ELEVATING CARE
PUTTING THE ANDROGEN DEPRIVATION THERAPY WITH RELUGOLIX (ORGOVYX®) 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 Androgen Deprivation Therapy with Relugolix (ORGOVYX®) PQI is written in sections, beginning with a Description and ending with Patient-Centered Activities and References.

Following the description, the background section gives pertinent historical data and information, clinical trial experience, and the main focus of the intervention. Regarding relugolix, the background discusses the mechanism of action, indication, and published data leading to approval. The background also discusses pertinent adverse effects, special patient population considerations, and the importance of adherence to achieve optimal outcomes.²

“MOST OF OUR PROVIDERS ARE DOING THAT PART OF THE COUNSELING, GIVING THEM THE INFORMATION ABOUT WHAT WAS SEEN IN TRIALS. BUT WE DO STILL HAVE PATIENTS ASK US FOR THAT. SO HAVING THIS QUICK, GO-TO GUIDE THAT GIVES THE NUMBERS SEEN IN TRIALS I THINK IS VERY HELPFUL.”

Stephanie White, PharmD
Clinical Pharmacist

THE PQI PROCESS: A TEAM EFFORT

The next section of the Androgen Deprivation Therapy with Relugolix (ORGOVYX®) PQI is the PQI Process. This section lays out the intervention in step-by-step points, contains clinician directed guidance, and critical clinical criteria that can benefit the entire team.

The first step of the Androgen Deprivation Therapy with Relugolix (ORGOVYX®) PQI includes identifying patients who are appropriate for treatment with relugolix. The PQI process continues with dosing information, drug interaction management, and monitoring parameters.

Dempsey notes that his providers utilize relugolix for multiple reasons. “I think we have a good population of younger patients with prostate cancer, who are intrigued by the ability to have testosterone levels rebound after therapy, which really doesn’t happen with classical Lupron®. There has been some data to suggest a quicker onset to reduction in testosterone. And then sometimes there is something lost in the transition of starting somebody on Lupron® and bicalutamide. We have had patients state that bicalutamide might get sent out to a retail pharmacy offsite, the refill request comes through, and...
they end up with two or three months of bicalutamide. So, I think ORGOVYX® avoids a lot of those pitfalls. And some of the new data suggesting that it is more beneficial in patients with cardiovascular risk. I think we have most patients that are male over the age of 55 with new onset prostate cancer, and a lot of them are going to have a cardiac risk factor.” The PQI also highlights these factors to assist practitioners in selecting patients most appropriate for relugolix.

Dr. Sharooz Eshaghian, MD, hematologist/oncologist at Los Angeles Cancer Network says he tries to use it for most of his patients if they have prescription coverage. He states, “When Firmagon® came out, which is a direct androgen blocker compared to Lupron®, I was a big proponent of it because I saw many of my patients had less side effects (hot flashes, fatigue, memory fog) and it also has a better cardiovascular profile. But the problem with Firmagon®, was after a few doses, it became really hard to inject.” Patients wanted to switch to Lupron® because it was injected every 3 to 6 months compared to monthly. He goes on to say, “I think ORGOVYX® was a game changer because you get the benefits of Firmagon®, but in a pill form.”

Relugolix is metabolized by cytochrome p450 3A4 (CYP3A4) and can be affected by alterations in P-glycoprotein (P-gp) function. Drug interaction management is another key piece of the PQI process in ensuring the safe and effective use of relugolix. When reviewing new relugolix prescriptions, Brooke Looney, PharmD, CSP, clinical specialty pharmacist at Vanderbilt University Medical Center says “We are looking at the main drugs that interact with relugolix, your CYP3A4 inducers, your P-gp inducers, your P-gp inhibitors, your QT prolonging agents. A lot of these patients do have comorbidities, where they will be taking other medications. Especially cardiovascular medications. And then obviously these patients with prostate cancer could be on anti-androgens. We’ve called several times where the patient is on apalutamide, so we need to adjust the dosing on ORGOVYX®.” Follow-up calls on refills are another opportunity to manage drug interactions. She says, “If the patient mentions that they have had a change in their medication list, it is another key time where pharmacists can review to see if the change is on their medication list and if it has any drug interactions.”

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 Androgen Deprivation Therapy with Relugolix (ORGOVYX®) PQI Patient Centered Activities suggests providing the patient with an Oral Chemotherapy Education (OCE) sheet. OCE sheets are NCODA-led initiatives that provide information about oral chemotherapy and hormone therapy 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.

All three institutions see the tremendous value in ensuring that a patient is counseled prior to initiating relugolix. Looney emphasizes, “Every patient gets a call from a Vanderbilt specialty pharmacist to go over initial counseling, whether they’ve received counseling from their provider or nurse, practitioner or other. We’ve got a hard stop where delivery doesn’t happen unless there’s a pharmacist counseling note in place.” Sharyan echoes the importance of the Los Angeles Cancer Network pharmacy team reinforcing education even after the initial counseling session with the physician or nurse. He says, “Regardless of whether the education is provided by the physician or the nurse, it’s always provided by a pharmacist to ensure that the patient really understands. The pharmacist is able to spend a little extra time and provide that information. Whereas in the physician’s office, when they’re diagnosed...
and start a new medication, a lot of that information could be overwhelming, and they might not catch it initially. I think just having that second person provide that education is important.” They frequently use the oral chemo education sheets on the NCODA website to facilitate their counseling.

The Patient-Centered Activities section also discusses how to take relugolix, what to do if a dose is missed, proper sign/symptom monitoring and management, and adherence evaluation.

Looney thinks one of the most important things you should counsel on is, “the unique dosing with relugolix. The patient takes three tablets on day one. And I do always emphasize three tablets at one time. I think that is important, so patients aren’t taking one tablet three times the first day. Then taking one tablet daily, thereafter, mentioning that if it is held for more than a week (if they miss more than seven days at a time), then they would restart with that loading dose.”

Crumb mentions that the pharmacists at Vanderbilt also use the OCE sheet to counsel on relugolix side effects. “I think they are really beneficial for patients. I think the most helpful part is the way they go through the side effect management portions as well.”

Fatigue and hot flashes are the top two side effects that practitioners at SUNY Upstate, Vanderbilt, and Los Angeles Cancer Center counsel on during relugolix education sessions. The OCE sheets can help busy practitioners focus their education on the most important side effects. But Dempsey adds that “A big question for most patients is the duration of therapy. Having that information prior to calling is helpful. Sometimes it requires contacting the physician through the EMR to get a better idea. Having that light at the end of the tunnel gives [early prostate cancer] patients a little bit of perspective to weighing the cost and benefits of managing side effects.”

Eshaghian emphasizes that when switching from injection to oral ADT, it’s important to educate patients on the importance of taking responsibility of their treatment. When switching from injections, he says “They were used to coming in and getting their Lupron® injection every 3 months and they were just a bystander in the disease. But now you’re making them an active participant. They have to take a pill every day. So I really talk to them about that.”

FINANCIAL ASSISTANCE: A BENEFIT OF MID AND THE MULTIDISCIPLINARY TEAM

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

Emily Kraft, certified pharmacy technician at Vanderbilt specializes in helping patients with financial assistance. From her perspective, the MID “Is really important, because I think as far as the patient standpoint, it runs pretty smoothly. They don’t have to speak to several different companies. And it eliminates confusion. It’s also a lot easier if patients have questions. We have a connection with the clinic and can get back to them faster. I think that’s important as well.” She also mentions that relugolix is fairly easy to get approved. Even if it doesn’t get approved, her team has processes in place to obtain a copay card, foundation assistance, or free medication.
from the manufacturer. She also finds the NCODA financial assistance tool a valuable addition to the PQI. She says, “I think it’s very resourceful. I think especially that link there would help with assistance. That would make it easier and a quick link that we could use.”

SUNY Upstate also focuses a lot of effort into patient assistance for relugolix. Alley states, “We assist them all the way to the end. We never drop them, even if it means we at Upstate financially get no benefit. We help them get set up through the free drug program. Anything like that, we take care of the patient. It’s always the patient first, not business first.”

“WE ASSIST THEM [PATIENTS] ALL THE WAY TO THE END. WE NEVER DROP THEM. ANYTHING LIKE THAT, WE TAKE CARE OF THE PATIENT. IT’S ALWAYS THE PATIENT FIRST, NOT BUSINESS FIRST.”

Abigail Alley, PharmD
Clinical Oncology Specialty Pharmacist

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

All team members agree that the MID model and the PQI Clinical Resource are valuable to the team and to patients. Every day the MID team can make a difference in the lives of patients. The team can continually learn something new or can begin a process that optimizes care. The PQI fosters this through appropriate patient identification, selection, increased speed to therapy, reduced cost, and hospitalization and by improving adherence techniques for the patient and their Medically Integrated Teams.

Adding relugolix to the prostate cancer landscape adds another option for ADT with unique considerations. Donahue mentions that patient preference, poor tolerance of injectables, and cardiovascular risk all play a role in her decision to prescribe relugolix. If a patient is hesitant to get back on hormone therapy after a poor experience, she says “It’s nice to say, ‘Okay, we have this other option. Maybe you will do a bit better with that as far as side effects.”

Crumb also mentions that the convenience of an oral option is good for patients. He says, “We do a lot of appeals to try to get patients access, especially for patients that are in rural communities that drive two to three hours to come get their injections. That can still take a toll on patients.”

Oral therapies are not going away any time soon. Eshaghian says, “I feel like every year we go more towards oral medications that are more targeted and less IV and injections, and the orals are the tricky part.”

The PQI provides the MID program with an easy to use, compact clinical resource guide when discovering the right patient and dispensing relugolix. It helps the team ensure they are providing patients with the tools and education to improve clinical outcomes. Pairing Medically Integrated Dispensing with the Androgen Deprivation Therapy with Relugolix (ORGOVYX®) PQI meets NCODA’s Guiding Values of being Patient-Centered and Always Collaborative.
REFERENCES


ON THE COVER:

- Vanderbilt Specialty Pharmacy employs technology to better serve patients.
Practice panelist’s comments reflect their experiences and opinions and should not be used as a substitute for medical judgment.

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