
PQI IN ACTION



**LAROTRECTINIB GENOMIC TESTING
MANAGEMENT AND OVERVIEW**



**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 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 VITRAKVI® (larotrectinib) PQI and explores how the medically integrated teams at Florida Cancer Specialists and Indiana University Simon Cancer Center care for patients starting VITRAKVI® therapy. It will discuss how utilizing the **Larotrectinib Genomic Management** and **Larotrectinib Overview** PQIs can elevate patient care.

Florida Cancer Specialists and Research Institute (FCS) is the one of the largest independent medical oncology/hematology practices in the United States with over 250 physicians and 220 nurse practitioners and physician assistants. They provide oncology care in the community setting at almost 100 locations. Rx To Go is the in-house pharmacy for FCS and provides convenient dispensing and delivery of oral oncology medications to FCS patients. Rx To Go is staffed by qualified pharmacists and trained support personnel and assists their patients in achieving optimal clinical outcomes while effectively managing the cost of therapies.

The Indiana University (IU) Simon Comprehensive Cancer Center is Indiana's only National Cancer Institute (NCI) designated Comprehensive Cancer Center and one of only 51 in the Nation. The center has nearly 250 research members, including basic, clinical, and population science investigators. Within the Simon Cancer Center, there are over 20 sub-specialized medical oncologists and access to over 700 adult and pediatric clinical trials. IU Health's specialty pharmacy, Advanced Therapies Pharmacy (ATP), collaborates with practice providers, insurance companies, manufacturers, and other healthcare providers to achieve the best possible outcomes for patients utilizing their services. ATP ensures convenient, continuous access to oral oncolytic therapy with specialized support from oncology pharmacists and clinical pharmacy technicians.

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PRECISION MEDICINE AND THE MID: BENEFICIAL FOR PATIENTS AND PRACTICES



Ribbon cutting for new Rx To Go facility located at the corporate offices of Florida Cancer Specialists.

NTRK gene fusions involving either NTRK1, NTRK2, or NTRK3 are oncogenic drivers of various adult and pediatric tumor types. These fusions can be detected using tumor DNA and RNA sequencing and plasma cell-free DNA profiling. The treatment of patients with NTRK fusion positive cancers with a first generation NTRK inhibitor, like larotrectinib, is associated with high response rates (>75%).¹ NTRK gene fusions are found in many types of solid tumors, including lung cancers, GI cancers, sarcomas, glioblastomas, pediatric malignancies, and thyroid cancer.²

Larotrectinib is indicated for the treatment of adult and pediatric patients with solid tumors that:

- Have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation
- Are metastatic or where surgical resection is likely to result in severe morbidity, and
- Have no satisfactory alternative treatments or that have progressed following treatment

As stated in the background section of the Larotrectinib Overview PQI, the efficacy of larotrectinib was studied in three clinical trials that included 55 pediatric and adult patients with solid tumors. Larotrectinib demonstrated a 75% overall response rate across different types of solid tumors, with 73% of responses lasting at least six months, and 39% lasting a year or

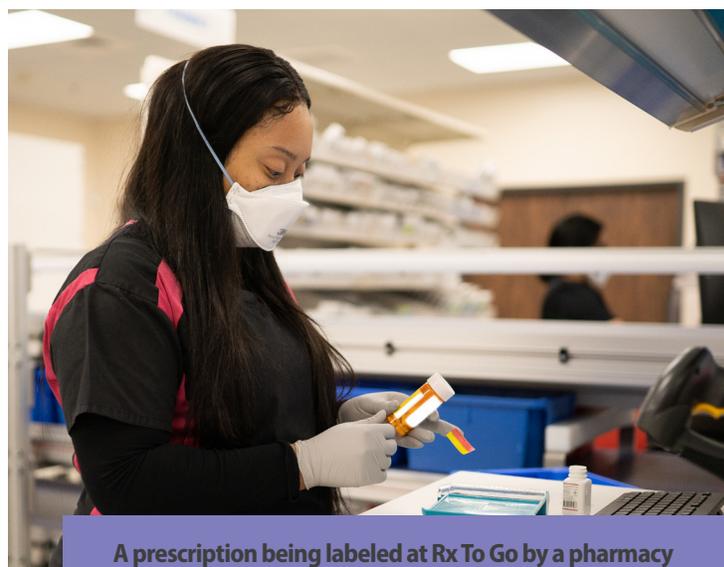
more at data cut-off. Presented at European Society for Medical Oncology 2020, a pooled analysis of three clinical trials including 175 patients, showed an overall response rate (ORR) of 78% and a median PFS of 36.8 months.³ Tumor types with an NTRK fusion that responded to larotrectinib include: soft tissue sarcoma, salivary gland cancer, infantile fibrosarcoma, thyroid cancer, lung cancer, primary CNS and cancers with CNS metastasis.⁴ In a study determining expected life-years and quality-adjusted life-years (QALYs) a larotrectinib base case found a mean pre-progression QALYs of 5.0 and mean total QALYs of 5.8.⁵ Evidence also suggests patients treated with larotrectinib see some degree of benefit with different lines of therapy and performance statuses.⁶

“HAVING A SPECIALTY ORAL AND TARGETED CHEMOTHERAPY PHARMACY GROUP HAS BEEN A REALLY HUGE ADDITION TO OUR CANCER CENTER.”

Greg Durm, MD

Larotrectinib can be dispensed by the Medically Integrated Team, and thus offers patients more comprehensive care. NCODA defines Medically Integrated Dispensary (MID) as a dispensing pharmacy within an oncology center of excellence that promotes a patient-centered, multidisciplinary team approach.⁷ 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.⁷ Both patients and providers benefit from the use of MID services. According to Katie Carter, clinical pharmacist at IU Health, “It is a huge advantage to have the pharmacy in house. From a clinical pharmacist standpoint, we can actually see a patient’s medical records and we can have more of an active role in their care through analyzing the labs, analyzing new medicines, seeing notes from new appointments or if they’ve gone to the emergency room recently.” Similarly, Greg Durm, medical oncologist at IU Health, states “having a specialty oral and targeted chemotherapy pharmacy group has been a really huge addition to our cancer center.”

The MID model can improve management of patients on therapies like larotrectinib in several ways including improved communication regarding issues, closely monitoring adherence, managing regimen changes, quicker therapy initiation, increased patient satisfaction, better access to financial assistance, and reduced drug-waste.⁸ NCODA offers multiple tools to aid the MID practice in managing oncolytics. This



A prescription being labeled at Rx To Go by a pharmacy technician.

toolbox contains a Patient Survey that is practice-customizable, a Cost Avoidance and Waste Tracker, a Financial Assistance database, Treatment Support Kits, Oral Chemotherapy Education sheets, and of course the Positive Quality Intervention clinical resource. After reviewing tools like the PQI, nurse supervisor at Rx To Go, Dawn Landolph, RN, BSN, MPA remarked “It’s really nice to have support from NCODA and to be able to have these references that add value to my team.”

THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

As cancer treatment continually grows in complexity containing injectable, oral, and combination regimens, the MID continues to offer an instrumental option for patient care. This article will explore the benefits of PQI utilization as a core standard of the MID and how utilizing this resource can benefit any practice.

According to Natatsha Khrystolubova, RPh, BPharm, BCOP at Florida Cancer Specialists and Rx To Go, utilizing the PQI as an educational tool can be really helpful. She states, “staff education for these agents is very important and can take a while with so much happening, so I really appreciate that NCODA has the PQIs available, not just for pharmacists but also for nurse practitioners and physicians in the clinic.” Furthermore, Dawn Landolph, RN, BSN, MPA adds that “this entire PQI is valuable to many different departments,

but specifically having the financial assistance piece is very valuable.”

“IT’S GREAT WE HAVE A RELATIONSHIP WITH THE PHYSICIAN, SO IF THERE ARE ANY ISSUES, WE CAN JUST GO DIRECTLY TO THEM IN PERSON TO ADDRESS THEM QUICKLY.”

Kevin Walker, CPhT

Both IU Simon Cancer Center (IUSCC) and FCS position their Medically Integrated Teams in a way to ensure appropriate treatment, increase compliance, and maximize clinical outcomes. We will highlight the MID process for each practice, how referencing the both Larotrectinib PQIs^{10,11} can benefit their staff and patients, and how they advance patient care on a daily basis.

[CLICK HERE TO GENOMIC TESTING MANAGEMENT PQI](#)

[CLICK HERE TO VIEW LAROTRECTINIB OVERVIEW PQI](#)

THERE'S SOMETHING NEW IN ONCOLOGY EVERY DAY AND WE RELY ON ORGANIZATIONS LIKE NCODA TO BRING US TIMELY INFORMATION. THE PQI SERIES IS FANTASTIC.

Dawn Landolph, RN, BSN, MPA

MEDICALLY INTEGRATED DISPENSING: ELEVATING CARE

The MID staff has unparalleled access to patient information and means of direct communication with other members of the multidisciplinary team, making the MID staff indispensable. The MID team also has direct access to communication with patients and can easily report information back to the clinic staff. This model greatly reduces fragmentation of care. When asked about the difference between filling a prescription through Rx To Go compared to other pharmacies, Natasha Khrystolubova proudly reflected on being part of the practice, stating “we are a part of the patient journey, so we are a part of this family, and that is



Indiana University Simon Cancer Center.

“WE’RE A PART OF THE PRACTICE, WE’RE A PART OF THE PATIENT JOURNEY, SO WE’RE A PART OF THIS FAMILY, AND THAT’S THE WAY WE TREAT OUR FAMILY. WE’RE ONE BIG FAMILY.”

Natasha Khrystolubova, RPh, BPharm, BCOP

the way we treat our family. We are one big family.” Similarly, Rebecca Garland reflected “I really enjoy talking with the patients and letting them feel heard, because I know, sometimes when they are in the clinic they are under a lot of stress and sometimes they don't ask all the questions they need to.”

Similarly, the MID team at IU Health felt strongly that patients receiving care through Advanced Therapies Pharmacy have more benefits than those filling externally. “I think that

we are able to provide a better service and quicker turnaround times to get our patients started on treatment quicker,” said Kevin Walker, a clinical pharmacy technician. He also noted, “It’s great we have a relationship with the physician, so if there are any issues, we can just go directly to them in person to address them quickly.” Katie Carter, PharmD, BCPS, BCOP remarked the pharmacy service is “very advantageous because we are working right there in the doctor's office and right there in clinic, so we can get any issues resolved quickly and more efficiently for the patient.”

“WITH DIRECT ACCESS TO THE PROVIDERS, I FEEL LIKE WE'RE ABLE TO PROVIDE A HIGHER LEVEL OF CARE THAN WE OTHERWISE WOULD BE ABLE TO.”

Katie Carter, PharmD, BCPS, BCOP

PUTTING THE PQI INTO ACTION

The PQI is a peer-reviewed clinical guidance document that provides Quality Standards and effective practices around a specific aspect of cancer care. The medically integrated pharmacy team is in a unique position to ensure appropriate treatment, increase compliance, and maximize clinical outcomes. Positive Quality Interventions (PQIs), an ASCO/NCODA Quality Standard, are designed to operationalize and standardize those practices to achieve these positive clinical outcomes.

“IT’S HELPFUL TO HAVE A QUICK RESOURCE TO CONFIRM DOSING AND WHEN TO REDUCE THE DOSE FOR TOLERANCE OR THINGS LIKE RENAL OR HEPATIC CHANGES.”

Pam Truitt, RN

The **Larotrectinib Overview** PQI begins by giving the reader a description of what the PQI will cover followed by a background section which gives the reader pertinent information regarding specific trial data and other helpful information for member of the medically integrated team. Regarding larotrectinib, the document discusses the tumor agnostic indication and the clinical trial data. The **Larotrectinib Genomic Management** PQI also starts with a description and background

information however, this PQI focuses solely on the genomic testing required in order to initiate larotrectinib therapy. According to Dr. Martin Dietrich of Florida Cancer Specialists, “Next-Generation Sequencing (NGS) is the preferred standard for detection of NTRK fusion. FoundationONE CDx is the applicable companion diagnostic. If a DNA platform does not detect any actionable mutations, I would repeat a next generation sequencing on RNA based platform. IHC can be used as a screening test; however, sensitivity and specificity have been questioned.” This aligns with the information included in the “PQI Process” portion of the genomics PQI. Khrystolubova adds “getting a patient started if they have a NTRK fusion is so important because the response rates are amazing and it’s a durable response.”

At IU Health, they often rely on their Precision Genomics clinic to sequence their patients and provide comprehensive testing and counseling. According to Dr. Durm, they typically send their patients for next generation sequencing, tissue and/or plasma based, at the time of the patient’s diagnosis. He states, “in the lung cancer realm, we’ve become very comfortable with genomic sequencing; however, the challenge with the increasing number for targets is finding tests that will encompass all the targets and do so in a timely manner.” When asked about the MID team and use of resources like the PQI, Dr. Durm added “there are a lot of targeted medications right now, and while we [physicians] can often keep track of the indications for them, it’s sometimes hard to remember all the finer details. Having the pharmacy team available is really invaluable because they help us remember the nuances between all the targeted agents. Without them, our jobs would be substantially harder.”

THE PQI PROCESS: A TEAM EFFORT

After reviewing the background information, the PQI Process is introduced in the **Larotrectinib Overview** PQI.¹⁰ This section of the document gives readers a step-by-step process to follow. This section lays out the intervention, contains clinician directed guidance, and critical clinical criteria that potentially could be missed or overlooked if not delivered in the PQI. This section is where the MID should begin upon receipt of an order for larotrectinib.

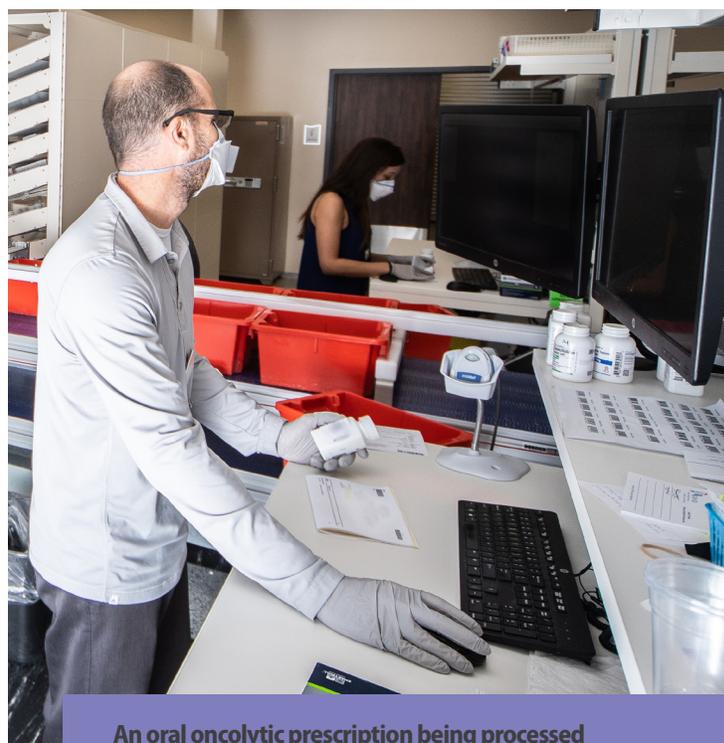
First, it is critical to confirm the patient’s genomic sequencing supports the finding of an NTRK fusion. Once confirmed,

the team will need to ensure the dosing is correct. Larotrectinib is dosed based on the patient’s body surface area (BSA). Since larotrectinib can be used in adults or pediatric patients regardless of solid tumor type, it is crucial to make sure a recent BSA is calculated and used to initiate treatment in your pediatric patients. If the patient is an adult or a pediatric patient with a BSA of 1 m² or greater, they will receive 100 mg by mouth twice a day. If they are a pediatric patient with a BSA less than 1 m², they will start with a weight-based dose of 100 mg/m² by mouth twice a day. Larotrectinib is available

in 25 mg and 100 mg capsules or as an oral solution of 20 mg/mL. Katie Carter shared “with VITRAKVI®, there are a lot of important things to mention to the patient during education. Especially with the different dosage forms, you want to make sure you review administration, dosing, storage, handling, and of course the side effects.” With the PQI process outlining the different doses and dosage forms, it ensures the clinical team is able to easily review that information prior to starting treatment. Pam Truitt, RN, nurse coordinator at IU Health, shares “It’s helpful to have a quick resource to confirm dosing and when to reduce the dose for tolerance or things like renal or hepatic changes.”

The PQI process continues with a review of drug interactions, and it highlights the need to screen for strong CYP3A4 inhibitors and inducers. If a patient is found to be on a CYP3A4 inhibitor or inducer and coadministration cannot be avoided, the larotrectinib dose should be altered. In the setting of strong CYP3A4 inhibitors, larotrectinib will need to be reduced by 50%; whereas, with strong CYP3A4 inducers, the larotrectinib dose will need to be doubled. Once medication reconciliation has been completed, and relevant drug interactions have been accounted for, it is safe for the patient to begin treatment.

While on larotrectinib, laboratory monitoring as well as toxicity screening will need to be routinely completed. The PQI process emphasizes the need to monitor liver function tests (LFTs) every two weeks during the first month of treatment and monthly thereafter. Additionally, patients need to be screened for common adverse events like neurotoxicity, fatigue, nausea, cough, vomiting, constipation, and diarrhea. At Rx To Go, Garland leads a team that is in charge of contacting patients and states “if there is an issue, we can immediately identify that and either get the pharmacist involved or



An oral oncolytic prescription being processed through Rx To Go's state of the art facility.

we can contact the clinic and ask them to confirm the plan.” Similarly, Kevin Walker, CPhT, emphasized the PQI as “a quick go to for a technician to know when to alert a pharmacist about a certain side effect a patient may experience.” In patient cases where adverse events require dose reductions, the PQI process outlines the appropriate dose modifications in an easy to reference table. Garland adds “honestly, I love the fact that you've got those modifications for second step, third step, or whatever needs to be done. I think it's very easy to read very straightforward easy to find that they can just look for the table.”

DOSE REDUCTIONS FOR VITRAKVI®

Dose Modification	Patients with BSA $\geq 1 \text{ m}^2$	Patients with BSA $< 1 \text{ m}^2$
1 st Dose Modification	75 mg orally twice daily	75 mg/m ² orally twice daily
2 nd Dose Modification	50 mg orally twice daily	50 mg/m ² orally twice daily
3 rd Dose Modification	100 mg orally daily	25 mg/m ² orally twice daily

PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

The Patient-Centered Activities section follows the PQI Process and gives specific patient-centered guidance for the team. The first point of the Larotrectinib PQI Patient-Centered activities is to provide an oral chemotherapy education (OCE) sheet to the patient. This will ensure they have written material to refer back to during their therapy. The Larotrectinib OCE sheet can be found here: www.oralchemoedsheets.com/. This handout provides medication information on the approved use, dose and schedule, drug and food interactions, storage and handling, possible side effects, serious side effects, and handling bodily fluids and waste. The team at IU Health tries to provide every patient starting Larotrectinib with the appropriate OCE sheet to supplement their education session.

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

“I REALLY ENJOY TALKING WITH THE PATIENTS AND LETTING THEM FEEL HEARD, BECAUSE I KNOW, SOMETIMES WHEN THEY ARE IN CLINIC THEY ARE UNDER A LOT OF STRESS, AND THEY DON’T ASK ALL THE QUESTIONS THEY NEED TO.”

Rebecca Garland, RPhT

According to Katie Carter, “the provider will go over broad education with the patient, and then all patients receive additional education from the pharmacist. Ideally, we try to provide that education in person to ensure the patient understands the information.”

The next point on the larotrectinib patient-centered activities section is reviewing potential side effects with patients. The most common adverse events include any neurological event (53%), increased ALT (45%), increased AST (45%), anemia (42%), fatigue (37%), nausea (29%), dizziness (28%), cough (26%), vomiting (26%), constipation (23%), and diarrhea (22%). Patients and caregivers need to be aware of these side effects and monitor accordingly at home. Patients should reach out

to their provider if they develop symptoms such as confusion, difficulty speaking, dizziness, coordination problems, tingling, numbness, or burning in their hands and feet. Patients should also be on the lookout for signs of hepatotoxicity, such as jaundice, pain in the upper right side of their abdomen, or nausea/vomiting.

Lastly, the Patient-Centered activities section reviews the appropriate counseling points for patients starting the oral solution formulation. This is crucial information to review for pediatric patients and their caregivers. In addition to the administration information, the patients and caregivers should be reminded to always place the child-resistant cap back on the bottle prior to putting it away. Larotrectinib oral solution should always be kept in the refrigerator, and it should never be frozen. Any remaining solution should be thrown away after 90 days.

Both FCS and IU Health take patient education very seriously and have it as a foundational element of their oral oncolytic programs. 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’s 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

“FILLING WITH RX TO GO WE GET AN ADDITIONAL LAYER OF SUPPORTIVE CARE OPPORTUNITY. IT IS VERY DIFFERENT THAN WHEN YOU FILL EXTERNALLY. THOSE PHARMACIES ARE NOT ACCOUNTABLE TO ME, BUT RX TO GO IS A PARTNER.”

Martin Dietrich, MD

MID: PROVIDING UNMATCHED SERVICE AND FINANCIAL ASSISTANCE FOR PATIENTS

In addition to close follow up and detailed education, MID allows the practice to provide excellent customer service, unmatched patient care, and help with finding funding so the patient can afford treatment. Many times, insurance mandates require that prescriptions must be filled outside of a practice instead of by the MID pharmacy. This can cause delays in therapy and more anxiety for the patient.

The last section of the Larotrectinib PQI offers guidance on financial assistance opportunities. TRAK assistance offers a \$0 copay program for eligible patients with commercial or private insurance. There is a bridge program available to privately insured patients who experience a coverage delay. Bayer US Patient Assistance Foundation is available for qualified uninsured or underinsured patients, and there is a Commitment Program that will refund the cost of up to 60 day supply in certain scenarios.

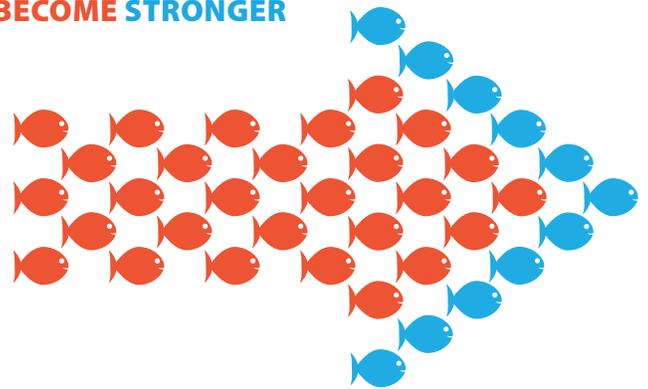
CONCLUSION: NCODA, THE MID AND PQI - OPTIMIZING PATIENT OUTCOMES

All team members agree that the MID model and the PQI Clinical Resource are valuable to the team and to patients. It has been shown time and time again that fragmented care can lead to increased spending and worse clinical outcomes for the patient.¹¹ Both Florida Cancer Specialists and Indiana University Simon Cancer Center have made it their mission to provide the highest quality cancer care to their patients, specifically when it comes to the management of oral oncolytic therapies.

Every day the MID team has the opportunity to make a difference in the life of patients. Every day the team can learn something new or can begin a process that optimizes care. The PQI fosters this through easy identification of the appropriate patient, quick initiation of therapy, concise review of the medication information, and a review of financial assistance resources. The PQI gives the MID program an easy to use, succinct clinical resource guide for identification of the right patient and best practices for the treatment of a larotrectinib patient. It helps the team ensure they are provi-

ding patients with the tools and education to improve clinical outcomes. Pairing Medically Integrated Dispensing with the Larotrectinib PQIs meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.

**WORKING TOGETHER,
WE BECOME STRONGER**



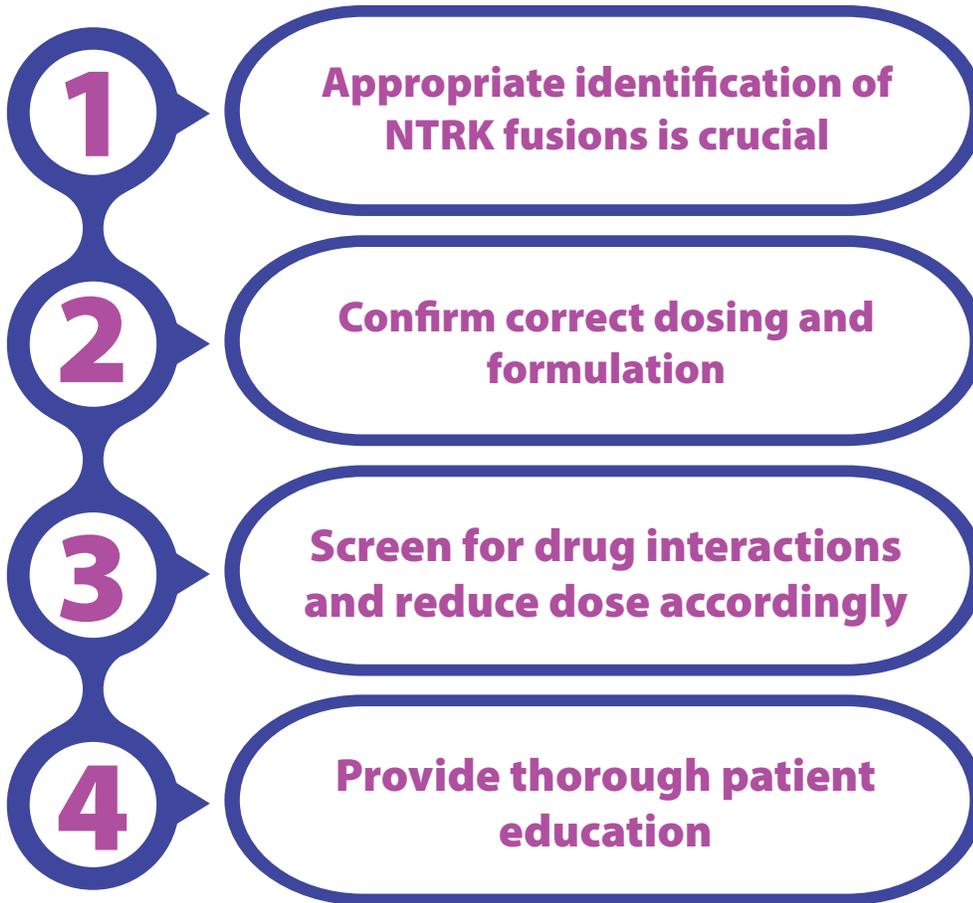
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ON THE COVER:

- IU Health Clinical Pharmacy Technician, Kevin Walker, working on financial assistance for a patient.

PQI PRINCIPLES:



Helpful Online Resources

- [NCODA Website](#)
- [Oral Chemotherapy Education Sheets](#)
- [Positive Quality Interventions](#)
- [Larotrectinib Genomic Testing Management PQI](#)
- [Larotrectinib Overview PQI](#)



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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