PQI IN ACTION

Positive Quality Intervention

NCODA

Tepotinib (Tepmetko®) for Non-Small Cell Lung Cancer with MET Exon 14 Alterations

INTRODUCTION

NCODA developed the peer-reviewed Positive Quality Intervention (PQI) as an easy-to-use and relatable clinical guidance resource for healthcare providers. By consolidating quality standards, real-life effective practices, clinical trial results, and package insert and other guidance, PQIs equip the entire multidisciplinary care team with a comprehensive yet concise resource for managing patients receiving oral or IV oncolytics.

This PQI in Action is a follow up to the Tepotinib (Tepmetko®) for Non-Small Cell Lung Cancer with MET Exon 14 Alterations PQI and explores how the medically integrated teams at Florida Cancer Specialists & Research Institute, Mayo Clinic, and Texas Oncology collaborate and utilize the information found in the PQI as part of their daily practice.

Scan or click here to access Tepotinib Positive Quality Intervention

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Treatment Landscape for NSCLC with a confirmed METEX14+ SKIPPING ALTERATION

THERE are over 200,000 new cases of lung cancer diagnosed in the United States each year, with non-small cell lung cancer (NSCLC) comprising 80-85% of these cases.[1] Various oncogenic drivers have been successfully targeted by tyrosine kinase inhibitors (TKIs) in NSCLC.[2] In recent years the activation of the MET proto-oncogene by exon 14 skipping (METex14) has been established as a targetable oncogenic driver.[2] METex14 skipping may be represented in around 3-4% of patients with NSCLC, occurs mainly in older patients and is associated with poor prognosis.[2,3] No characteristic has been found to rule out METex14 skipping so it is important to test all patients with NSCLC for the mutation.[2]

WHAT THE GUIDELINES SAY

The National Comprehensive Cancer Network (NCCN®) guidelines strongly recommend that clinicians test for actionable biomarkers in eligible patients with metastatic NSCLC before administering first-line immune checkpoint inhibitor (ICI) therapy ± chemotherapy, if clinically feasible.[4]
Treatment recommendations for metastatic NSCLC with
METex14 skipping mutation discovered prior to first-line systemic therapy include tepotinib and capmatinib as preferred agents.[4]

Tepmetko: INDICATION AND CLINICAL DATA

TEPMETKO INDICATIONS AND MECHANISM OF ACTION

TEPMETKO is a kinase inhibitor indicated for the treatment of adult patients with metastatic NSCLC (mNSCLC) harboring mesenchymal epithelial transition (MET) exon 14 skipping alterations.[5]

Tepotinib inhibits hepatocyte growth factor (HGF)-dependent and -independent MET phosphorylation and MET-dependent downstream signaling pathways. Tepotinib also inhibited melatonin 2 and imidazoline 1 receptors at clinically achievable concentrations. In vitro, tepotinib inhibited tumor cell proliferation, anchorage-independent growth, and migration of MET-dependent tumor cells.[5]

TEPMETKO CLINICAL TRIAL DATA

On February 15, 2024, the US Food and Drug Administration (FDA) granted full approval for tepotinib in the treatment of adult patients with mNSCLC harboring METex14 skipping alterations based on the efficacy and safety results from Cohort C of the VISION trial.[6] The VISION trial is the largest clinical trial evaluating mNSCLC patients harboring METex14 skipping alterations. Mazieres et al. reported that in treatment-naive patients (cohorts A and C; n=164), ORR was 57.3% (95% CI, 49.4%-65.0%) and mDOR was 46.4 (95% CI, 13.8-NE) months.

In previously treated patients (n=149), ORR was 45.0% (95% CI, 36.8%-53.3%) and mDOR was 12.6 (95% CI, 9.5-18.5) months.[6]

Among patients with NSCLC with a confirmed METex14+ skipping alteration, tepotinib demonstrated meaningful activity across subgroups by prior therapies and brain metastases, with a manageable safety profile and few treatment discontinuations indicating that results were favorable.[3,6]

Tepmetko Patient Profile: HEALTHCARE PROVIDER INSIGHTS

MEDICAL oncolgists and nurse practitioners at Texas Oncology and FCS shared their insights on how they select patients with NSCLC for therapy with tepotinib. Their insights are aligned with the recommended guidelines and prescribing information. FCS physicians order NGS testing on stage 4 NSCLC patients once staging is complete. Medical Oncologist Alexander Glick, MD shares they strive to be compliant with NCCN guidelines. He explains "if studies reveal some type of targetable mutation, we devise a plan of action" and that plan can include Tepmetko. Nurse practitioner Rebecca Monti, MSN, AGCNS-BC, APRN, AOCNS shares that at Texas Oncology, oncologists order genomic testing if the surgeon has not, and also provide patients with education on what the testing means and how it guides treatment selection.

> "If studies reveal some type of targetable mutation, we devise a plan of action."
>
> – Alexander Glick, MD

According to Austin Arzanga, PharmD, at Texas Oncology their group of pharmacy technicians work with insurance on documentations showing the METex14 skipping alteration. Pharmacists review physician notes to ensure alignment with NCCN guidelines and Texas Oncology Value pathways if warranted. Nicole Bentivegna, PharmD, BCOP and her FCS team utilize a Formulary Navigator, which includes both IV and oral medications and can be accessed virtually through every clinic. At FCS, medications are reviewed by the Pharmacy and Therapeutics (P&T) committee based on their clinical data once FDA approved. Formulary selection is based on discussion during P&T of clinical data, place in NCCN guidelines, as well as Trade team feedback.

ELEVATING PATIENT CARE THROUGH MEDICALLY INTEGRATED PHARMACY (MIP)

Once a treatment regimen decision has been rendered, the multidisciplinary team kicks into gear to continue providing optimized patient care. The availability of MIP to process and dispense oral anti-cancer prescriptions in pharmacies located in oncology clinics has improved medication management, streamlined patient care, and improved patient convenience and continuity of care. Matthew Smith, PharmD, CSP notes MIP leads to fewer delays in dispensing and better patient safety. He shares "Health record access is one of the biggest benefits of medically-integrated pharmacies – being able to look at that providers' note, being able to look at that clinical pharmacist colleagues note to see what she has already addressed"

THE PHARMACIST AS AN INTEGRAL TEAM MEMBER

Our multidisciplinary oncology panel agreed that the pharmacist is integral to the clinical management of patients with NSCLC and utilization of MIP for their oral medication needs. Figure 1 highlights some of the critical functions

> "Health record access is one of the biggest benefits of medically-integrated pharmacies –being able to look at that providers note, being able to look at that clinical pharmacist colleagues note to see what she has already addressed"
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> – Matthew Smith, PharmD, CSP

pharmacists provide to the MIP team. Arzanga believes the advantages of MIP are extensive and names reduced delays in receiving medication, pharmacists monitoring labs, ease of resolving insurance issues, preventing lapses in therapy and better safety for patients as ways MIP improves patient care. Nurse Practitioner Rebecca Monti adds "we have to understand that each specialty has its role. I lean on my pharmacists a lot, specifically for adverse reactions or for drug dosing modifications." Dr. Glick relies on his pharmacists to alert him of drug interactions and contraindications, and believes they are critical to patient safety.

BENEFITS OF MIP FOR PATIENTS PRESCRIBED TEPMETKO

Having a MIP option at the oncology clinic for prescriptions that the patient's insurance approves, offers convenience to patients. According to Mayo Clinic

Tepmetko Patient Profile: Healthcare Provider Insights - continued

Senior Manager of Oncology Care in Pharmacy Clay Irvine, PharmD, MBA, MS, everyone on the multidisciplinary team brings a unique set of skills to the table. He shares, "I think leveraging those skills and experiences really helps us to be able to manage patients in every regard. We are able to address concerns, we're able to talk about what we know is likely to happen. We can anticipate certain toxicity, certain side effects, and it makes our team really equipped to be able to stay ahead of them, stop patients from discontinuing therapy, from having dose reductions, and from needing to be admitted into the hospital."

Lipsi Melendez, Sr.CPhT, oncology pharmacy technician, offers perspective on the seamless care MIP offers. "Having a pharmacy within the clinic makes it easier for patients on top of everything else they are dealing with, and I think it makes it easier for the physicians as well. It is easier for them to communicate with us and vice versa, regarding the treatment plan, any drug interactions or any other issues."

Monti provides her reasoning for using the MIP and again highlights the staff as medication experts. "If we fill prescriptions in house, our pharmacists are specialized in all the oncology medications. They can provide patients the correct kind of side effect profile that maybe the advanced practice provider hasn't already provided. They give patients a detailed outline of what to expect. Specifically, our pharmacists at Texas Oncology, at least at my side, they're phenomenal."

ATTRIBUTES THAT MAKE PHARMACISTS AN INTEGRAL PART OF THE MIP TEAM:

01	Medication expertise
02	Improves medication management and safety
03	Contributes to personalized and optimized treatment plans
04	Anticipates potential problems
05	Reviews NGS results to determine/confirm treatment options
06	Double checks orders and patient characteristics (height, weight, labs)
07	Provides extra layer of communication between HCPs and patients
08	Assists with health literacy or language barriers
09	Assists with prior authorization process
10	Coordinates care to ensure cycle days of oral and IV medications are aligned

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NCODA'S PQI RESOURCE

THE PQI resource contains clinician-directed guidance and criteria that can benefit the whole team. Key segments illustrate how medically-integrated pharmacists support physicians and clinical staff by lending their medical and administrative expertise. The Tepotinib (Tepmetko®) for Non-Small Cell Lung Cancer with MET Exon 14 Alterations PQI covers clinical trial information, dosing, side effects, monitoring, drug interactions and patient-centered educational pearls. Monti values the Tepmetko PQI for its utility for Advanced Practice Providers and shares "it is impossible for us to remember all of the side effects that come with every medication, so I find it very helpful." She appreciates the dosing chart in this PQI.

Bentivegna comments on the utility of the PQI for management of drug toxicities and supportive care measures that are being implemented in real world practice. She adds "the PQI is a valuable tool to help standardize care."

Tepmetko Dosing, Dosing Modifications, and COST CONSIDERATIONS

DOSING

TEPMETKO comes in 225 mg tablets. The recommended dosage of Tepmetko is 450 mg orally once daily with food until disease progression or unacceptable toxicity.[5] Tepmetko may be dissolved in water for patients who have difficulty swallowing solids.[5] Guidance from the manufacturer on dispersion is shown in Figure 3.

Dose reductions are shown in Table 1. Smith notes that at Mayo Clinic, packaging and strengths of formulations are looked at closely. He appreciates the ability to reduce the dose of Tepmetko without having to dispense a new prescription and says, "the flexibility is very underrated." He points out the value in flexibility not only from a reduced pill burden standpoint, but also in reducing waste from a tablet strength the patients can no longer use.

Figure 3 Administration to Patients Who Have Difficulty Swallowing Solids[5]

Place TEPMETKO tablet(s) in a glass containing 30 mL (1 ounce) of non-carbonated water.

No other liquids should be used or added.

Stir, without crushing, until the tablet(s) is dispersed into small pieces (tablets will not completely dissolve) and drink immediately or within 1 hour.

Swallow the tablet dispersion. Do not chew pieces of the tablet.

Rinse the glass with an additional 30 mL and drink immediately ensuring no residue remains in the glass and the full dose is administered.

If an administration via a naso-gastric tube (with at least 8 French gauge) is required, disperse the tablet(s) in 30 mL of non-carbonated water as described above.

Administer the 30 mL of liquid immediately or within 1 hour as per naso-gastric tube manufacturer's instructions.

Immediately rinse twice with 30 mL each time to ensure that no residue remains in the glass or syringe and the full dose is administered.

COST CONSIDERATIONS

A recent study estimated the cost of drug wastage due to dose modification and discontinuation for oral anticancer drugs that were recently approved by the FDA or that are commonly prescribed, including both tepotinib and capmatinib.[7] The results suggested that oral anticancer drugs have considerable cost in wastage from pills that are not usable after a dose reduction or that are wasted due to discontinuation.[7] The median cost of wastage from dose reduction and discontinuation across all of the oral anticancer medications was $1,750 (range: $43-$27,200) per patient. The median cost of tepotinib wastage per person was more than 50% less than that of capmatinib wastage ($1,097 vs. $2,766).[7] This may be attributed to the dose reduction strategy with tepotinib that Smith describes as not requiring a different dosage form and new prescription.

Tepmetko Dosing, Dosing Modifications, and Cost Considerations - continued

Dose Reductions from 450 mg Starting Dose[5]	
Interstitial lung disease (ILD)/Pneumonitis	**Intervention**
Suspected	Hold
Confirmed	Permanently discontinue
Hepatoxicity	**Intervention**
Increase ALT/AST without increase tbili Grade 3	Hold until recovery to baseline • Recovery ≤ 7 days: resume at same dose • Recover >7 days: reduce dose to 225 mg daily
Increase ALT/AST without increased tbili Grade 4	Permanently discontinue
ALT/AST>3x ULN with total bilirubin >2xULN in absence of cholestasis or hemolysis	Permanently discontinue
Increase tbili without increased ALT/AST Grade 3	Hold until recovery to baseline • Recovery ≤ 7 days: resume at same dose • Recover > 7 days: reduce dose to 225 mg daily
Increase tbili without increased ALT/AST Grade 3	Premanently discontinue
Other adverse reactions	**Intervention**
Grade 2	Maintain dose - if tolerable consider holding and restart at 225 mg
Grade 3	Hold until resolved, resume at 225 mg
Grade 4	Permanently discontinue

Concerning Tepmetko dosing Smith adds, "what may be overlooked is the total cost of therapy is subsequently cut in half for the ongoing reduced dose, given the proportional cost per tablet. This is in stark contrast to the costs associated with meds that are flat priced and require different strength tablets or capsules for dose adjustments. The Tepmetko packaging also allows for reduced dose dispensing, without the increased risk of waste due to short-term stability barriers and original container dispensing requirements."

Irvine shares it is important to consider the overall financial toxicity of healthcare. He comments, "looking at cost effectiveness is also an important part of that, because we always want to do what is right for our patients and a part of that is helping to reduce financial toxicity across the system." He goes on to say that from the formulary standpoint his team is weighing efficacy, safety, and cost effectiveness. The clinic has a specific oncology drug focused subcommittee of P&T that meets monthly to evaluate new approvals, new indications and new data so needed changes can be made quickly and the

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> – Matthew Smith, PharmD, CSP

Tepmetko Dosing, Dosing Modifications, and Cost Considerations - continued

clinic can remain up-to-date.

From the US Medicare perspective, Yang et al. published the cost-effectiveness analysis of tepotinib versus capmatinib for treating patients with mNSCLC with tumors harboring METex14 skipping.[9] The analysis showed that tepotinib dominated in frontline settings. In line agnostic context, tepotinib produced an Incremental Cost-Effectiveness Ratio (ICER) of $105,383 per quality-adjusted life year (QALY), with the incremental QALYs and costs of 0.2794 and $29,447, respectively.[9] The authors concluded tepotinib may be cost-effective compared with capmatinib in treating patients with mNSCLC harboring METex14 skipping in the frontline and line agnostic setting.[9]

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Irvine feels that the favorable ICER in the frontline treatment setting aligns with Medicare's cost effectiveness thresholds. He elaborates, "I think when you take that and the reduced waste you have a really nice economically viable option for Medicare beneficiaries". He sees a drastic need for healthcare professionals to pay more attention to the financial piece to help reduce cost, not just for the health system, but for all the players involved. Bentivegna echoes his sentiments and shares, "pharmacoeconomic data is extremely beneficial information, especially from a Trade and Payor perspective." She says the cost studies highlight the benefits of Tepmetko, including ease of once daily administration for patients and ease of dose reductions.

Monitoring Patients and ADVERSE EVENT MANAGEMENT

ELECTRONIC medical record (EMR) software, such as Epic and OncoEMR, has helped shape and standardize treatment plans, monitoring, and refills. Laboratory tests are built into the EMR to facilitate monitoring. Texas Oncology Pharmacists review the treatment plan to ensure labs are ordered for the patient throughout therapy. Smith mentions the ease building labs into the Epic treatment plan allows. Mayo Clinic has labs built into each cycle to make them easier to order, and Smith says it is important to encourage patients to follow through and have labs drawn. He also mentions patients that live out of town often complete lab work in their local community and have it sent to Mayo Clinic. FCS uses a flow sheet in the EMR and once the patient has the prescription in hand, Dr. Glick and the pharmacists follow the patient while on therapy.

The team members discussed the most common side effects that may occur with Tepmetko. Peripheral edema was the most common treatment related adverse event (TRAE)(67.1%) in VISION, with 11.2% experiencing Grade ≥3 events. Other TRAEs occurring in >20% of patients included hypoalbuminemia (23.6%), nausea (23.3%), diarrhea (22.4%), and blood creatinine increase

PQI PROCESS

- **Monitor LFTs prior to start, then every 2 weeks for the first 3 months, then monthly or as clinically indicated**
- **Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (ex: dyspnea, cough, fever)**
- **Monitor WBC, CMP, and creatinine prior to start and then monthly or as clinically indicated[5]**

Monitoring Patients and Adverse Event Management - continued

(22.0%), and were mostly Grades 1–2.[2]

All centers counsel patients on potential edema. In Mayo Clinic Specialty Pharmacy Smith helps patients manage edema by encouraging physical activity, limb elevation and sometimes diuretics. Arzanga and team also utilize diuretics, specifically furosemide, when necessary. He shares side effects are graded using CTCAE criteria.

In the event of lab abnormalities such as elevated liver enzymes, the Texas pharmacy team will reach out to physicians for guidance, sometimes holding treatment until recovery. Arzanga and pharmacist colleagues also have a practice agreement with the Texas Oncology physicians that allows them to prescribe anti-emetics when needed for nausea.

When managing diarrhea, Monti shares her patients typically start out with OTC loperamide. If it is not working, her office will see the patient and check lab work to determine if the patient needs IV hydration. The team may also incorporate diphenoxylate/atropine and tincture of opium in their diarrhea management strategy if warranted.

Dr. Glick highlights the importance of potential pulmonary toxicities and educating the patients to contact the office for potential pneumonitis or ILD. He shares adverse event management strategies can vary patient to patient depending on the situation.

SIDE EFFECTS

- **Most common (≥20%): edema, increased creatinine, increased alk phos/AST/ALT, lymphopenia, anemia, fatigue, nausea, diarrhea, musculoskeletal pain, and dyspnea**
  - **Consider furosemide based on severity of edema**
- **Clinically relevant (<10%): ILD/pneumonitis, rash, fever, dizziness, pruritus, and headache**
- **Serious adverse reactions occurred in 45% of patients:**
  - **Grade 3/4 adverse reactions in >2% of patients included: pleural pneumonia (5%), edema (3.9%), dyspnea (3.9%), pulmonary embolism (2%), and musculoskeletal pain (2%)**
  - **Fatal adverse reactions included hepatic failure (0.4%), pneumonitis (0.4%), and dyspnea from fluid overload (0.4%)**

EDUCATION ENHANCES PATIENTS' UNDERSTANDING OF TEPMETKO

EDUCATION is important for patients with NSCLC who are taking Tepmetko. All three practices use Oral Chemotherapy Education (OCE) sheets, an NCODA-led resource, to provide education to their patients. OCE sheets provide a tool that caregivers can pass on to their patients with cancer to answer drug-related questions and empower patients to become active participants in their cancer treatment. Arzanga explains that OCE sheets are comprehensive, address adverse event management strategies, and are "a great tool to use" for education.

At Texas Oncology, Advanced Practice Providers sit down with patients for an entire hour prior to starting an oral or IV therapy. During these sessions, Monti and colleagues review when to take the medication, potential adverse events and adverse event management. She feels safety is the most important item to educate patients on. She also relies on her pharmacist to assist with medication education, since this is where their expertise truly shines.

Education Enhances Patients' Understanding of Tepmetko - continued

Mayo Clinic Specialty Pharmacy pharmacists counsel each patient on the medication before they begin therapy. Smith describes the resources at their fingertips and explains Mayo Clinic relies on internal documents for counseling to ensure less variability depending on the pharmacist providing the education. Again, they rely on OCE sheets and use smart phrases for document templates in their EPIC EMR system. When educating patients on Tepmeko Smith shares the most important counseling points include education on the potential for edema and any changes to lung function. His team lets patients know that if they have new onset or worsening shortness of breath or a cough, they need to report it to their care team immediately.

FCS utilizes OCE sheets for patient education and clinical pharmacists use the sheets as a guide when counseling the patient. FCS is also able to provide the OCE sheets in an email to patients requesting additional written information. "Being able to provide a concise and easy to read handout to patients is valuable in helping them understand what to expect with their treatment" Bentivega comments.

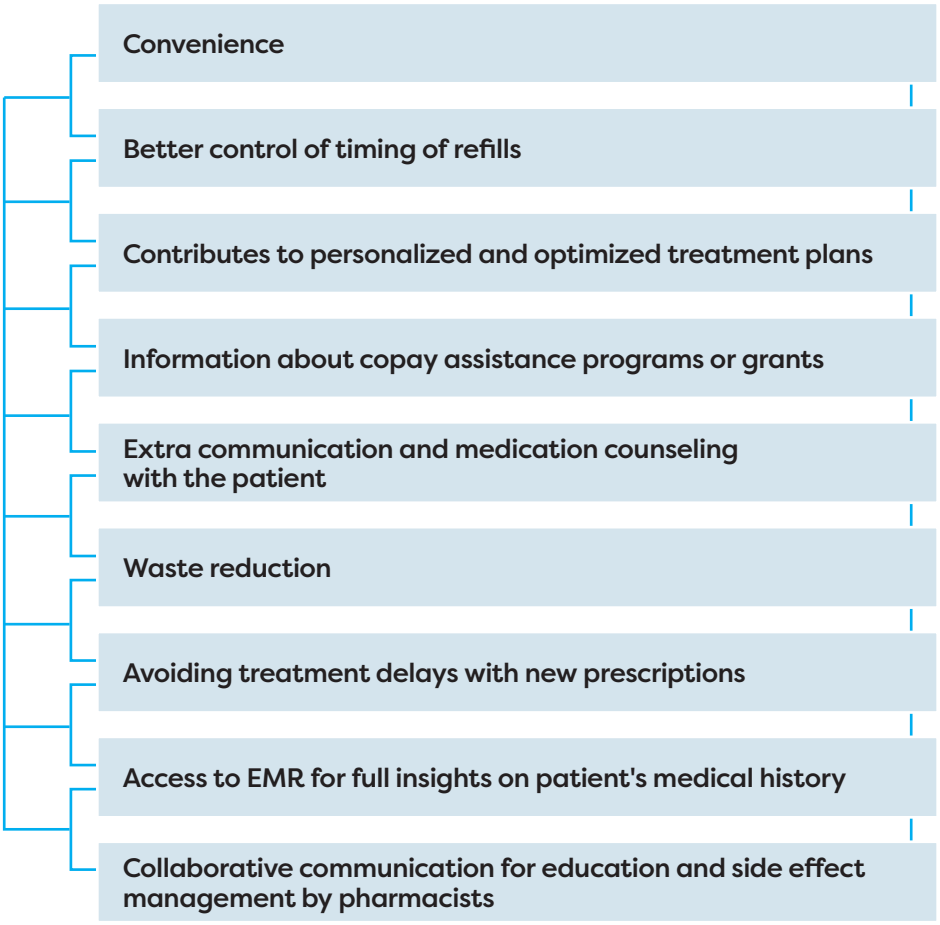
Scan or click here to access Tepotinib Oral Chemotherapy Education Sheet

ACCESS TO THERAPY

MIP pharmacies provide multiple services to assist patients with access to therapy including prior authorizations and patient assistance. These services are foundational to positive patient outcomes. As Smith shares, "if a patient cannot afford the medication, nothing else matters because they will not be able to start their therapy." Following an initial prior authorization and benefit check, in-network prescriptions are routed to Mayo Clinic Specialty Pharmacy's Enrollment Team.

Patient Enrollment Supervisor Arlene Bahr explains the process for Tepmetko. Once her team receives the prescription, they assess the patient. They evaluate insurance, the medication label and programs available. Bahr comments, "if it is a commercial payer, we are looking to see if the patient would be eligible for a copay assistance copay card. If it is a Part D plan, we are looking to see if there are any foundations open. We are also looking for free drug if needed." She shares a best practice of weekly huddles with her financial team to keep track of

Figure 2. Benefits in Using MIP



Access to Therapy - continued

any changes to assistance programs or challenges as one secret to success. Her team truly works together to help each other and in turn, their patients.

Pharmacy Technician Simone Washington-Morris, Sr.CPhT. elaborates on the full process for dispensing an oral oncolytic from their MIP which includes submitting the prescription to their Prior Auth team for approval. The rest of their process hinges on the critical step of approval and copay affordability.

Limited Distrubution Drug

Tepmetko has a limited distribution model that supports the Medically-Integrated Pharmacy. Limited Distribution models that support MIP allow practices a way to maintain control of a patient's therapy and protect positive patient outcomes.[10]

SUMMARY

THE team commended NCODA for providing immediately accessible drug information via the PQI resource. Several team members vocalized their appreciation to NCODA for developing concise and useful information (E.g., clinical trial data, dosing modifications, and monitoring parameters) on Tepmetko that is easy to navigate.

The PQI provides the MIP program with an easy to use, compact clinical resource guide when discovering the right patient and dispensing Tepmetko. It helps the team ensure they are providing patients with the tools and education to improve clinical outcomes. Pairing Medically Integrated Pharmacy with the Tepotinib (Tepmetko®) for Non-Small Cell Lung Cancer with MET Exon 14 Alterations PQI meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.

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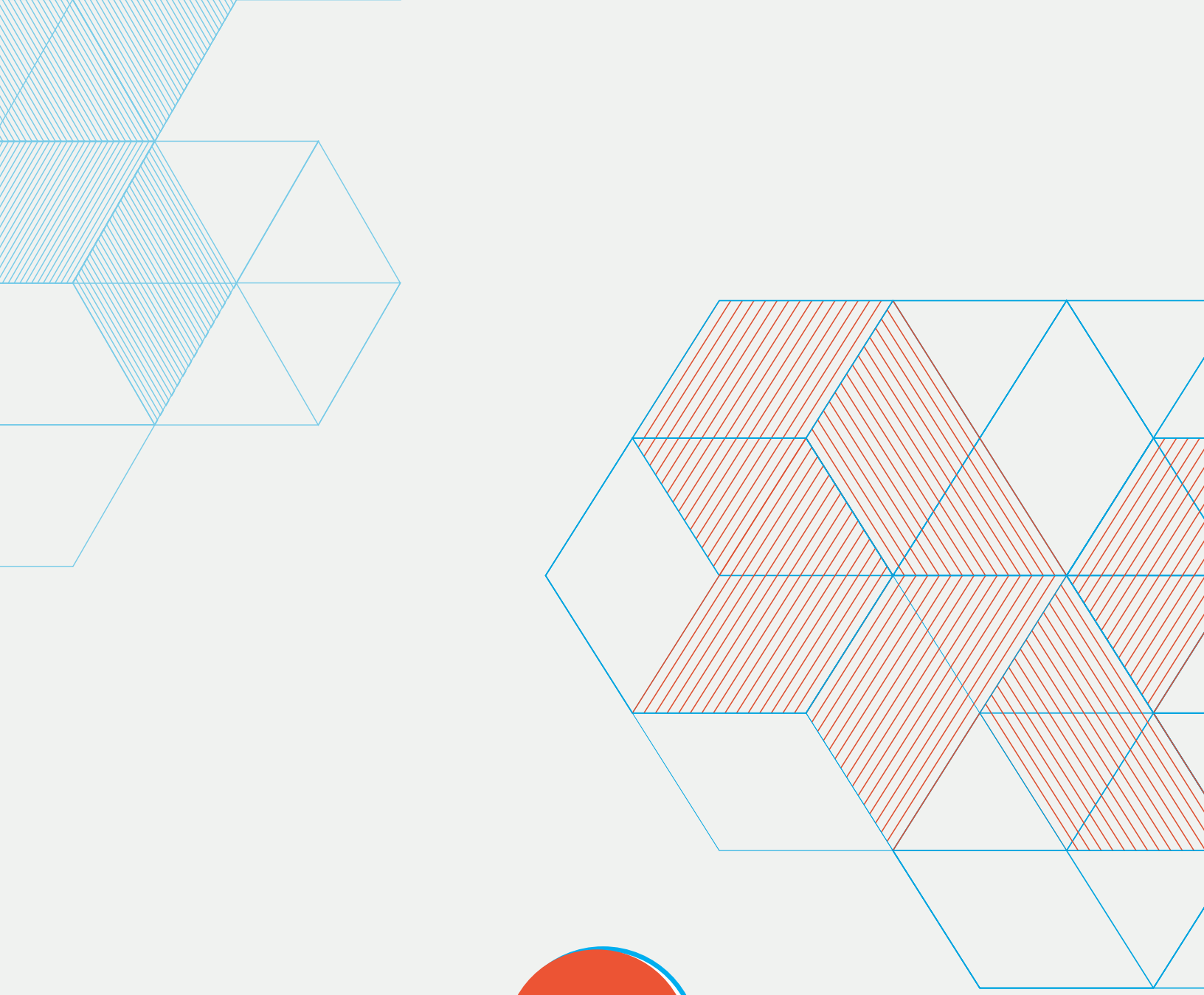

Practice panelist's comments reflect their experiences and opinions and should not be used as a substitute for medical judgment.