PQI IN ACTION

Abiraterone acetate (Yonsa®) Patient Selection and Management PQI

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, 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 Positive Quality Intervention: **Abiraterone acetate (Yonsa®) Patient Selection and Management** PQI and explores how the medically integrated teams at AtlantiCare Cancer Care Institute (AtlantiCare) and Cancer Specialists of North Florida (CSNF) collaborate and utilize the information found in the PQI as part of their daily practice.

Abiraterone acetate (Yonsa®) Patient Selection and Management PQI

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YONSA® (ABIRATERONE ACETATE) FOR METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

Metastatic castration-resistant prostate cancer (mCRPC) is a progressive form of prostate cancer that continues to advance despite androgen deprivation therapy (ADT), the foundational treatment strategy targeting testicular testosterone production.[1] While ADT effectively suppresses testicular androgen synthesis, mCRPC persists due to androgen production from extragonadal sources such as the adrenal glands or even the tumor itself.[1] These alternative androgen sources maintain activation of the androgen receptor, promoting disease progression and underlining the need for more complete androgen suppression strategies.[1]

Abiraterone acetate (AA), a prodrug of abiraterone, functions as an inhibitor of CYP17 and androgen biosynthesis. By inhibiting CYP17, AA effectively suppresses androgen production in both extragonadal and testicular tissues, leading to a reduction in serum testosterone levels.[1] Abiraterone acetate fine-particle formulation (AAFP) was approved for the treatment of patients with mCRPC in 2018.[2] Micronization of abiraterone in AAFP increases bioavailability and improves absorption in the gastrointestinal tract allowing for more reliable dosing with lower amounts of the drug.[3] The fine particle formulation also allows for administration with or without food and does not necessitate taking the dose on an empty stomach.[2] The STAAR clinical trial, a randomized, open-label, phase II trial involving 53 men with mCRPC (mean age of 75.1 years; 54.7% with a Gleason score greater than 7), aimed to evaluate the therapeutic equivalence of once daily AAFP 500 mg combined with methylprednisolone compared to the original formulation of abiraterone acetate (OAA) 1000 mg once daily combined with prednisone.[4]

The primary endpoint was comparison of combined average serum testosterone level in both groups on days 9 and 10 after starting treatment. The least squares (LS) mean difference in serum testosterone levels, measured on the planned days, between AAFP and OAA was 0.04 ng/dl (95% CI: −0.063 to 0.135) with no statistically significant difference between the groups (P = 0.4703). Average serum testosterone levels for each group were also measured on days 28, 56, and 84 and no statistically significant differences were observed. LS means difference in trough plasma concentrations between the treatment groups were not statistically significant at any time points.

Additionally, a decrease of ≥ 50% in PSA level from baseline was seen in > 65% of patients in both groups consistently on days 28, 56, and 84. Adverse events (AE) of any grade occurred in 18 AAFP patients (75.0%) vs 24 OAA patients (82.8%), with the most common AE in the AAFP group being infection (n = 7, 29.2%) and in the OAA group being musculoskeletal disorders (n = 11, 37.9%).[4] Common adverse events seen with AAFP are fatigue, joint swelling and discomfort, muscle discomfort, hypertension, edema, flushing, diarrhea, constipation, hypertriglyceridemia, increase in AST, hypokalemia, and hypophosphatemia.[2]

YONSA PATIENT PROFILE: HCP INSIGHTS

Healthcare providers emphasize the importance of aligning use of Yonsa with its approved indication. Patients considered for Yonsa therapy should be on concurrent gonadotropin-releasing hormone (GnRH) analog therapy or have undergone bilateral orchiectomy. The formulation is not interchangeable with other abiraterone products and use in patients with severe hepatic impairment (Child-Pugh Class C) is contraindicated.[2]

In clinical practice, many providers begin treatment with androgen deprivation therapy (ADT) and consider the addition of abiraterone in the first line setting for patients with high-risk or metastatic disease. Devon McKenzie, MD, a medical oncologist at AtlantiCare, shared that he tends to initiate therapy with an all-oral regimen and, for most appropriate patients, incorporates abiraterone

Yonsa Patient Profile: HCP Insights - continued

alongside ADT. His decision-making is guided by key clinical trial data, notably the LATITUDE trial, which demonstrated improved overall survival in patients receiving abiraterone plus prednisone compared to placebo.[5] In his words, "I tend to use abiraterone in the first line in combination with androgen deprivation therapy for most patients."

Advanced practice providers also weigh disease severity when considering abiraterone. Chelsea Cramer, APN, explained that the team typically prescribes abiraterone for patients with high-risk, castrate-sensitive prostate cancer or metastatic disease. When deciding between formulations, factors like insurance coverage and patient convenience come into play. Satish Shanbhag, MD of Cancer Specialists of North Florida noted that while all AR pathway inhibitors (ARPIs) are effective, Yonsa's lack of food restrictions and simplified dosing can make it a practical choice when covered by insurance.

Pharmacists also play a critical role in ensuring proper selection and safety when dispensing abiraterone. David Borrone, RPh, highlighted that prescriptions must be carefully reviewed to verify the correct formulation and dosage. Since electronic health record systems often default to generic "abiraterone" without specifying the formulation, errors can occur. "We have to double check the dosage, the co-prescribed corticosteroid, and most importantly, confirm that the correct abiraterone formulation has been ordered," he said, underscoring the importance of pharmacist oversight in preventing prescribing errors and supporting optimal patient outcomes.

ELEVATING PATIENT CARE THROUGH MEDICALLY INTEGRATED PHARMACY (MIP)

ONCE a treatment decision is made, the full strength of a multidisciplinary team comes into play. Central to this approach is the Medically Integrated Pharmacy (MIP) model, which allows for oral anti-cancer therapies to be dispensed and managed within the oncology clinic itself. This model improves medication access, strengthens communication, and supports consistent, high-quality care throughout the patient journey.

At CSNF, the team shared how the presence of MIP enables deeper relationships with patients and better coordination of care. Shenitha Edwards, CPhT, explained that as a pharmacy technician, she often uncovers symptoms or concerns that patients may forget to share with other providers. This creates opportunities to advocate on behalf of the patient and ensure nothing is overlooked. "Being part of a multidisciplinary team allows us to treat the patient comprehensively, from multiple angles, and to connect with them personally in ways that improve their overall care."

The value of this integration is echoed at AtlantiCare, where Dr. McKenzie described their model as a true patient-centered cancer home. With pharmacy, nursing, genetics, and social work all accessible on site or nearby, the structure supports real-time collaboration and prevents things from slipping through the cracks. "The Swiss cheese model does not exist here," Dr. McKenzie said, "because multiple people are engaged and catching what others might miss."

Dr. Shanbhag emphasized the critical difference between having a medically integrated pharmacy team and relying on an external pharmacy. "My internal team is far superior in their ability to talk to the patient and communicate directly with me. It is an effective channel for sharing information. The delays that would occur without this integration, between ordering the drug and the patient receiving it, would be amplified."

That same efficiency is felt on the ground. Barrone described how his shared office with oncologists supports proactive collaboration. Nurses alert him when oral therapy is planned so he can begin the prior authorization process in advance and often walk in with approval and cost details in hand. "Being on-site allows me to take calls about adverse reactions directly, support the care team,

Elevating Patient Care Through Medically Integrated Pharmacy (MIP) - continued

and provide feedback after every patient encounter."

From the nursing perspective, Merideth Arnold, RN, BSN, a nurse educator at CSNF, highlighted the impact on care consistency. With everything centralized or within the same organization, the entire team delivers unified messages and coordinated support, which reduces confusion and builds patient confidence. "You are not trying to outsource. You are not tracking people down. Everyone is on the same page."

"The Medically Integrated Pharmacy is invaluable. It strengthens communication, prevents delays, and allows us to treat patients in the most effective and compassionate way possible."

-Satish Shanbhag, MD

THE MIP TEAM IN ACTION: ROLES THAT SUPPORT THE PATIENT JOURNEY

THE MIP model succeeds because of the collaboration among a dedicated team of healthcare professionals who each bring their expertise to the patient's care journey. From diagnosing and prescribing treatment, to patient counseling, facilitating access to therapy, and ongoing monitoring, every role plays a part in ensuring patient safety, adherence, and quality of life. The physician, advanced practice provider (APP), pharmacist, nurse, and pharmacy technician work in constant communication, each adding a layer of support that helps prevent delays, reduce confusion, and build trust with patients.

MIP MULTIDISCIPLINARY CARE

PHYSICIAN

Leads diagnosis and treatment selection

"I prescribe therapies and coordinate with the team to ensure comprehensive care."

– Devon McKenzie, MD

Prescribes oral therapies, oversees clinical care, and collaborates with the team.

ADVANCED PRACTICE PROVIDER

Supports education and lab monitoring

"Helping patients know what to expect improves compliance."

– Chelsea Kramer, APN

Reinforces dosing instructions, reviews lab results, and ensures patient understanding.

PHARMACIST

Provides medication counseling and follow-up

"I follow patients closely and collaborate with physicians to manage their therapy."

– Dave Borrone, RPh

Educates patients, manages authorizations, monitors adherence, and checks for interactions

NURSE

Delivers ongoing assessments and symptom management

"We provide weekly check-ins early on to ensure safety and understanding."

– Merideth Arnold, RN, BSN

Conducts patient education, schedules labs, and tracks side effects

PHARMACY TECHNICIAN | *Manages logistics and communication*

"I ensure the right medication reaches the right patient at the right time." *– Shenitha Edwards*

Handles data entry, order processing, inventory, billing, and coordination across sites.

PQI PROCESS: STREAMLINING SAFE AND SUPPORTIVE YONSA INITIATION

AT the core of the PQI for Yonsa is a structured and team-based process that ensures appropriate patient selection, optimized prescribing, and meaningful education that supports adherence. Borrone emphasized the critical role of pharmacy in leading this effort, from verifying initial orders to counseling patients on the nuances of therapy.

When an order for abiraterone acetate is received, the pharmacy team first confirms that the patient is an appropriate candidate for the AAFP formulation. This includes verifying the indication. The team also reviews whether the patient has previously been on abiraterone, as AAFP is not interchangeable with other formulations.

The pharmacy also confirms that the correct steroid, methylprednisolone 4 mg twice daily, has been prescribed. Borrone noted that this often requires special attention, as patients may be more familiar with the once-daily prednisone typically used with other abiraterone products. Borrone makes a point to counsel patients on taking the steroid component with food to reduce gastrointestinal side effects. "Some of these medications can be very harsh on the stomach," he explained. "Especially for patients who already have GI conditions or are on H2 blockers or PPIs, it's important to prevent irritation whenever possible."

The dosing for Yonsa is typically 500 mg (four 125 mg tablets) by mouth once daily with methylprednisolone, but the team also adjusts dosing for patients with moderate hepatic impairment (Child-Pugh Class B) to 125 mg daily. Importantly, Yonsa may be taken with or without food, which offers a level of flexibility that helps support real-world adherence. From clinical verification to individualized education, the PQI process at this practice demonstrates how pharmacy leadership can enhance both safety and patient-centered care. As Borrone highlighted, small adjustments in timing, education, and support can make a significant difference in ensuring patients stay on track with treatment.

PATIENT-CENTERED ACTIVITIES: A MULTIDISCIPLINARY APPROACH TO EDUCATION AND SUPPORT

Educating and supporting patients on Yonsa therapy is a shared responsibility across the entire oncology care team. The process begins at treatment initiation. Patients receive a Patient Education Sheet and counseling on how to take Yonsa: once daily, with or without food, and always along with with methylprednisolone 4 mg twice daily. Pharmacy team members carefully review the patient's complete medication list, including over-the-counter, herbal, and supplement use, to proactively manage drug interactions, particularly those involving CYP3A4. Patients with diabetes are counseled on the risk of hypoglycemia, and the team ensures that any hypokalemia or uncontrolled hypertension is addressed before therapy begins.

Dr. McKenzie emphasized the importance of a strong foundation: "Before we start abiraterone, we walk through all of the side effects, the risks and benefits, and alternatives. That is part of informed decision-making." Arnold explained, "Education is not a one-time thing. When patients first start a drug, they are often overwhelmed. Weekly nursing assessments, even if they are not side effect–focused, help us confirm they understand how to take their medication, what to avoid, and how to stay safe." Dr. Shanbhag added that building understanding starts with context: "I explain the 'why' behind treatment including why we are using this medication, how it works, and what side effects to watch for. I adjust my explanation based on the patient's level of knowledge and how much they are able to take in at once."

Patient-Centered Activities - continued

Borrone shared how he complements the provider's education by creating a relaxed, approachable environment. "Before I even start my counseling, I ask patients if they have any questions about what the doctor just covered. Sometimes they are hesitant to ask the oncologist directly, or they think of questions after they have had time to reflect. My role is to meet them where they are, whether it is in the clinic or following up by phone after their visit." This additional touchpoint can be especially valuable. "Sometimes I do not speak with the patient until after they have left the building," Borrone noted. "But when I call them, it gives them time to think. Maybe a family member brought up a concern, or they remembered something they forgot to ask. I can answer most questions or bring it back to the physician and follow up."

Borrone also reviews critical treatment logistics during his education sessions. He reminds patients to monitor their blood pressure and blood sugar closely, especially those with diabetes, and ensures they have access to testing supplies. "If they do not, we have a program where we provide them at no charge," he added. This layered, multidisciplinary approach ensures that patients are not only informed, but also empowered and supported throughout their treatment journey.

> "Education is not a one-time thing. We check in, re-educate, and make sure patients are truly prepared, not just the day they start, but throughout treatment."
>
> — Merideth Arnold, RN, BSN

MANAGING ADVERSE EVENTS: A PROACTIVE, COLLABORATIVE STRATEGY

RATHER than waiting for problems to arise, the multidisciplinary teams at CSNF and AtlantiCare focus on monitoring, educating, and adjusting early. "We do a lot of upfront, invisible work," shared Dr. McKenzie. "That includes checking drug interactions, managing preexisting conditions, and preparing patients for what to expect." One of the most crucial areas of monitoring is liver function. Because abiraterone is hepatically metabolized, baseline screening and regular liver function tests (LFTs) are standard. "We follow LFTs closely, and patients are counseled on alcohol reduction to minimize liver strain," said Dr. McKenzie. If elevated enzymes are observed, the team pauses therapy, repeats testing, and, if stable, resumes treatment at a reduced dose.

Electrolyte monitoring, especially potassium, is another essential part of the protocol. Cramer noted that patients receive a comprehensive metabolic panel prior to starting, and ongoing labs check for hypokalemia and other imbalances. If potassium is low, the team replaces it before starting therapy and continues supplementation as needed. Arnold added, "We also counsel patients to eat potassium-rich foods early on, so we can hopefully avoid IV replacement later."

Blood pressure is monitored closely due to the potential for hypertension. Arnold explained how patients are often referred back to their primary care providers for medication adjustments, and home blood pressure logs are used to guide management. "Diet and hydration matter too," she said. "We talk about salt intake, fluids, and heart-healthy foods." When needed, providers may manage antihypertensives in-house or coordinate care with cardiology or nephrology teams, depending on the patient's history.

Borrone highlighted the small but critical actions that keep patients safe. "If a patient does not have a working blood

Managing Adverse Events: A Proactive, Collaborative Strategy - continued

pressure monitor or glucose meter, we give them one," he said. "It's a minor investment that helps them stay adherent and confident in managing their care." His team also performs ongoing medication reconciliation to prevent interactions, particularly from medications prescribed by external providers who may not be familiar with oral oncolytics. "We have to be the bridge. Primary care providers and retail pharmacists don't always know what to look for with these therapies."

Hormonal side effects, often stemming from ADT, are an area of proactive conversation. Dr. McKenzie and Dr. Shanbhag both emphasized setting expectations with patients about fatigue, mood changes, and metabolic shifts. "If you taper up and explain things clearly, patients are less surprised by the side effects," said Dr. Shanbhag. "In my experience, most effects have been mild, grade 1 or 2, and manageable."

Ultimately, the team's success lies in its shared commitment to prevention and partnership. "It is about keeping patients on therapy safely," said Borrone. "That means anticipating challenges, educating them early, and removing barriers wherever we can."

TEAM TIPS: ADVERSE EVENT MANAGEMENT

Team Tip: Proactively Prevent Hypokalemia

"Start potassium-rich foods early and monitor labs closely. If levels begin to drop, oral replacement can often prevent the need for IV repletion."

— Meredith Arnold, RN, BSN

Team Tip: Give Patients the Right Tools

"We provide blood pressure monitors and glucose testing supplies if patients don't have them or if their devices aren't working. It is a small step that has a big impact on adherence and safety."

— Dave Borrone, RPh

Team Tip: Align Monitoring With Patient Counseling

"We check electrolytes, liver function, and blood pressure routinely, but we also explain why each lab matters. When patients understand the purpose, they're more engaged in their own care."

— Chelsea Cramer, APN

Team Tip: Set Expectations, Not Just Warnings

"Most side effects are mild and manageable if patients know what's coming. It is about preparing—not alarming—them."

— Satish Shanbhag, MD

PRIOR AUTHORIZATIONS AND PATIENT ASSISTANCE:

A COORDINATED, RAPID-RESPONSE EFFORT

Ensuring timely access to Yonsa requires a coordinated process that moves swiftly from prescription to therapy initiation. The practices have built a robust infrastructure to handle prior authorizations and patient assistance efficiently. "We have someone who handles all of our prior authorizations for every provider across the practice," said Edwards. "She is very experienced, and that consistency helps us get quick turnaround times. If a peer-to-peer is needed, she is instrumental in facilitating it and working with the office and physician directly."

As soon as a prescription is processed, the workflow is triggered. "Once I send the prescription and hear back that prior authorization is required, I notify the pharmacist right away," said Shockey. "They contact the insurance company, notify the physician, and keep the process moving. In most cases, we can receive an answer within 24 to 48 hours." As soon as approval is given, the team updates both the patient and the provider to ensure therapy can begin immediately. Borrone plays a key role in accelerating this process by being embedded within the clinic. "I get the call that a PA is needed, and because I have EMR access, I can confirm the diagnosis and treatment plan right away," he explained. "If anything needs clarification, I just walk down the hall and speak to the provider directly. It's more efficient than a phone call and fosters real-time collaboration."

Beyond the logistics of coverage, the team also focuses on affordability. "We know cost can be a barrier, so we look into every possible option," said Edwards. "If the patient is commercially insured, we check for copay assistance. If the patient needs additional help, we involve social workers and explore every available resource to support them." This proactive and highly coordinated approach ensures patients are not delayed by paperwork or financial uncertainty. The team's streamlined communication and deep familiarity with the process help patients start treatment as soon as possible.

TRANSITIONING FORMULATIONS:

PATIENT EDUCATION IS KEY

WHEN patients switch from a traditional abiraterone formulation (such as Zytiga®) to Yonsa, a clear and thorough education process is essential. While both therapies share the same active ingredient, they are not interchangeable. Differences in dosing, administration, and steroid components must be clearly communicated to avoid confusion and potential harm.

Arnold emphasized the nursing team's role in reinforcing this distinction. "From our perspective, it is about clear education," she said. "Patients need to understand that these are different formulations. You can't go back and forth between them. The dosing is different, and the steroid component is different. Even though the steroid may change, it is still just as critical to take it properly to prevent side effects."

Cramer echoed the importance of this re-education, especially around administration. "One major difference is that Yonsa can be taken with or without food, while the older formulation should be taken on an empty stomach," she explained. "That is a big lifestyle adjustment for many patients. We want to be sure they understand how to properly take both the abiraterone and the associated steroid."

Borrone shared that when patients transition between formulations, education becomes his top priority. "We have to be certain they are no longer taking the previous 1000 mg dose. Yonsa is dosed differently, so we reinforce that from the start," he said. "We also walk them through the steroid change, making sure they are taking the correct dose of methylprednisolone, and not continuing prednisone by mistake."

One key advantage of Yonsa, Borrone noted, is its dosing flexibility. "Because it can be taken with or without food,

Transitioning Formulations: Patient Education is Key - continued

patients no longer have to wake up early just to take their medication on an empty stomach," he said. "That small change can make adherence easier and less disruptive to daily life."

"That small change can make adherence easier and less disruptive to daily life."

– Dave Borrone, RPh

TRANSITIONING BETWEEN ABIRATERONE FORMULATIONS: YONSA® VS. ZYTIGA®

CATEGORY	YONSA® (AAFP)	ZYTIGA® (TRADITIONAL)
Formulation	Fine particle (AAFP)	Standard abiraterone acetate
Dosing	500 mg once daily (4 x 125 mg tablets)	1000 mg once daily (4 x 250 mg tablets)
Administration	With or without food	On an empty stomach (no food ≥2 hrs before/after)
Steroid Required	Methylprednisolone 4 mg twice daily	Prednisone 5 mg once or twice daily
Flexibility	No fasting required	Requires fasting and morning dose timing
Interchangeable?	Not interchangeable	Not interchangeable
Education Focus	Confirm correct dose and new steroid	Confirm fasting and food restrictions

Important Counseling Point: Patients switching formulations must receive clear education on differences in dose, timing, and steroid type.

CONCLUSION: ELEVATING ACCESS AND OUTCOMES

THROUGH THE PQI FRAMEWORK

THE implementation of the Yonsa PQI illustrates how NCODA's PQI initative empowers the medically integrated team to deliver timely, coordinated, and patient-centered oncology care. This multidisciplinary approach, uniting pharmacists, nurses, providers, technicians, and administrative staff, ensures that patients receive not only the right treatment but also the education, monitoring, and support necessary to remain on therapy.

The team's proactive workflows around access, adverse event prevention, and transitions in care highlight the strength of the PQI in turning best practices into everyday standards. Yonsa's flexible formulation offers patients convenience without compromising efficacy, and the pharmacy's embedded role within the clinic allows for real-time collaboration and fast decision-making.

An important yet sometimes overlooked piece of the equation is the support of pharmaceutical representatives. As Edwards shared:

"One thing I love is reaching out and having relationships with drug reps. Sometimes we hit a brick wall when trying to dispense or treat a patient, and we may not even know what resources are available. Having those connections helps us resolve issues quickly. They have reimbursement managers, MSLs, and people who can answer questions and help us get patients treated as efficiently as possible."

This kind of collaboration between care team members and external partners reflects the very heart of the PQI: equipping practices with actionable resources, improving patient access, and reinforcing the team-based, patient-centered approach that defines NCODA's mission.

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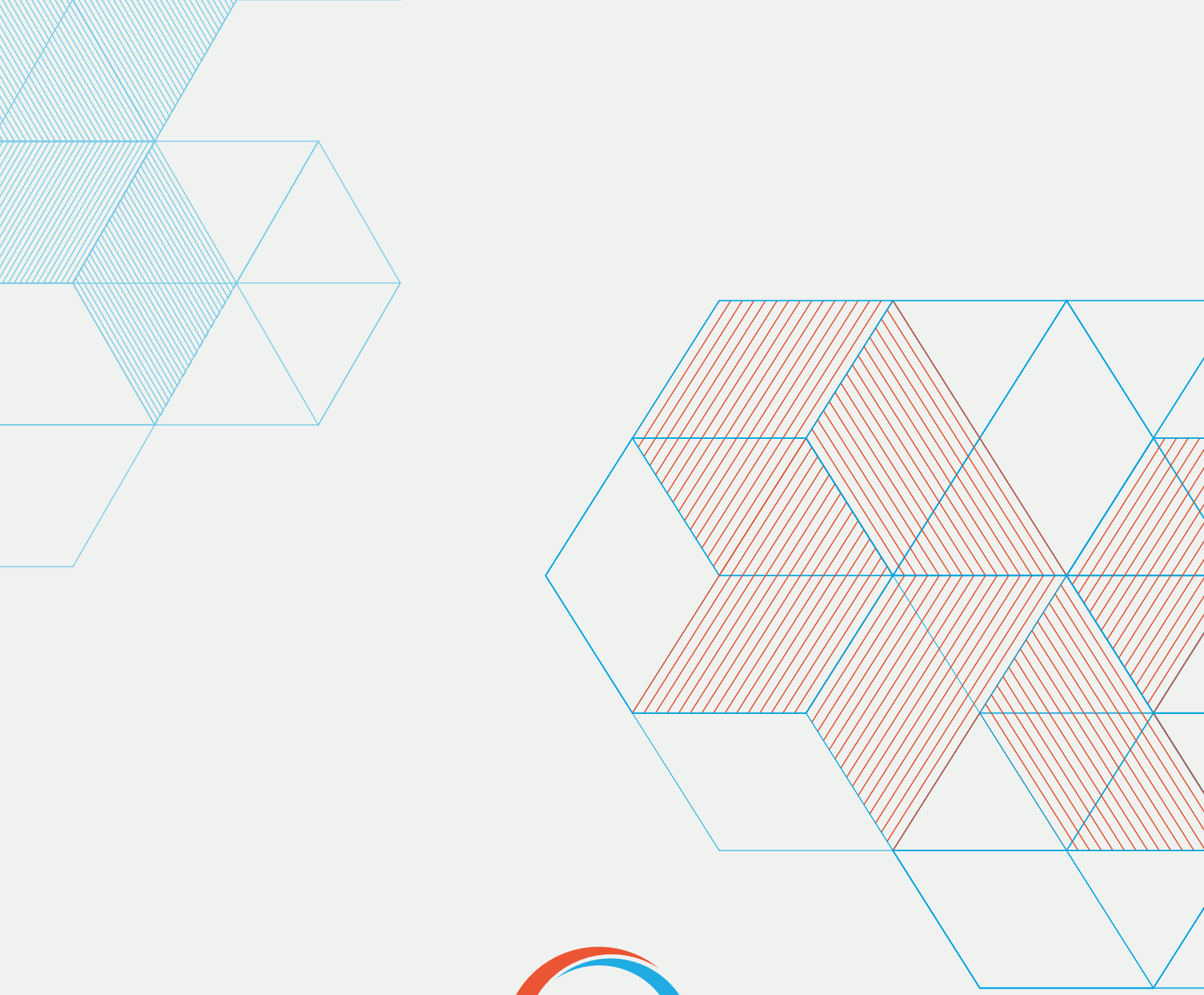

Practice panelist's comments reflect their experiences and opinions and should not be used as a substitute for medical judgment.

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