PQI IN ACTION

Positive Quality Intervention

NCODA

Sonidegib (Odomzo®) Patient 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 Sonidegib (Odomzo®) Patient Management PQI and explores how the medically integrated teams at UCLA Medical Center (UCLA), The Ohio State University Comprehensive Cancer Center (The James), and WVU Medicine (WVU) collaborate and utilize the information found in the PQI as part of their daily practice.

Scan or click here to access Sonidegib (Odomzo®) Patient Management Positive Quality Intervention

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BASAL CELL CARCINOMA TREATMENT WITH SONIDEGIB

BASAL cell carcinoma (BCC) is the most common form of skin cancer, representing about 80% of non-melanoma skin malignancies.[1] Abnormal hedgehog (HH) pathway activity related to mutation in the PTCH1 gene is associated with development of BCC.[3] Sonidegib is a HH pathway inhibitor that binds to and inhibits the smoothened homologue (SMO) involved in HH signal transduction.[2] Wildtype PTCH1 inactivates SMO upon binding with sonic HH ligand. In BCC, PTCH1 is mutated and can no longer inactivate SMO. HH inhibitors such as sonidegib bind to SMO to inhibit its activity, hence functioning as a wildtype activated PTCH1.[1]

Sonidegib is indicated in the treatment of patients with locally advanced BCC (laBCC) that has recurred following surgery or radiation therapy, or in those who are not candidates for surgery or radiation therapy.[1] In the multicenter, double-blind, phase 2 BOLT trial, patients with locally advanced, unresectable, or metastatic BCC were randomized (2:1) to receive either sonidegib 800 mg or 200 mg orally, once daily, until disease progression or intolerable toxicity.[3] At a follow-up of 30 months, patients with laBCC achieved an overall response rate (ORR) of 56.1% in the 200 mg arm vs 45.3% in the 800 mg arm.[4] Sonidegib 200 mg had a better safety profile compared to 800 mg, with lower rates of grade 3/4 adverse events (AEs; 43.0% vs. 64.0%) and AEs leading to discontinuation (30.4% vs. 40.0%). The median duration of response in the 200 mg group was 26.1 months (95% CI:10.1, not reached).[4]

Frequently seen AEs associated with sonidegib, including muscle spasms (71.2%), alopecia (66.3%), dysgeusia (55.8%) and weight loss (50%), can be severe and lead to tolerance issues.[5] There has been investigation of adjusted dosing schema for sonidegib treated patients. In a single center retrospective analysis of 20 BCC patients treated with sonidegib, 9 patients were treated using a modified treatment schedule of every other day dosing to avoid severe AEs.[5] Patients in the dose adjustment group had comparable clinical responses to those on the daily dosing regimen, but experienced fewer AEs overall. In the dose adjustment group, 66.7% (6/9) achieved complete responses, and 33.3% (3/9) had partial responses. All 9 patients experienced only mild (grade 1-2) adverse events, with no severe AEs reported.[5]

A post hoc analysis comparing sonidegib to vismodegib, another HH inhibitor, in advanced BCC found sonidegib-treated patients had a delayed median time to onset for all AEs versus vismodegib-treated patients, except fatigue and weight decrease.[6] In vismodegib-treated patients, most treatment-emergent adverse events occurred within the first two months. After three cycles of vismodegib, muscle spasms, dysgeusia, and alopecia rates were around 60%, 60%, and 25%, respectively. In contrast, the rates for sonidegib were lower, at 32.9%, 15.2%, and 5.1%, respectively. Sonidegib has a longer elimination half-life (30–41 days vs. 4–12 days for vismodegib) and a much larger volume of distribution (>9,000 vs. 26.6L for vismodegib), indicating greater tissue penetration.[1,6,7]

SONIDEGIB PATIENT PROFILE: HCP INSIGHTS

MEDICAL oncologists at UCLA and Ohio State shared their insights on how they select patients for sonidegib. Their approaches align with the recommended guidelines and prescribing information, emphasizing the drug's role in treating a select group of patients with laBCC who are not candidates for curative surgery or radiation. Deborah Wong, MD, PhD explained, "sonidegib is a very unique drug that is specifically approved for locally advanced basal cell carcinoma... So patients who have big, locally advanced basal cell cancers that cannot be addressed fully with surgery or radiation—those are the patients in whom I would consider sonidegib." Claire Verschraegen, MS, MD, FACP noted that she typically initiates therapy with a Hedgehog inhibitor like sonidegib and evaluates response over a four-month period, allowing time for partial remission, often marked by a 50% reduction

Sonidegib Patient Profile: HCP Insights - continued

in lesion size. She prefers sonidegib due to its pharmacodynamic profile and longer half-life in soft tissue.

While molecular alterations in the Hedgehog pathway (e.g., SMO and PTCH mutations) are commonly associated with laBCC, Dr. Wong emphasized that treatment decisions are generally not dependent on the presence of these specific mutations. She discussed her use of next-generation sequencing (NGS) as part of a broader precision oncology approach. She incorporates NGS testing frequently for patients with advanced cancers, including laBCC, particularly when the treatment goal is long-term disease control rather than cure. While mutations in the Hedgehog signaling pathway, such as those affecting SMO or PTCH, are known to drive BCC, she clarified that sonidegib remains effective regardless of whether these mutations are detected. "The selection of treatment choices for locally advanced basal cell carcinoma is not predicated on the presence or absence of a specific mutation," she said, noting that the drug's approval and efficacy are not limited to biomarker-defined populations. Dr. Verschraegen always checks the mutational profile which she says helps her direct therapy. For example, if a resistant SMO mutation to HH inhibition is found, she combines itraconazole with the sonidegib.[8]

ELEVATING PATIENT CARE THROUGH MEDICALLY INTEGRATED PHARMACY (MIP)

ONCE a treatment regimen has been determined, the multidisciplinary care team, including physicians, pharmacists, nurses, and pharmacy technicians, works collaboratively to ensure seamless, patient-centered care. The presence of a Medically Integrated Pharmacy (MIP) within oncology clinics plays a critical role in this model by enabling the in-house processing and dispensing of oral anti-cancer therapies like sonidegib. This integration streamlines medication access, enhances coordination, and supports adherence through direct communication among care team members. The result is improved efficiency, patient convenience, and continuity of care, all of which are essential for achieving optimal outcomes.

UCLA nurse practitioner Meetal Dharia, MSN, NP-C AOCNP, emphasized the importance of this collaboration in managing both the therapy and the patient experience. Dr. Wong agreed and shared, “I cannot emphasize enough the importance of the multidisciplinary team...within oncology it’s a critical piece of being able to get patients what they need and cared for in the best possible way.” She explained that access barriers, such as insurance approvals, copays, and specialty pharmacy logistics, are often resolved through the expertise of the pharmacy team. “My pharmacy technician and pharmacist are really helpful,” she noted, also crediting the pharmacist and nurse practitioner for ongoing patient education and toxicity management. Frequent touch points with patients help ensure timely interventions and reinforce adherence. “One person alone can’t do it all,” Dr. Wong concluded, underscoring the essential value of a team-based approach.

THE PHARMACIST AS AN INTEGRAL TEAM MEMBER

Pharmacists play a pivotal role within the medically integrated oncology care team, providing clinical oversight, medication safety, and patient-centered education. Their contributions extend across the treatment continuum, from clinical trial support and toxicity monitoring to medication access and adverse event management. UCLA Research Pharmacist Shirin Khorashadi, PharmD, APh, BCOP, emphasized her involvement in reviewing clinical trial protocols and educating nurses and pharmacy technicians. WVU Clinical Pharmacy Specialist Christine Barrett, PharmD, BCOP highlighted the pharmacist’s ability to bridge communication gaps among providers, specialty pharmacy, and patients, and her role in directly counseling patients on new therapies like sonidegib. “We can serve as an advocate for our patients in

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

this setting to make sure that our therapies are safe and effective," she noted. The pharmacist's expertise ensures that oral oncolytics are prescribed, dispensed, and monitored with precision and compassion.

FIGURE: PHARMACISTS AS PART OF THE MIP TEAM

Key Responsibilities Include:

01	Collaborating with physicians on dosing strategies and clinical monitoring
02	Monitoring for adverse effects and managing toxicity
03	Educating nurses, pharmacy technicians, and patients on oral oncolytics
04	Supporting access via prior authorizations and formulary navigation
05	Reviewing medication profiles for drug-drug interactions
06	Facilitating transitions from clinical trial protocols to practice
08	Collaborating with specialty pharmacy to enhance communication and care coordination
07	Advocating for patients' safety and optimal treatment outcomes

DRUG INTERACTIONS AND MEDICATION RECONCILIATION

THE PQI contains an overview of the process for managing patients on sonidegib, starting at the point of treatment initiation. A thorough review of all current medications is essential before initiating sonidegib, as drug interactions may impact both efficacy and safety. Strong CYP3A inhibitors should be avoided, as should long-term use of moderate CYP3A inhibitors (beyond 14 days).[2] Strong and moderate CYP3A inducers should be avoided due to the potential for altered drug metabolism and increased toxicity.[2]

Pharmacists play a central role in this process, ensuring a complete and accurate medication reconciliation is conducted. WVU pharmacist Corbin Sypult, PharmD shared, "Typically, as part of our process, we perform that medication reconciliation up front. I will check a patient's medication list within the EMR, but that doesn't always capture every-

Drug Interactions and Medication Reconciliation - continued

thing, especially if they have outside providers." He noted the importance of reviewing over-the-counter medications and supplements directly with the patient and using drug interaction databases such as Lexicomp or Facts & Comparisons when evaluating real-time concerns.

Barrett emphasized, "An important piece that can sometimes get missed is making sure we have the most up-to-date record of the patient's medications at home." She often finds discrepancies or omissions during this process, particularly involving drugs like statins, which may pose interaction risks when paired with sonidegib. "Looking at those things in the bigger picture lets me clinically assess for anything that could cause issues down the line."

DOSING, MONITORING AND AE MANAGEMENT

SONIDEGIB is administered as a 200 mg capsule taken orally once daily on an empty stomach, either at least one hour before or two hours after a meal.[2] While the dosing regimen is straightforward, appropriate monitoring is essential to ensure patient safety and maintain treatment adherence.

As outlined in the PQI, treatment holds or interruptions are recommended in cases of severe or intolerable musculoskeletal adverse reactions or if serum creatine kinase (CK) levels rise between 2.5 to 10 times the upper limit of normal (ULN). Permanent discontinuation is advised for CK elevations exceeding 10x ULN, elevations greater than 2.5x ULN with renal impairment, or for recurrent severe musculoskeletal toxicity.[2] These criteria reinforce the importance of consistent monitoring throughout therapy. Dr. Verschraegen highlighted the unreliability of CK labs if the patient has exercised the previous day, and therefore the importance of asking the patient about potential exercise.

Pharmacists and providers emphasize vigilant and proactive monitoring to preserve treatment efficacy while minimizing harm. Barrett shared:

"We are often the primary healthcare professional making sure that monitoring is being done, baseline and periodic CKs, creatinine, potentially liver function tests. We stay vigilant with follow-up calls and assessments, especially during windows where side effects can begin to emerge."

Dr. Verschraegen integrates monitoring protocols directly into the electronic medical record prescribing plans:

"We see patients back within two weeks of starting, then every six weeks. We monitor a comprehensive metabolic panel including CK, and if they report muscle aches, we may test aldolase because that is a good marker for muscle inflammation. The key is modifying the dose or holding the drug based on symptoms, and making sure patients know how to contact us if something arises."

UCLA nurse practitioner Dharia described a similar approach:

"We bring patients in every two weeks to check CBC, CMP, and CK. If they report muscle weakness, dark urine, or anything concerning, we evaluate them sooner. I tell patients to report anything new, even if it's not listed, as it could still be drug-related."

Dr. Wong emphasized that tolerability is essential for long-term success:

"These drugs are taken daily and intended to be continued while they're still effective, so managing side effects is critical. If we don't stay ahead of nausea or fatigue, we risk having to stop a drug that is otherwise working."

Finally, Khorashadi noted that adverse event management is often shared:

"Most of our AE management is done by our nurse practitioners, but we collaborate closely to support safe dosing and continuation."

This team-based vigilance ensures that adverse effects are identified and addressed early, helping patients stay on

Dosing, Monitoring and AE management - continued

therapy longer and with better quality of life.

MANAGING ALOPECIA WITH SONIDEGIB

Alopecia is a known but variable side effect of sonidegib, and while not universal, it is a concern frequently voiced by patients. The multidisciplinary team plays a key role in preparing patients for what to expect and providing supportive strategies throughout treatment.

Barrett explains how she frames the discussion:

"I explain how it's different from chemotherapy—it doesn't usually present as quickly and is usually more of a gradual hair thinning."

Dharia shares that this side effect often comes up early in conversations.

"Patients are concerned about alopecia. We tell them that it is reversible, that you can expect regrowth in four to six weeks after stopping the drug." She also advises patients to avoid hair dyes or chemical treatments during therapy to help protect the scalp and promote healthier regrowth.

Dr. Wong notes the visible impact this toxicity can have.

"Hair loss can be pretty disfiguring. Sometimes minoxidil can be tried, but our dermatology colleagues can also be helpful in managing this side effect."

MANAGING GI TOXICITIES AND ALTERED TASTE

Gastrointestinal adverse events including nausea, vomiting, diarrhea, weight loss, and decreased appetite are among the most common challenges reported with sonidegib. These side effects often interconnect and, if not addressed early, can significantly affect a patient's nutritional status, quality of life, and treatment adherence.

Dr. Wong emphasizes the need to proactively support patients with nutritional guidance.

"There are a lot of GI side effects—abdominal pain, nausea, diarrhea, weight loss, decreased appetite. With altered taste and decreased intake, I often connect patients from the start with nutrition support." She encourages strategies like tracking caloric intake, choosing nutrient-dense foods, and working with dietitians to create sustainable plans.

Dharia discussed the added difficulty patients face when taste is affected.

"Changes in taste can be a real barrier because patients don't take in as much nutrition, they start losing weight, and that leads to deconditioning. We recommend smaller, more frequent meals, foods at room temperature, avoiding metal utensils, and good oral hygiene." She also suggests personalized seasoning, checking zinc levels when warranted, and increasing chewing time to support salivary stimulation.

For nausea and diarrhea, Dharia advises prompt intervention with supportive medications.

"We recommend antiemetics for nausea and loperamide for diarrhea as first-line tools."

Dr. Wong added that the accumulation of side effects can quickly derail treatment:

"You might think altered taste isn't a big deal, but when it is combined with weight loss, decreased appetite, and fatigue, it becomes a significant challenge. These are often the reasons patients struggle to stay on therapy, even when the drug is working."

Together, early counseling, dietary support, and symptom management help preserve patient well-being and allow for sustained therapy.

MANAGING MUSCLE-RELATED ADVERSE EVENTS

Musculoskeletal side effects, including cramping, muscle spasms, myalgia, and elevations in creatine kinase (CK), are among the most notable and dose-limiting toxicities associated with sonidegib. These events can be particularly challenging due to their delayed onset and variability across patients.

Dr. Verschraegen shared that muscle cramping is common and often requires a layered mitigation approach.

"We try to prevent cramping with calcium, cyclobenzaprine, and sometimes Coenzyme Q10. If symptoms persist, we'll hold treatment for a week or two depending on the drug and then resume at a reduced schedule. For some, I've gone to Monday–Friday dosing or even twice weekly, which seems to maintain benefit with better tolerability."

Dharia added that symptom onset often takes a few months.

"Muscle cramps tend to develop around two to three months into therapy. We manage with mag-

Dosing, Monitoring and AE management - continued

nesium supplements, analgesics like ibuprofen, and occasionally muscle relaxants. Symptoms typically resolve within a month after stopping the drug. Some clinicians even consider one-month-on/one-month-off pulse therapy, though that's not aligned with FDA labeling."

Dr. Wong emphasized the unique pathophysiology of Hedgehog inhibitor–related muscle toxicity.

"You can see joint pain, muscle spasms, and even muscle inflammation with CK elevation. Interestingly, there are small studies suggesting benefit from supplements like L-carnitine or medications like amlodipine, which may help reduce spasms." She also encouraged maintaining physical activity, which may support symptom reduction.

Pharmacists also play a key role in monitoring and intervention.

Sypult explained, **"If a patient reports muscle symptoms, we often recommend checking CPK levels—even if the provider hasn't ordered them yet."**

Barrett, added, **"We look at the big picture, including other medications like statins that could compound toxicity. I also talk to patients about using calcium or CoQ10 early to reduce dose interruptions or delays."**

PATIENT EDUCATION AND COUNSELING

COUNSELING PATIENTS: SETTING THE FOUNDATION FOR ADHERENCE

Comprehensive counseling at treatment initiation helps patients understand sonidegib's purpose, how to take it correctly, and how to manage potential side effects. Providers across institutions emphasize the importance of combining verbal counseling with written instructions, follow-up accessibility, and family engagement.

Dr. Verschraegen shared that once treatment is prescribed, patient education is a clear handoff to the pharmacist.

"The pharmacist has a written handout with all the potential side effects, tells them how to take the medicine, and makes sure they understand things like fasting requirements and storage."

At UCLA, Dharia takes a layered approach:

"We go through administration, missed doses, interactions, and all the common side effects. We talk about contraception, give written instructions, ideally in the patient's primary language, and prefer a family member to be present. We also encourage patients to message us via MyChart if they have questions later."

Sypult described a robust counseling process at therapy initiation and during refills:

"We provide education on administration, storage, expected side effects, and CYP interactions. We also follow up at the first and second refill, then quarterly, or every six months after a year on therapy. We encourage patients to call with any concerns and reinforce that we're easy to reach."

EDUCATIONAL TOOLS AND OPERATIONAL BEST PRACTICES

Written education, including the Oral Chemotherapy Education (OCE) Sheet, is a key part of standard workflows. The sheet includes counseling pearls such as:

- Swallow capsules whole; do not crush or chew
- Take on an empty stomach (at least 1 hour before or 2 hours after food)
- Skip missed doses; do not double up
- Avoid grapefruit products
- Use contraception during and well beyond therapy (8 months for males, 20 months for females)
- AE Management

Barrett emphasized storage and administration as top priorities in pharmacist counseling.

"Patients don't always know how

Patient Education and Counseling - continued

it should be stored or what to avoid with food. We explain how a high-fat meal can increase drug exposure—not to scare them, but to help them understand why that fasting window matters." She added that each patient interaction may involve "20 minutes of information," so pharmacists also stress their availability for follow-up questions.

Together, these approaches, verbal, written, and accessible, equip patients and caregivers with the knowledge needed to confidently manage sonidegib treatment and minimize preventable interruptions.

Adherence monitoring is seamlessly built into the care model. At the first two-week follow-up, Dharia confirms medication use and reinforces administration guidance. "**We go over it again at that visit to ensure they're taking it correctly,"** she noted. At WVU, pharmacy technicians play a frontline role. Rebekka Bissett, CPhT, explained:

"When patients aren't due for a pharmacist call, a specialist tech reaches out. We ask about missed doses, medication changes, or side effects, and then triage any concerns to a pharmacist."

Sypult added, "**The medication is going to work best if you're able to take it consistently. So we make it clear that if anything comes up, side effects, insurance, adherence, they can call us right away."**

This ongoing support structure that is anchored by proactive communication and timely check-ins ensures patients are set up for success, from initiation through long-term management.

TOP TIPS FOR ADHERENCE SUPPORT

Start Strong

Reinforce medication timing, fasting requirements, and common side effects at the first follow-up visit. Use verbal and written materials, ideally in the patient's primary language.

Stay Connected

Ensure patients know who to call for questions. Encourage ongoing communication between visits using MyChart, phone, or pharmacy access lines.

Include Caregivers

When possible, involve a family member or support person in counseling sessions to improve recall and reinforce instructions.

Handle Logistics Early

Proactively manage refills, prior authorizations, and insurance changes 7–10 days in advance to avoid treatment gaps.

Use the Whole Team

Pharmacy technicians assess adherence and triage concerns; pharmacists and clinicians address barriers and provide solutions collaboratively.

Normalize the Check-Ins

Regular touchpoints—at 2 weeks, refills, and quarterly—build trust, catch issues early, and help patients stay on track with treatment.

NAVIGATING ACCESS AND FINANCIAL BARRIERS

Accessing sonidegib is a coordinated effort that often begins with the pharmacy team and patient assistance staff well before the first dose is taken. At many clinics, pharmacy technicians are the "first eyes" on the prescription, conducting benefits investigations, submitting prior authorizations, and communicating outcomes to both the provider and patient. Bissett described this workflow as **"transparent and fully integrated into the patient chart, regardless of where the medication is dispensed."**

Khorashadi highlighted how critical this support is, particularly from the patient's perspective:

"We are the facilitators for these patients who are really struggling. The last thing they want is to be running around trying to get their medication."

UCLA Patient Assistance Coordinator Tamala Risher, HLT III added,

"My goal is to get the co-pay down to zero. If a patient is commercially insured, I can usually get them a co-pay card or access the manufacturer's program. We always follow up to ensure patients can afford the medication before it's dispensed."

While most sonidegib use is on-label and processed smoothly, the team must still contend with insurance hurdles, specialty pharmacy communication gaps, and the burden those delays place on patients. These teams advocate relentlessly to avoid interruptions in care.

THE VALUE OF THE PQI

Positive Quality Interventions offer quick, evidence-based guidance that supports safe, consistent care across the multidisciplinary team. For therapies like sonidegib, having a concise reference is especially helpful.

"You can quickly get the rundown and become a quote-unquote expert," said Sypult. Bissett added, "If we see something that doesn't align with the PQI, we flag it right away, it's built into our workflow."

When paired with an MIP model, the Sonidegib (Odomzo®) Patient Management PQI helps ensure alignment across roles, enhances patient safety, and supports proactive, team-based care from access to adherence.

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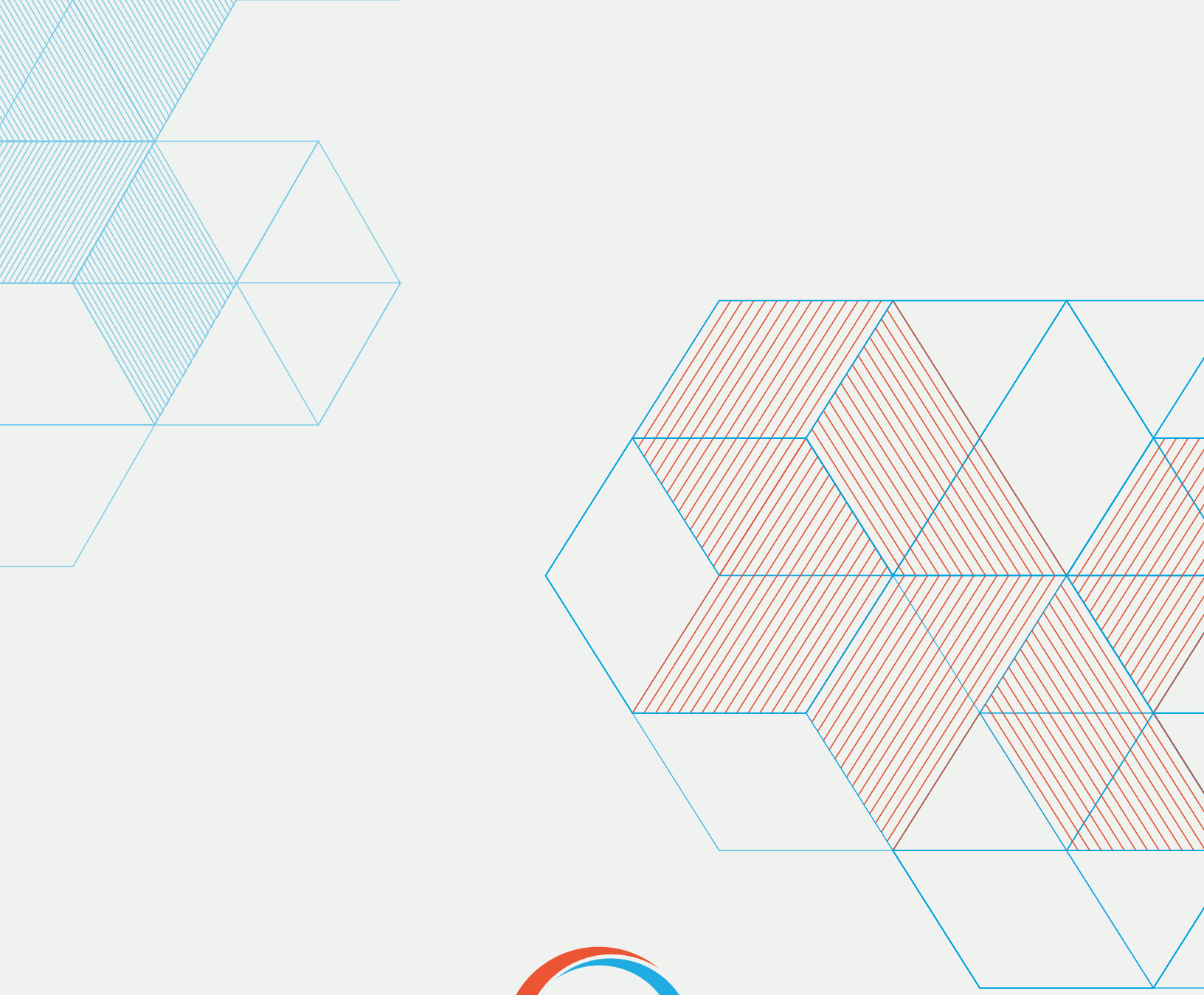

Practice panelist's comments reflect their experiences and opinions and should not be used as a substitute for medical judgment.

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