

# PQI IN ACTION



## TUCATINIB (TUKYSA®) MANAGEMENT



## NCODA'S POSITIVE QUALITY INTERVENTION IN ACTION

# INTRODUCTION

To promote higher quality patient care, NCODA created the Positive Quality Intervention (PQI) as a peer-reviewed clinical guidance document for healthcare professionals. By providing quality standards and effective practices around a specific aspect of cancer care, each PQI equips the entire multidisciplinary care team with a sophisticated, concise resource for managing patients receiving oral or IV oncolytics.

This PQI in Action expands on the Tucatinib Management PQI. Significant results continue to emerge from research on tucatinib (TUKYSA®), an FDA-approved oral medication for adults with advanced unresectable or metastatic HER2-positive breast cancer.<sup>1</sup>

Key elements in this clinical how-to guide include starting doses, adjuvant medications, side effect management and dose reduction.

Patient-centered activities are highlighted to enhance education/understanding, compliance and well-being.

This article explores how the medically integrated teams at Mays Cancer Center, home to UT Health San Antonio MD Anderson, and Cancer Care Specialists of Illinois incorporate PQIs in their daily workflow and how the TUCATINIB (TUKYSA®) MANAGEMENT PQI elevates patient care.

## THE PARTICIPANTS

### Mays Cancer Center | San Antonio, Texas

Mays Cancer Center, the only National Cancer Institute (NCI)-designated cancer center in South Texas, draws more than 120,000 patient visits to San Antonio yearly. The academic medical center, aligned with MD Anderson Cancer Center and University of Texas (UT) Health, is known for leading-edge care and trials, drug development and high-touch amenities like gentle yoga. Many staffers are bilingual; the region is nearly 85% Hispanic. The adjacent UT Health San Antonio Multispecialty and Research Hospital Science Center is slated to open in 2024. Mays and this new, \$500 million hospital will be connected by a sky bridge, allowing the cancer center to expand inpatient treatment and research.

### Cancer Care Specialists of Illinois | Decatur, Illinois

Cancer Care Specialists of Illinois (CCSI) is a physician-owned, community-based oncology practice in Southern and Central Illinois. The 20 physicians and five advanced practice nurses provide care to patients at 21 clinics, with the latest site serving the St. Louis area. The multidisciplinary team is known for quality medical oncology, hematology and radiation oncology services, affiliated with several NCI research organizations, and the recipient of 15-plus individual awards for research excellence. Three clinics have on-site infusion pharmacies, Decatur has tucatinib and other oncology drugs delivered for on-site dispensing. The oncologists provide close-to-home resources via clinics and select community hospitals.

#### Mays Cancer Center San Antonio, Texas



**Heidi Ko, DO**  
Oncologist



**Marcela Mazo Canola, MD**  
Oncologist



**Bradi L. Frei, PharmD,  
MSc, BCPS, BCOP**  
Clinical Oncology  
Pharmacy Specialist



**Yvonne Wade, MSN, RN**  
Oncology Nurse



**Christel Wheeler, FNP-BC**  
Family Nurse Practitioner



**Michelle Heidel, PharmD**  
Staff Pharmacist



**Robyn Dunker, CPhT**  
Lead Pharmacy Technician/  
Financial Coordinator

# DEFINING MEDICALLY INTEGRATED PHARMACY AND THE POSITIVE QUALITY INTERVENTION

A Medically Integrated Pharmacy (MIP) is a service model where patients receive oral and IV therapies at the site of care with their doctor and are managed by one staff. State-of-the-art pharmacy services within the cancer center deliver timely and ongoing care as part of a single, multidisciplinary team. Complexity of cancer treatment has increased with a growing number of both oral and IV therapies delivered across an often-confusing, payer-driven healthcare system.

Various treatment settings, including community, institutional, and academic centers, have successfully transitioned to this integrated service model to maintain continuous patient care and achieve the best possible clinical outcomes. Empowered with innovative tools like the Positive Quality Intervention (PQI), Medically Integrated Teams have improved the quality of care delivered at their institutions through adoption of NCODA resources.

Leading oncology centers such as the Mays Clinic and Cancer Care Specialists of Illinois (CCSI) value the PQI's concise, clinical guidance. In a world where new and novel treatments arise almost daily, healthcare professionals need an easy-to-use reference to enact key clinical principles for each therapy.

Mays cancer specialist Heidi Ko, DO, values the precise guidelines for her clinical team – starting with the busy oncologist herself.

Briefing herself with a PQI is time-efficient “when you're so busy in clinic,” the oncologist-hematologist said. “Sometimes, I have to pull up FDA package insert – a huge document – and scroll through, searching through it.”

CCSI family practitioner Christel Wheeler, FNP- BC, relies on PQIs to educate/update staff and patients on matters ranging from dosages to patient-centered activities.

She finds NCODA's Oncology chemotherapy Education (OCE) sheets invaluable, distributing them and reviewing them with new patients. She reserves an hour to go through the pages with each patient.

“I like these and the patients understand them, she said. “They're usually a little bit more informative when it comes to the side effects and management and so forth.”

Sometimes patient jot notes on the handouts and circle back to confirm instructions. “If it takes longer than an hour, I'm OK,” Wheeler said.

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## MECHANISM OF ACTION

Breast cancer is the most common cancer worldwide and accounts for one in every eight cancers 2020.<sup>2</sup> Up to 20% of breast cancers may overexpress human epidermal growth factor receptor 2 (HER2) and up to half of patients with metastatic HER2-positive disease may develop brain metastases.<sup>3</sup> Patients with HER2-positive metastatic breast cancer whose disease progresses following therapy with multiple HER2-targeted agents have limited treatment options.<sup>2</sup>

TUKYSA® (tucatinib) is a HER2 tyrosine kinase inhibitor approved in combination with trastuzumab and capecitabine for the treatment of HER2-positive metastatic breast cancer.<sup>4</sup> The long-term regimen is approved for patients with inoperable or metastasized cancer who have undergone one or more

HER2-plus-based regimens in the metastatic setting (including patients with brain metastases).<sup>4</sup>

A potent oral tyrosine kinase inhibitor, TUKYSA® (too-ki-suh) penetrates cell membranes and binds to the HER2- protein in tumor cells. This inhibits the cell's signaling pathways and blocks the growth of HER2-plus-expressing cells.<sup>1,3,5</sup>

TUKYSA® was approved by the U.S. Food and Drug Administration (FDA) in collaboration with Health Canada, Australian Therapeutic Goods Administration, Swissmedic and Health Sciences Authority in April 2020.<sup>4</sup>



# CLINICAL RESEARCH ON TUCATINIB (TUKYSA®)

The FDA approved TUKYSA® based on the results of a clinical trial enrolling 612 patients with HER2-positive advanced unresectable or metastatic breast cancer and had prior treatment with trastuzumab, pertuzumab and ado-trastuzumab emtansine (T-DM1).<sup>3</sup>

Patients with stable, previously treated or untreated brain metastases also were eligible; 48% of enrolled patients had brain metastases at the start of the trial.<sup>5</sup>

The endpoint was progression-free survival (PFS). The median PFS in individuals who received tucatinib, trastuzumab, and capecitabine was 7.8 months compared to 5.6 months for patients who received placebo, trastuzumab, and capecitabine.<sup>3</sup>

Researchers analyzed the subgroup of patients with brain metastases and found significantly increased PFS with tucatinib in patient population as well, reporting primary results of PFS at one year of 24.9% in the tucatinib group compared to 0% in the placebo group.<sup>3</sup>

An exploratory analysis in the HER2CLIMB trial of intracranial efficacy in patients with brain metastases who received

tucatinib combination versus placebo group was presented at the 2020 ASCO Annual meeting. The authors found a 42% reduction in the risk of death, a 68% reduction in the risk of CNS disease progression or death, and an increase in intracranial response rate (47% vs. 20%) for patients with active, measurable intracranial lesions at baseline.<sup>6</sup>

An updated Phase 3 analysis followed in JAMA Oncology in December 2022 – and suggests the tucatinib-trastuzumab-capecitabine regimen may change the treatment landscape for patients with HER2-positive metastatic breast cancer, including those with brain metastases.<sup>1,6,7</sup>

The survival benefits were clinically meaningful. For patients with brain metastases at baseline, median overall survival rate was 21.6 months. Among all 612 patients, median new brain lesion-free survival was 21.6 months in the tucatinib group vs 13.8 months in the control group.<sup>1,6,7</sup>

Tucatinib in combination with trastuzumab and capecitabine prolonged median overall survival by 9.1 months in patients with brain metastases and reduced the risk of developing new brain lesions as sites of first progression or death by 45.1% in all patients.<sup>1,6,7</sup>

## THE PQI PROCESS

The first step of the Tucatinib (TUKYSA®) PQI Management Process is to identify eligible HER2-positive patients as potential candidates for tucatinib. This life-extending combination of tucatinib, capecitabine and trastuzumab has a Category 1 recommendation by NCCN Guidelines for second-line systemic treatment of HER2-positive metastatic breast cancer.<sup>8</sup>

Physicians and nurses typically provide education for the treatment, which is ongoing as well as complex. The regimen includes oral tablets (tucatinib and capecitabine) and on-site infusions (trastuzumab). The recommended dose of TUKYSA® is 300 mg twice daily, taken 12 hours apart with or without food. Tablets should be swallowed whole.<sup>9</sup>

At Mays, once a physician approves the drug order, a nurse enters and processes it via the patient electronic health record. Insurers are contacted and treatments coordinated.

A well-integrated care team “is a very good resource/luxury,” said



**A member of NCODA's video team films an educational video with a member of the UT Health San Antonio MD Anderson Mays Cancer Center team.**

Marcela Mazo Canola, MD, a breast cancer specialist at Mays.

A native Spanish speaker, Canola is a natural go-to within the heavily Hispanic patient caseload.

Briefing patients on side effect management in their language is essential. A bilingual nurse follows up with more education. “Telling the patients what to expect is very important so they prepare,” the physician said.

A major resource: NCODA’s Oral Chemotherapy Education (OCE) sheets, handouts discussing side effect management, oncology treatment terms, insurance terms and more. Ten have already been translated into Spanish and a NCODA task force committee is slated to complete the rest this year.

Integrated care continuity is a priority, agreed Bradi Frei,

PharmD, MSc, BCPS, BCOP. “It’s important to have that interdisciplinary care, bringing a lot of different points of patient care together,” the oncology pharmacy specialist said.

If physicians and nurses serve as generals, pharmacists serve as the frontline in the battle against cancer. These foot soldiers are armed with information on expectations, dosages and toxicities as well as medications.

## COMMUNICATION FOSTERS COMPLIANCE

A seven-day check-in is standard at Mays: a pharmacist phones patients, discusses compliance and answers questions. These one-on-one Q&A’s “translate into better education for our patients and better compliance with the medications,” Canola said. “It also reduces medication errors because they know how to take them.”

At CCSI, two pharmacists staff the central retail/specialty-accredited pharmacy in Decatur, Ill. The small but dedicated team coordinates/dispenses medications at their on-site “one-stop shop” and courier medications to 20 other rural sites.

Close quarters enable ongoing updates. “We’re all communicating with our patients so everybody knows what’s going on in everyone’s respective discipline. We don’t end up working in a silo,” said pharmacist Michelle Heidel, PharmD.

Teammate Robyn Dunker, CPhT, assists with authorizations and dispensing duties and doubles as financial coordinator. She works with insurers, Medicare and manufacturers for free drug assistance on behalf of patients.

If you can’t afford a drug, “you don’t take it, and you can’t get better or go in remission,” the pharm tech said.

She regards the pharmacy team as go-betweens between pa-



A peak behind the camera as members of the UT Health San Antonio MD Anderson Mays Cancer Center team prepared to film educational videos on tucatinib.

tients and physicians. “We figure it out and get it all coordinated,” she said.

All pharmacists are aware of drug interactions: Standard directives: avoid concomitant strong CYP3A4 and CYP2C8 inhibitors and inducer; know when to adjust which agent; determine which drug is related to the side effect: test for renal function abnormalities; and more.



# SIDE EFFECTS: SUPPLEMENTAL EDUCATION FOR PATIENT-CENTERED MEDICATION MANAGEMENT OF TUCATINIB

**A**s interest in the tucatinib regimen grows, so does awareness of side effects and prophylaxis.

Severe diarrhea is a common complaint, one that can lead to dehydration, hypotension, acute kidney injury, and death. In the HER2CLIMB trial, 81% of patients who received TUKYSA® experienced diarrhea, including 12% with Grade 3 and 0.5% with Grade 4.<sup>3</sup> Median time to onset of the first episode of diarrhea was 12 days and the median time to resolution was eight days.<sup>3</sup> Diarrhea led to TUKYSA® dose reductions in 6% of patients and TUKYSA® discontinuation in 1% of patients.<sup>3</sup>

If diarrhea occurs, administer antidiarrheal treatment as clinically indicated, physicians and nurses said. They can order diagnostic tests to exclude other causes of diarrhea.

Based on the severity of the diarrhea, interrupt dose, then dose reduce or permanently discontinue TUKYSA®.<sup>10</sup> If patients experience severe diarrhea, tucatinib should be interrupted or the dosage reduced to 250 mg by mouth twice daily, and, if necessary, reduced again to 200 mg twice daily, then to 150 mg twice daily.<sup>10</sup>

For Mays nurse Yvonne Wade, MSN, RN, patient self-care is essential. Every patient should know “how to take TUKYSA®, expected side effects, and how to manage side effects,” she listed.

She empowers patients by dispensing easy, preventive, self-help tips, e.g., they should rinse their mouth with water throughout the day to prevent or lessen the incidence of mouth sores.

## DOUBLE-CHECKING HERBAL SUPPLEMENTS

**O**ther common side effects include palmar-plantar erythrodysesthesia (63.4%), and nausea (58%). Fatigue, vomiting, hepatotoxicity (liver damage), stomatitis (inflammation of the mouth and lips), decreased appetite, abdominal pain, headache, anemia and rash.<sup>3</sup>

Mays pharmacist Bradi Frei, PharmD, MSc, BCPS, BCOP, counts medication reconciliation among her duties. That includes investigating whether a patient is rounding out their regimen with herbal supplements or over-the-counter medications. Unexpected toxicities can ensue.

No lectures are forthcoming, just advice. Her recommended source for real-time information: Memorial Sloan Kettering Cancer Center’s About Herbs, a database devoted to herbal remedies and their interactions with cancer treatment.

“It’s a pharmacist-run herbal database that’s very specific to oncology. It’s excellent. It’s also available as an app,” she said.

“Patients are afraid we’re going to come down on them, which is not the case,” the oncology pharmacy specialist said. “We mostly want to know what they’re taking in case of drug interactions.”



## PATIENT ENGAGEMENT

Staff at the Mays Clinic and CCSI credit NCODA as a source for patient-centered education and support. Beside the popular, patient-friendly (OCE) sheets, takeaways include Tucatinib Patient Guided Resource, and NCODA Financial Assistance Tool.

The hometown ambience of their clinics is an advantage for clinicians and patients at the 21 CCSI sites. Pharmacists not only answer questions, they buttonhole physicians and nurse for on-site, real-time input.

When pharmacist Michelle Heidel, PharmD, needs to run matters by a physician, she dials their direct extension or walks over to them. “It’s very convenient,” she said.

Patients appreciate the quick, personal responses and how the Decatur “hub” is a one-stop shop for their prescriptions. When patients feel unwell, “they don’t want to stop in multiple places and be exposed (to more germs) ... especially in this climate of Covid,” Heidel said.

For colleague-nurse practitioner Wheeler, in-house proximity begets trust and adherence.

“It gives us a chance to be able to build a better relationship and better rapport with the patients because we’re seeing them and going through each step with them,” Wheeler said. “Because we see them so much, we can tell when something’s off, if they haven’t been in to pick up their medication, or they don’t look like they’re feeling well.”

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## GOING MULTIMEDIA

The Mays clinic, with its high-volume caseload, recently teamed with NCODA for seven educational videos -- featuring five providers, a pharmacist and a nurse -- to help patients navigate tucatinib treatment 24/7. The five- to six-minute videos are available to NCODA members through <https://www.ncoda.org/>

Each Mays specialist introduces themselves, then discusses different aspects of tucatinib with the viewer. For example, Andrew Brenner, MD, PhD, provides background on the HER2CLIMB trial. Pharmacist Frei explains the combination medication regimen.

**“IF YOU EXPERIENCE RASH, REDNESS, PAIN,  
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CALLOUSED SKIN”**

Yvonne Wade, MSN, RN

Senior nurse Yvonne Wade, RN, MSN, focuses on symptom management, the topic – generally speaking – of main interest to patients.

Wade is virtually reassuring, urging patients to alert their provider in the event of severe diarrhea. Her tips to prevent bowel issues: hydrate, eat bland, low-fiber foods like bananas and rice, and avoid greasy, fried and spicy foods.

Her self-care equals self-empowerment messaging extends to oft-unreported symptoms like red hands and sore feet, signs of medication hand-foot syndrome (palmar-plantar erythrodysesthesia syndrome).

“If you experience rash, redness, pain, swelling or blisters on the palms of your hands or the soles of your feet, be sure to soak your feet in a water bath with Epsom salt and gently pumice any calloused skin,” Wade directs in the video. “Exfoliate and keep hands and feet moisturized. Avoid tight shoes or socks. Use gloves or anything cushioning when doing activities that increase pressure on the palms of your hand.”



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

The CCSI and Mays staff agree that the MID model and the PQI Clinical Resource are valuable to the team and patients. Every day the MID team makes a difference in the life of patients.

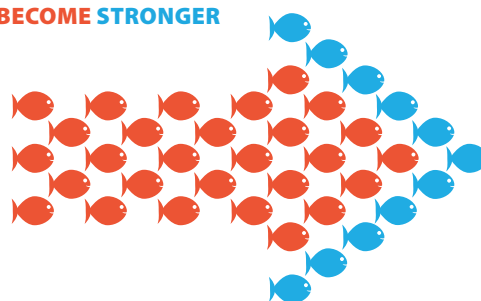
Confirming details like side effect management is easier with an at-a-glance PQI chart. “It’s like, “These are the common side effects. Here is what you do. These are the adjustments,” Mays oncologist Ko summed up. “That’s extremely helpful.”

Some patients ask to see statistics about their cancer and clinical trials, “the specific numbers” teammate Canola added. The PQI has the answers in black and white.

The resource also enables educators, nurses and pharmacist to know what to expect in every phase of treatment, she said. “And I like the summary of patient-centered activities. I see myself using them in my clinic, to provide more education to the staff and even to the patient.”

Their teams can continually learn or begin a process that optimizes care, clinicians said. The PQI fosters this through appropriate patient identification, selection, increased speed to therapy, reduced cost, and hospitalization and by improving adherence techniques for the patient and their Medically Integrated Teams. Pairing Medically Integrated Dispensing with the Tucatinib Management PQI meets NCODA’s Guiding Values of being Patient-Centered and Always Collaborative.

**WORKING TOGETHER,  
WE BECOME STRONGER**



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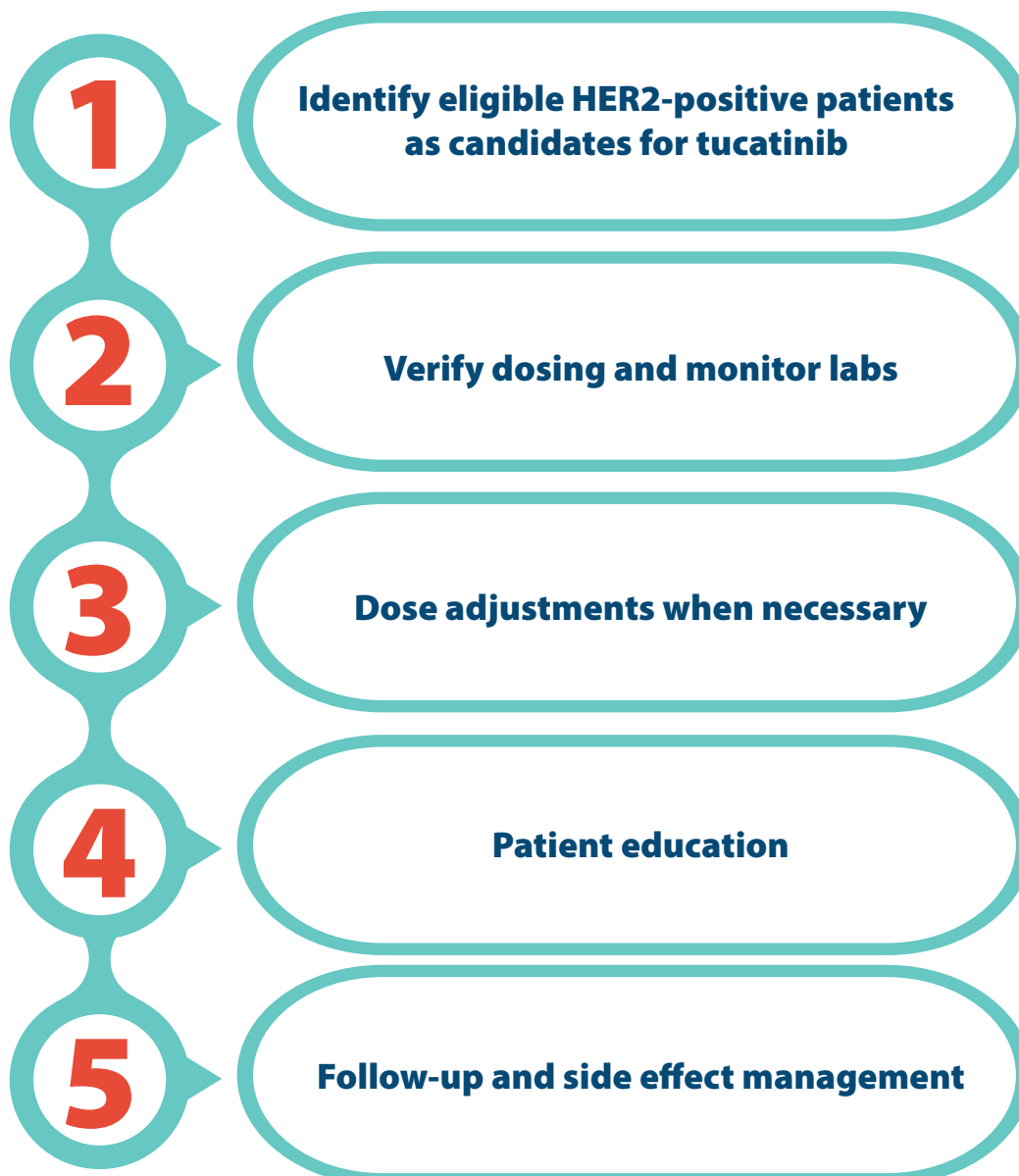
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## PQI PRINCIPLES:



- Marcela Mazo Canola, MD, (left) along with colleagues from UT Health San Antonio MD Anderson Mays Cancer Center filmed educational videos for tucatinib with NCODA's Director of Operations, Stephen Ziter, MBA (right).



## Helpful Online Resources

- [Tucatinib Management PQI](#)
- [Positive Quality Interventions](#)
- [NCODA Website](#)
- [NCODA Financial Assistance Tool](#)

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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