

Enfortumab Vedotin-ejfv (Padcev®) and  
Pembrolizumab (Keytruda®) Management for  
Advanced or Metastatic Urothelial Carcinoma

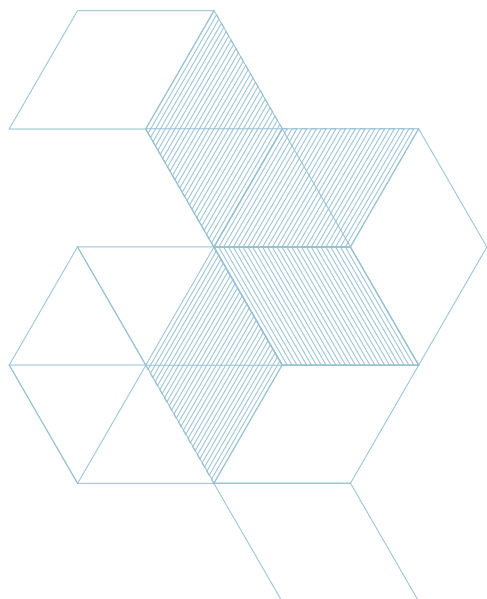
# INTRODUCTION

**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 Enfortumab Vedotin-ejfv (Padcev®) and Pembrolizumab (Keytruda®) Management for Advanced or Metastatic Urothelial Carcinoma PQI and explores how the medically integrated teams at Huntsman Cancer Institute and University Hospitals collaborate and utilize the information found in the PQI as part of their daily practice.



[Enfortumab Vedotin-ejfv \(Padcev®\) and Pembrolizumab \(Keytruda®\) Management for Advanced or Metastatic Urothelial Carcinoma PQI](#)



# PARTICIPANTS

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## UNIVERSITY HOSPITALS

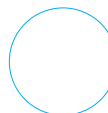
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# UROTHELIAL CARCINOMA TREATMENT WITH ENFORTUMAB VEDOTIN AND PEMBROLIZUMAB

**PLATINUM**-based chemotherapy has long been the standard first-line treatment for locally advanced or metastatic (LA/m) urothelial carcinoma, though it offers limited long-term survival and persistently low five-year survival rates.<sup>1</sup> While adding immune checkpoint inhibitors (ICIs) like nivolumab to gemcitabine-cisplatin has shown modest improvements in overall survival (OS), other chemo-ICI combinations have not demonstrated similar benefits.<sup>2-4</sup>

Enfortumab vedotin-ejfv (EV), an antibody-drug conjugate targeting nectin-4 and linked to the microtubule-disrupting agent monomethyl auristatin E (MMAE), received accelerated FDA approval for patients diagnosed with locally advanced or metastatic urothelial carcinoma previously treated with a PD-1/PD-L1 inhibitor and platinum-containing chemotherapy.<sup>5</sup> Subsequent trials confirmed EV's survival benefit both as monotherapy and in combination with the PD-1 inhibitor pembrolizumab. Based on the EV-103/KEYNOTE-869 tri-

al,<sup>9</sup> the EV-pembrolizumab combination was approved as first-line therapy for cisplatin-ineligible patients. Later, the EV-302/KEYNOTE-A39 trial<sup>10</sup> demonstrated superior progression-free and overall survival with EV-pembrolizumab compared to standard platinum-gemcitabine chemotherapy, supporting broader first-line approval regardless of cisplatin eligibility.<sup>5</sup> As a result, the EV-pembrolizumab combination is now a guideline-recommended first-line option for patients with LA/m urothelial carcinoma.<sup>11</sup>

## EV-PEMBROLIZUMAB PATIENT PROFILE: HCP INSIGHTS

### PATIENT SELECTION & CLINICAL CONSIDERATIONS

Vinay Thomas, MD, medical oncologist at Huntsman Cancer Institute, explained that the approval of enfortumab vedotin in combination with pembrolizumab was a defining moment in the treatment of advanced urothelial carcinoma. "Everything changed in the bladder cancer space," Thomas shared, referencing the pivotal EV-302 trial. According to Thomas, appropriate patient selection is critical for the success of this regimen. He reviews the following factors before initiating therapy:

- **Performance status:** "patients should not be extremely frail, many of these treatments can be toxic."
- **Age** is considered, but not a deciding factor.
- **Comorbidities and functional status** are assessed to ensure patient tolerability.
- For pembrolizumab:
  - Patients with organ transplants (especially liver or kidney) are approached cautiously due to the heightened risk of graft rejection.
  - Autoimmune conditions may flare during treatment. Treatment decisions are individualized based on the type and severity of the underlying condition.
- For enfortumab vedotin:
  - Patients with pre-existing dermatologic issues or grade  $\geq 2$  peripheral neuropathy may not be suitable candidates.
  - Diabetic patients are not excluded but require vigilant monitoring of blood glucose levels and signs of diabetic ketoacidosis. Patients with baseline hemoglobin A1C  $\geq 8\%$  or HbA1c  $\geq 7\%$  with associated diabetes symptoms (polyuria or polydipsia that are not otherwise explained) were excluded from clinical trials with EV.<sup>5</sup>

Although ongoing research is exploring potential predictive biomarkers such as PD-L1 expression and nectin-4 levels, Dr. Thomas emphasized "The drug is



## EV-pembrolizumab Patient Profile: HCP Insights - continued

approved regardless of biomarker status.” He also considers prior treatments when determining eligibility. If a patient progressed more than one year after adjuvant pembrolizumab, he would typically proceed with the EV-pembrolizumab combination. In contrast, for patients who relapse within six months, or while still receiving pembrolizumab, he exercises caution. Additionally, neuropathy from prior chemotherapy (e.g., gemcitabine/cisplatin) may limit the use of enfortumab vedotin in the metastatic setting. Patients with ongoing sensory or motor neuropathy Grade 2 or higher were excluded from clinical trials with EV.<sup>5</sup> “Patient selection is key,” Dr. Thomas reiterated individualized treatment selection and that caution should be used in those “for whom clinical red flags exist”.

### EXPERIENCE & OUTCOMES IN PRACTICE

Jason Brown, MD, medical oncologist at University Hospitals, has treated over 30 patients with this combination and

considers it his frontline regimen for eligible patients outside of a clinical trial.

“If you look at what the alternatives are, comparing EV and cisplatin, neuropathy will be an issue for both. Hyperglycemia may be more specific to EV, but it is manageable.” Dr. Brown treats a broad range of patients, including those with ECOG performance status 0 to 2. He shared one particularly impactful case:

“I treated a 100-year-old patient... he went to Florida for the winter and he’s doing quite well.”

For Dr. Brown, the combination’s tolerability and efficacy have made it a reliable go-to for patients with advanced urothelial carcinoma.

### PHARMACIST PERSPECTIVE

Emma Jones, PharmD, BCOP, Oncology Pharmacy Supervisor at Huntsman Cancer Institute, plays a key role in patient selection and care coordination.

“As the clinical pharmacist, I’m working with the physicians to determine the

appropriate patients for EV and pembrolizumab.”

She noted that treatment discussions have become more simplified with broader approval:

“Bladder cancer used to be very complicated with cisplatin-eligible versus ineligible patients. We’re fortunate now that enfortumab and pembrolizumab are approved in both categories. Luckily, most patients who have metastatic bladder cancer receive EV and pembrolizumab, and it is quite well tolerated,” she said.

This streamlined collaboration between pharmacists and providers helps simplify complex treatment decisions and ensures patients are appropriately supported from the start.

## 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 integration of a Medically Integrated Pharmacy (MIP) within this team has significantly enhanced medication management,

streamlined the care process, and improved both patient convenience and continuity of care,

Dr. Thomas underscored the value of collaboration in early toxicity recognition:

**“Prompt recognition of adverse events can prevent severe complications. That is where we heavily rely on our nurses**

**and pharmacists, because they are the ones getting those patient calls and picking up toxicities early. Pharmacists are invaluable in making dose interruptions and modifications.”**

Jones echoed this collaborative ethos: “We’re a very collaborative team, and I feel lucky to be a pharmacist here. Ev-



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

everyone has a seat at the table, and I'm able to sit with my providers to help with chemotherapy choices, supportive care meds, or coordinating repeat labs. I also write letters of medical necessity to support technicians in getting medications approved. We truly are a united force in every part of the patient care process."

The value of embedded multidisciplinary support was highlighted by Dr. Brown: "We have a cancer-specific pharmacist embedded in clinic who calls patients directly. Our nurse practitioners and nurses also identify concerns early, before I even see the patient. And for something like skin peeling, I will loop in Onco-Derm or Ophthalmology. Having allied health providers close by, like occupational therapy and physical therapy, is critical for managing issues like neuropathy."

Jeffrey Pasucal, PharmD, CSP, Clinical Pharmacy Specialist at University Hospitals illustrated how layered communication across disciplines helps ensure no patient falls through the cracks: "I track my patients closely and coordinate with nurses and doctors constantly. If I notice a missed follow-up or cancelled appointment, I check in. Sometimes the nurse will catch it first, maybe the patient called in with concerns, and then

we can loop in the provider for a goals-of-care discussion. That back-and-forth ensures patients feel supported and solid in their treatment plan."

Together, these perspectives underscore how MIP empowers teams to act swiftly and holistically, enhancing every step of the patient care journey.

## THE POWER OF THE TEAM: DEFINING ROLES IN MEDICALLY INTEGRATED CARE

Successful implementation of a MIP model hinges on seamless communication and clearly defined roles across the care team. From physicians and pharmacists to nurses and pharmacy technicians, each team member contributes specialized expertise. When aligned, this collaborative approach ensures that patients receive safe, timely, and effective treatment. Physicians lead clinical decision-making, but they do so with deep trust in their team. As Jones shared: "He will ask me— 'is it on label? Is there literature to support this? Are the provider notes clear for approval?' We work very closely on these decisions. It's all about the right people doing the right work."

Pharmacists play a central role in opti-

mizing treatment plans, managing side effects, navigating drug access, and ensuring safety:

Jones explained, "As the clinical pharmacist, I'm working directly with providers to choose therapy, manage dose reductions, and collaborate with techs like Colby to ensure authorizations. We hone in on safety and education every day."

Pasucal added, "It is full-circle communication. I coordinate with the nurses and doctors on dose holds, patient questions, and even payers if needed. We are all checking in constantly."

Nurses are often the first to notice changes in a patient's well-being and are essential for continuity and patient education.

Kendra Baxter RN shared, "We educate patients and families, make sure schedules align with labs and meds, and often call high-risk patients before they even reach out. I tell people—I'm the mom. I make sure everyone did their job, the ducks are in a row, and the patient is taken care of."

## MIP MULTIDISCIPLINARY CARE



### PHYSICIAN

Leads clinical decision-making

"We work closely to make decisions based on safety, coverage, and best practices."

Collaborates on drug choices, patient selection, and treatment goals



### PHARMACIST

Ensures safe, effective medication use

"We manage dosing, education, and coordinate closely with nurses and techs."

Dose adjustments, side effect management, patient counseling



### NURSE

Patient education and follow-up care

"I'm making sure the whole plan is followed and the patient is supported."

Educates patients/families, triages symptoms, ensures follow-through



### PHARMACY TECHNICIAN

Access, affordability, and documentation

"I handle insurance, copay help, ordering meds, and document everything."

Verifies benefits, manages PAs, secures free drugs, insurance updates

## Patient-Centered Activities - continued

Pharmacy Technicians ensure access through diligent coordination of insurance benefits, prior authorizations, free drug programs, and more.

Colby Gordon, CPhT described, “From benefit investigation and submitting prior authorizations to tracking approvals, denials, appeals, and drug orders, I handle the logistics so patients can get

their meds. I also document everything in the EMR for full transparency across the team.”

## ENFORTUMAB VEDOTIN + PEMBROLIZUMAB PQI AND MONITORING CONSIDERATIONS

**THE** PQI provides key clinical and operational guidance for the safe, effective use of EV and pembrolizumab in patients with advanced urothelial carcinoma. It underscores that treatment initiation does not require biomarker testing, outlines recommended dose modifications, and highlights critical drug interaction concerns. Notably, the MMAE component of EV is metabolized via CYP3A4, necessitating caution with dual p-gp and strong CYP3A4 inhibitors due to the potential for heightened toxicity.<sup>5</sup>

For pembrolizumab, drug interactions are less well-defined, though immunosuppressants like corticosteroids may reduce efficacy and should be used judiciously.

Monitoring is seamlessly integrated within the standard 21-day treatment cycle. Jones noted that patients are typically evaluated at least once per cycle, including lab work and clinical assessments such as CBCs, CMPs, blood glucose, and TSH. These help detect potential side effects like myelosup-

pression, hyperglycemia, or autoimmune-related events. “Certainly, there are cases where we will see patients more frequently,” she added, emphasizing the team’s adaptability in tailoring follow-up based on individual needs. This consistent engagement enables the multidisciplinary team to proactively address issues and reinforces the foundation for patient-centered management strategies described in the next section.

## PATIENT-CENTERED ACTIVITIES

**GIVEN** the complexity of dual-agent therapy, managing adverse events in patients receiving EV and pembrolizumab requires a patient-centered and highly informed approach. In clinical trials (EV-103 and EV-302), the most frequently reported adverse events included peripheral sensory neuropathy, pruritus, rash, fatigue, alopecia, diarrhea, decreased appetite, and others, with multiple side effects appearing in more than 20% of patients.<sup>4,8</sup>

As Dr. Thomas noted, distinguishing between immune-related adverse events (irAEs) and toxicities related to EV’s cytotoxic payload is essential. “If it were a side effect from pembrolizumab, the treatment would be immunosuppression,” he explained. “If it’s EV, you generally need a dose hold, dose reduction, or supportive care.”

He noted that timing, presentation, and treatment response are key diagnostic clues. For example, EV-related skin tox-

icities tend to occur early and compromise skin integrity, while pembrolizumab-associated rashes appear later and usually spare the skin barrier. Peripheral neuropathy is common with EV, especially after multiple cycles, whereas it is rare with immune checkpoint inhibitors. Hyperglycemia is also more frequent with EV, as opposed to a 1–2% incidence with ICIs. “I’m more prone to blame the EV rather than the pembrolizumab for hyperglycemia,” Thomas said.



## Patient-Centered Activities - continued

### MANAGING SKIN TOXICITIES

Dermatologic toxicity is among the most common and burdensome side effects associated with the EV and pembrolizumab combination. Dr. Thomas shared that patients frequently develop maculopapular rashes or pruritus, and in rare cases, severe reactions like Stevens-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN). “If someone were to develop a dermatologic toxicity, depending on the grade, we would hold the dose, reduce the dose, and treat with topical steroids, supportive wound care, and all of those kinds of things,” explained Dr. Thomas. Grade 3 toxicities are held until improvement to Grade 1 or lower, followed by dose reduction. Grade 4 or life-threatening events lead to permanent discontinuation. “If we see a rash within less than a week, I’m probably thinking it is EV. We will look at it, adjust it, and provide either a dose hold, reduction, or some topical therapy,” said Pasucal.

Baxter added, “Rash is probably one of our most significant side effects that patients are calling us about,” emphasizing the importance of early patient education: “We tell patients ‘if this happens, give us a call. We have things we can do.’” Jones noted that most rashes are manageable with supportive strategies like topical corticosteroids, antihistamines, and dose adjustments—such as modifying enfortumab vedotin to 1 mg/kg from 1.25 mg/kg.

### MANAGING PERIPHERAL NEUROPATHY

Peripheral neuropathy is a significant and often persistent adverse event associated with EV, occurring in up to 67% of patients when combined with

pembrolizumab.<sup>5</sup> While some cases resolve, most symptoms endure. Dr. Brown stressed the value of early detection: “Even if symptoms aren’t serious, it might be time for a dose hold or reduction.” He noted that early dose adjustments don’t seem to impact efficacy. “A lot of my patients do have a dose reduction by cycles three or four,” he said, adding that referrals to PT or OT can support recovery and treatment continuation.

Dr. Thomas highlighted the importance of ongoing neurological assessments, both patient-reported and clinical, especially in those with baseline risk factors like diabetes or spinal cord disease to monitor for cumulative toxicity. “If someone has baseline risk factors, I keep a very close eye,” he said. Management depends on severity: Grade 2 events prompt a dose hold until symptoms improve, with re-challenge at the same or reduced dose depending on recurrence.

Jones shared that dose reduction has been the most effective strategy. “You can prescribe supportive agents like gabapentin or pregabalin, but dose reduction works best.” In some cases, providers opt to begin at an empiric reduced dose, particularly for patients with pre-existing neuropathy. Pasucal added, “If someone starts at a lower dose and does well, there is usually no incentive to escalate.” Baxter reinforced the importance of patient education: “We talk a lot about numbness and tingling, when to call, what to look out for. It’s one we see often.” With collaborative monitoring and timely intervention, many patients are able to continue treatment while minimizing long-term functional impact.

### MANAGING HYPERGLYCEMIA AND OCULAR TOXICITIES

While dermatologic and neurologic adverse events often receive the most attention, clinicians are also vigilant about metabolic and ocular effects associated with EV. Hyperglycemia is frequently encountered, especially in patients with diabetes or those receiving steroids. “If someone has a blood glucose greater than 250, I usually hold EV until it’s under control,” said Dr. Thomas, who stressed the importance of close monitoring and individualized insulin management. Baxter added, “We do have many patients who are already type 1 or type 2 diabetics, so we expect some elevation—especially if steroids are in play—but it’s something we stay on top of.”

Ocular toxicities, though less common, require early recognition. Patients may report dry eyes, blurred vision, or ocular irritation. “With enfortumab, we often see dry eye-type symptoms, and I sometimes even use prophylactic artificial tears,” noted Dr. Thomas. “If symptoms go beyond that, I don’t hesitate to refer to ophthalmology.” Baxter echoed that approach: “If it is anything not managed by artificial tears, we get ophthalmology involved to rule out more serious issues.” Dr. Brown shared that while he doesn’t routinely perform baseline eye exams, he encourages patients with existing eye care providers to stay in close contact. Across the team, the consensus is clear: proactive education, early symptom detection, and timely referral are essential for managing these less prominent but clinically significant effects.

## Patient-Centered Activities - continued

### COMPREHENSIVE EDUCATION AND ONGOING SUPPORT

Comprehensive education and ongoing support are integral to the patient journey. This is not a one-time event, but a continuous process embedded throughout care. As patients prepare to start EV and pembrolizumab, multidisciplinary teams collaborate to ensure that both patients and their families feel informed and supported. “We try to give pharmacy education in person as much as possible, because many of our patients are hard of hearing, and often their family members attend as well,” Baxter shared.

Before treatment begins, patients meet with pharmacists for personalized education that outlines how the drugs work, dosing schedules, potential side effects, and when to seek help. “We cover how the drugs work, dosing schedules, side effects, what symptoms to watch for at home, and when to call us,” said Jones. She emphasized breaking down complex clinical trial data into understandable terms while also reviewing premedications and home management strategies.

Pasucal highlighted the importance of reinforcing information over time. “I will often ask to see a rash or symptom at infusion so I can track it. We also offer visits by referral after their first cycles once the initial information has had time to sink in.” To support understanding, patients are provided with multiple resources, including site-specific educational packets, NCODA’s Patient Education Sheets, chemotherapy teaching materials, and side effect reference books—all reviewed during these sessions. Megan noted that teach-back methods are employed to confirm patient understanding and that clinical

staff are available 24/7 for any arising concerns.

Once therapy begins, the team continues its proactive clinical and emotional support. Monitoring for serious toxicities like pneumonitis is critical. “We watch for respiratory symptoms very carefully. Depending on the grade, patients may need steroids, dose holds, or permanent discontinuation,” explained Dr. Thomas. Fatigue is another near-universal challenge. “We talk upfront about fatigue, review labs regularly, and help patients understand how to pace themselves while staying active when possible,” added Baxter.

Helping patients integrate treatment into daily life is a constant priority. “Scheduling becomes part of the care,” Baxter noted. “We adjust everything—labs, infusions, work accommodations, even disability letters—to help the treatment fit into their lives.” Consistent check-ins further help patients manage the emotional and logistical complexities of ongoing care. “If a patient wants to travel or take a break, we coordinate to make that happen,” Pasucal said. “It is about letting them live their lives while still receiving excellent care.”

### FINANCIAL NAVIGATION AND ACCESS ADVOCACY

In tandem with clinical care, financial navigation is essential to ensuring patients can access treatment without delays or unmanageable costs. The financial access team navigates complex insurance landscapes, including Medicare, Medicare Advantage, commercial plans, and coverage gaps for uninsured patients. “For traditional Medicare patients with supplemental plans, coverage is generally straightforward,” Gordon explained. “But Medicare

Advantage plans can present significant out-of-pocket expenses, often around \$5,000, requiring discussions about financial feasibility.” With limited grant funding available for bladder cancer, the team works closely with patients to explore every option and provide accurate cost estimates upfront.

Commercial insurance introduces different challenges, particularly with the increasing influence of alternate funding programs (AFPs). “We sometimes see outright denials from insurers who want us to seek free-drug programs first, even when those programs may not apply,” Gordon noted. “These delays can be stressful for patients and financially burdensome if insurers maximize copay assistance early, leaving patients exposed to high out-of-pocket costs.”

To address these issues, the team collaborates with drug manufacturers, insurance providers, and patient assistance programs to streamline processes and advocate for system improvements. “We meet regularly with patient assistance reps and drug manufacturers to push for improvements including more online portals, DocuSign adoption, and faster application processes,” Gordon said. “For many of our patients who may struggle with technology, making the process easier directly impacts how quickly they can start treatment.”

This dedicated advocacy allows patients to focus on their care while the financial team manages the behind-the-scenes complexities, helping to reduce financial hardship and ensure timely treatment access.





# CONCLUSION: PATIENT-CENTERED EXCELLENCE THROUGH TEAMWORK, PQIs, AND PERSONALIZED DRUG MANAGEMENT

**THE** EV and pembrolizumab treatment journey extends far beyond drug administration. It is a comprehensive, patient-centered approach that integrates evidence-based protocols, proactive toxicity management, financial advocacy, and tailored support. At its core, the PQI framework provides a structured clinical guide,

enabling teams to deliver safe, effective care with timely interventions.

This level of excellence is made possible by the collective effort of the entire care team—physicians, pharmacists, nurses, technicians, and financial counselors—who transform protocol into personalized care. Through thorough education,

vigilant monitoring, reduced access barriers, and flexible scheduling, patients are empowered to manage their treatment while preserving their quality of life. This shared commitment ensures that patients receive not only therapy, but compassionate, holistic support at every stage of their journey.

**“It is about letting them live their lives while still receiving excellent care.”**

—Jeffrey Pasucal, PharmD, CSP

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## HELPFUL ONLINE RESOURCES:

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[Enfortumab Vedotin-ejfv \(Padcev®\) and Pembrolizumab \(Keytruda®\) Management for Advanced or Metastatic Urothelial Carcinoma PQI](#)



[Enfortumab Vedotin-ejfv \(Padcev®\) Management for Advanced or Metastatic Urothelial Carcinoma PQI](#)



[Chemotherapy Induced Peripheral Neuropathy PQI](#)



[Immune-Related Adverse Event \(irAE\) Management Tool](#)



[NCODA Patient Assistance Tool](#)







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

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.