

# PQI IN ACTION



**CEMIPLIMAB-RWLC (LIBTAYO®)  
PATIENT 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 providers. 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 discusses patient management for Cemiplimab-rwlc (LIBTAYO®), an FDA-approved medication with indications for basal cell carcinoma, cutaneous squamous cell carcinoma and non-small cell lung cancer. Categorical disease states and treatment histories will be covered in this PQI. This article explores how the medically integrated teams at Allegheny Health Network and Memorial Cancer Institute incorporate PQIs in their daily workflow and how the LIBTAYO® PATIENT MANAGEMENT PQI elevates patient care.

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## THE PARTICIPANTS

### *Allegheny Health Network Pittsburgh, Pennsylvania*

Allegheny Health Network (AHN), based in Pittsburgh, is a 14-hospital academic medical system in Western Pennsylvania and Western New York. A subsidiary of Highmark, Inc., AHN consists of a flagship hospital/transplant center (Allegheny General Hospital), community and neighborhood hospitals, and 200 primary- and specialty-care practices in more than 300 clinical locations. The network employs more than 21,000 people and is affiliated with Drexel University College of Medicine and Lake Erie College of Osteopathic Medicine. The Allegheny Cancer Institute collaborates with Johns Hopkins Medicine for cancer research and treatment.

### *Memorial Cancer Institute Hollywood, Florida*

Memorial Cancer Institute (MCI) is part of Memorial Healthcare System, a five-hospital, Florida-based health organization spanning multiple primary care clinics, surgery centers, and more. Located within the Memorial Regional Hospital flagship in South Florida, the MCI treats 4,300 new patients annually and provides diagnosis, treatment, clinical trials and patient- and family-centered support services. Oncologists, surgeons and nurses collaborate with patient navigators, nutritionists, pharmacists and support staff to provide comprehensive care. An MCI research alliance with Florida Atlantic University led to Cancer Center of Excellence designation last year.



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*Medical Oncologist*



**Tiffany Koss, DNP**  
*Nurse Practitioner*



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# 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 are built within the cancer center to help to 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 care for the patient 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. These leading oncology organizations value the PQI's concise, clinical guidance information to raise the standard of care across all professional disciplines.

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. The PQI serves that need.

The PQI “is good at providing that very important information, but in a very concise manner,” said oncology pharmacist Matthew Villanueva, PharmD, of Memorial Cancer Institute (MCI).

“It’s ‘the quick-and-dirty, exactly-what-you-need to know (info).’ ... A lot of very detailed clinical data is important for making decisions, framing our expectations in terms of side effects and the effectiveness we expect to see,” Villanueva said.

As a pharmacist, he compares MCI protocols with the PQI and other resources to evaluate care delivery processes.

Justin Julius, PharmD, oversees about 40 pharmacists embed in Allegheny Health Network's (AHN's) system of hospitals and clinics serving Western Pennsylvania and neighboring states. As Manager of Clinical Pharmacy, the PQI “is a full walk-through – of not only what the drug is, not only how it's utilized, but the nitty-gritty of how to do (administer) it, all the way down to mixing instructions and how to hang the IV,” he said.



**Memorial Cancer Institute is one of the largest cancer centers in Florida, treating more than 4,600 new patients each year.**

When his network started out as a small private practice, clinical teams “didn’t have a ton of resources, a one-stop shop,” he said. As such, the PQI is a guide for coordinated, comprehensive care. “The PQI is remarkably succinct and provides the information that’s necessary for you to know, in the treatment decision part but also the logistical,” he said.

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Justin Julius, PharmD

# CEMIPLIMAB-RWLC (LIBTAYO®) BACKGROUND

Skin cancer is the most common cancer in the United States and the world. Basal cell carcinoma (BCC) is the most prevalent, followed by squamous cell carcinoma (SCC).<sup>1</sup> An estimated 5.4 million basal cell and squamous cell cancers are diagnosed yearly in the United States, occurring in about 3.3 million Americans (some have more than one).<sup>2</sup> Basal cell cancers account for eight out of 10 skin cancers.<sup>1</sup>

Light-complected individuals are at the highest risk; about 90 percent of nonmelanoma skin cancers are associated with exposure to ultraviolet (UV) radiation from the sun.<sup>3</sup> Mortality rates, largely untracked, are wide-ranging. The American Cancer Society reports these malignancies account for about 2,000 U.S. deaths each year; a 2020 study, suggests that SCC alone claims 15,000 U.S. lives annually.<sup>1,3</sup>

Most people who die from these cancers are elderly and may not have seen a doctor until the cancer visibly enlarged. Other

vulnerable groups include individuals with suppressed immune systems, such as organ transplant patients.<sup>2</sup>

The elderly make up a high percentage of LIBTAYO® patients at the AHN, “so, we have a decent amount of utilization of the drug,” Julius said. “They’ve already been radiated. They’ve already been surgically resected. Now they’re left with disfiguring masses, that we can treat effectively without chemotherapy options.”

An estimated 236,740 adults (117,910 men and 118,830 women) in the United States will be diagnosed with lung cancer this year. Most will be smokers. Non-small cell lung cancer (NSCLC) will account for 82% of lung cancer diagnoses.<sup>4</sup>

Close to 70% of patients with lung cancer present with locally advanced or metastatic disease at the time of diagnosis.<sup>5</sup> Prognosis is poor for patients with advanced NSCLC not candidates for surgery or radiation. The five-year survival rate is 7 percent.<sup>6</sup>

## CEMIPLIMAB-RWLC (LIBTAYO®) MECHANISM OF ACTION

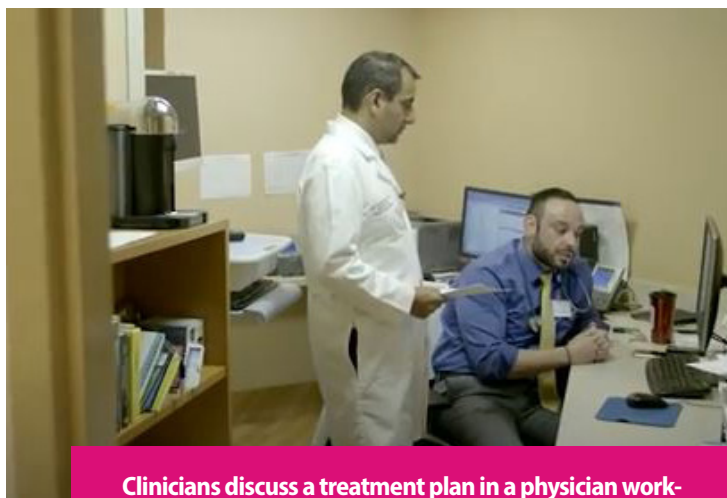
Cemiplimab (LIBTAYO®) is an infusion drug that works by blocking the programmed death receptor-1 (PD-1) pathway — a major player in immune response — to inhibit binding with the cancer cell protein. The T cell then remains active, so it can attack and kill the cancer cells and decrease tumor size.<sup>7</sup>

This relatively new monoclonal antibody drug therapy is deployed to halt and/or prevent recurrence of cancer in difficult-to-treat cutaneous squamous cell carcinoma (CSCC), basal cell carcinoma (BCC) and non-small cell lung cancer (NSCLC).<sup>7</sup>

The recommended dosage is 350 mg every 3 weeks for all indications. These 30-minute infusions are effective for long-time maintenance and quality of life.<sup>7</sup>

LIBTAYO® was FDA-approved in 2018 as the first and only treatment for patients with locally advanced BCC previously treated with a hedgehog pathway inhibitor (HHI). LIBTAYO® is the first treatment to show a clinical benefit in patients with advanced BCC after HHI therapy.<sup>8,9</sup>

Three years later, the FDA designated LIBTAYO® as the first systemic treatment of CSCC that has metastasized or cannot be cured by surgery or radiation.<sup>7</sup> The same year, the FDA



Clinicians discuss a treatment plan in a physician workroom at Memorial Cancer Institute.<sup>7</sup>

approved LIBTAYO® as a first-line treatment for inoperable NSCLC that is not locally advanced and cannot be treated with radiation or chemotherapy. The immune-targeted therapy would not be used if the patient has an EGFR, ALK or ROS1 mutation.<sup>7,10,11</sup>

# CLINICAL RESEARCH ON CEMIPIMAB-RWLC (LIBTAYO®)

## BASAL CELL CARCINOMA (BCC)

Cemiplimab is also indicated in patients with locally advanced BCC and metastatic BCC previously treated with an HHI or who are non-candidates for HHI treatment. (The malignant BCC indication has accelerated approval status in the U.S.; the European Union has granted regular approval for cemiplimab for this indication.)<sup>7</sup>

An open-label, multicenter, non-randomized single-arm study (Clinical Trial 1620) showed that LIBTAYO® was effective in patients with malignant BCC. LIBTAYO® was administered at 350 mg every 3 weeks for up to 93 weeks.<sup>7,8</sup>

Tumor assessments were performed every 9 weeks for the first 45 weeks of treatment. Patients with locally advanced BCC had an ORR of 29% (95% CI, 19-40), and the patients with metastatic BCC had an ORR of 21% (95% CI, 8-41). One hundred percent of patients with metastatic BCC had a DOR longer than 6 months, as did 79.2% of patients with locally advanced BCC.<sup>7-8</sup>

## CUTANEOUS SQUAMOUS CELL CARCINOMA (CSCC)

Two open-label, multicenter, non-randomized, multicohort studies (Clinical Trials 1423 and 1540), showed beneficial effect in objective response rate (ORR) and duration of response (DOR) in patients with CSCC.<sup>7,10</sup> In study 1423, patients received LIBTAYO® 35 mg/kg intravenously every 2 weeks for up to 48 weeks, or, in study 1540, up to 96 weeks. An additional cohort of patients in study 1540 received 350 mg every 3 weeks for up to 54 weeks. Tumor response assessments were performed every 8 or 9 weeks.<sup>7,10</sup>

In study 1540, the combined cohort of patients with locally advanced and metastatic CSCC had an ORR of 46% (95% CI, 37-55), and 76% of patients with metastatic CSCC had a DOR longer than 12 months, while 35% of patients with locally advanced CSCC had a DOR longer than 12 months.<sup>7,10,12</sup>



Members of the Allegheny Health Network team pose with a patient in their care.

## NON-SMALL CELL LUNG CANCER (NSCLC)

Another study (1624) found that LIBTAYO® is useful in the treatment of NSCLC with high expression of PD-L1 (Tumor Proportion Score of more than or equal to 50%).<sup>7</sup> Patients were randomized (1:1) to receive LIBTAYO® 350 mg intravenously every 3 weeks for up to 108 weeks or a platinum-doublet chemotherapy. Both the patients with PD-L1 expression and those with metastatic NSCLC showed a beneficial effect with the drug.<sup>7,11</sup> None of the patients in this study had mutations of the EGFR, ALK, or ROS1 genes.<sup>7,13</sup>

The primary mission was to evaluate overall survival (OS) and progression-free survival (PFS). Patients treated with cemiplimab had a median survival of 22.1 months (95% CI, 17.7-NE), while the patients treated with chemotherapy had an OS of 14.4 months (95% CI, 0.49-0.72).<sup>7,12</sup>

Grade 3 or 4 side effects presented in patients with BCC (48%), NSCLC (28%), and CSCC (45.2%), respectively. A substantial proportion were immune-mediated adverse reactions.<sup>7</sup>

# THE MEDICALLY INTEGRATED TEAM: BEST APPROACH FOR PATIENTS IN LONG-TERM ONCOLOGY TREATMENT

**L**IBTAYO's® arrival as a long-term, stabilizing drug therapy for difficult-to-treat cancers underlines the need for multidisciplinary communication and cooperation. It takes a clinical village to manage a medical regime that can continue for years.

When Luis Raez, MD, meets a patient at a first consult, he discusses the treatment, timing, and an advanced practice provider (APP) “will hold a class to go over education,” said Raez, Medical Director and Chief Scientific Officer of Memorial Cancer Institute.

Clinical pharmacists and residents are key collaborators on the healthcare team at MCI. “They work with us in the clinics, they work with us on the hospital floors. They are not only checking for adverse events, they are helping us make decisions – especially now when there are so many treatment options,” Dr. Raez said.

The MCI in-house specialty pharmacy adheres to both NCCO and ASCO guidelines for integrated patient management. Consulting the pharmacists “is so important,” Dr. Raez said. “When we work with pharmacy benefit managers, they aren't providing any help. They may call every three months to see how a patient is doing. But our team is constantly evaluating the patient.”

Frequent check-ins and shared updates are care cornerstones as well at Allegheny Health Network. “It's very collaborative,” said medical oncologist Syed Ali Akbar, MD.

After he meets with a LIBTAYO® candidate, he shares medication protocols and processes. A nurse or physician assistant follows up with a 30-minute review. “If the patient is agreeable, the pharmacy team is alerted so the plan gets set up in Epic and gets sent to our authorization team. They authorize it as quickly as they can and get the ball rolling,” Dr. Akbar said.

“It's a good setup,” he said. “There's little room for any confusion or misunderstanding because we work pretty closely together.”

The collaboration continues with infusion sessions, combining patient care with multidiscipline updates. AHN nurse practitioner Tiffany Koss does rounding, provides support services, and records transfusion reactions. She and other team members may also coordinate patient access to social services and a dietician for nutrition counseling.

Care coordination is especially necessary due to the LIBTAYO® patients' ongoing needs, said Koss, NP. “The most important aspect of the way we provide care is the communication, everyone speaking to each other, making sure all the pieces are in place.”

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TIFFANY KOSS, DNP

Pharmacists at both groups evaluate patient-specific labs and the current medication list. They also have real-time access to EHRs to monitor clinical updates, such as changes in weight, labs, active medications and completing prioritizations. They also are on call for toxicity management.

Even payment plans can be a cooperative effort. AHN has revenue cycles down to a science, a system embedded in the network. Pre-treatment, a billing and authorization team reviews the costs; a team of nurses clears the plan with insurers; and a third team works with patient assistance programs (PAPS) and foundations to secure funds for drug therapy or free medications for the patient. Details are recorded in the electronic record.

The process eliminates worst-case scenarios, like “the patients coming in for therapy, and then they decide, ‘Whoa, there's no way I can pay for this,’” Julius said.

## THE PQI PROCESS

The PQI Process for the use of cemiplimab (LIB-TAYO)<sup>®</sup> fosters better care for patients by guiding the clinical team on precise steps to prepare the drug for infusion.

The first step is to confirm the patient has an order for cemiplimab – delivered as an IV infusion over 30 minutes – every 3 weeks for all indications.<sup>13</sup>

Pharmacy staff dilute and mix the solution, which should range from colorless to a pale yellow hue. A single-dose vial contains 350 mg of cemiplimab in 7 ML of solution.<sup>13</sup> The drug should be refrigerated between 36°F to 46°F.<sup>13</sup> Management of a grade 1-2 infusion reaction includes interrupting or slowing the rate of infusion. Cemiplimab should be permanently discontinued for a grade 3-4 infusion reaction and supportive care should be initiated.<sup>13</sup>

Pharmacy technician Ivan Rosado, RPhT, of MCI, appreciates the concise directives. In a typical day, the 17-year tech veteran may help locate, dispense and pack prescriptions. Yet he counts mixing IV medications as one of his most important duties. The PQI checklist spans dosage, formulation, and admin-

istration as well as side effects and preventive medicines.

“This is where, as a technician, I learn how to dilute the medication and know which solution it is compatible with,” Rosado said.

“THIS IS WHERE, AS A TECHNICIAN, I LEARN HOW TO DILUTE THE MEDICATION AND KNOW WHICH SOLUTION IT IS COMPATIBLE WITH.”

IVAN ROSADO, RPhT

That accuracy is inherent to the task, where “we double-check math calculations and make sure we use aseptic technique when mixing going by the USP 797 and USP 800 guidelines,” he said.

## PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS, LONG-TERM COMPLIANCE

The Patient-Centered Activities section follows the PQI process in the document, outlining the key patient-centered guidance for the team.

An engaged patient is a compliant self-advocate and the most important member of the team, AHN and MCI clinicians agree. Due to LIBTAYO'S<sup>®</sup> long-term duration of therapy, ongoing education and dialogue are standards of care at both organizations. The PQI encourages specialists to monitor patients for changes, consider the initiation of steroids when appropriate, urge patients to keep lab and office appointments, and to phone providers to report adverse effects of infusion reactions.

While these guidelines are outlined at first consults, AHN and MCI staffs reinforce them via in-person “teaching” sessions, take-home guides, online resources and ready access to care providers.

“It helps when patients prepare themselves that this is not a short treatment. The reality is that they will be on treatment



Dr. Syed Ali Akbar counsels a patient on their treatment options at Allegheny Health Network.

for a long time, hopefully. Second, the reason we may stop after two years is because we know that some people can improve. About 20% may go into remission,” Dr. Ruez said. “It’s amazing to have people surviving for so long on these drugs.” The PQI is important because it can be easily shared within a network, he said. “Our academic practices are very knowle-

dgeable and well-resourced, but our community settings can sometimes dispense chemotherapy even without a pharmacist. So, it is useful to have a resource to educate themselves on the things they need to do at minimum. I think they (PQIs) are very valuable.”

## ADVERSE REACTION MANAGEMENT

**C**emiplimab-rwlc (LIBTAYO®) is an infusion therapy shown to have a long-term stabilizing effect on patients with locally advanced, metastatic basal cell carcinoma, cutaneous squamous cell carcinoma or non-small cell lung cancer.

The recommended 350 mg dosage every 3 weeks. These 30-minute infusions provide patients with more time to enjoy life and have inspired researchers to delve further – and to pool data – on cemiplimab’s impact on quality of life as well as duration. Addressing adverse reactions is critical. The medication can cause the immune system to attack normal organs and tissues in the body and affect their function. Side effects range from rashes and fatigue to life-threatening conditions.

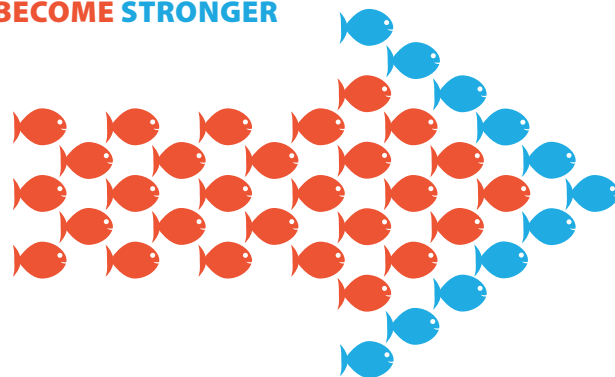
PQI principles promote quality care and create an environment where care teams-patients communicate openly, respect the importance of regular check-ins, and share updates on health status. Backed by an integrated, multidiscipline team of experts, patients with advanced basal cell, squamous cell or non-small cell lung cancer are positioned to stay committed to ongoing therapy.

It takes a clinical village to care for an oncology patient. The Positive Quality Interventions (PQIs) and the PQIs in Action are clinical guides designed to empower MID teams and patients to co-navigate the treatment process, managing adverse reactions and/or toxicities and enhancing long-term outcomes together.



Oncology pharmacists are a crucial part of the healthcare team at MCI. Currently the pharmacy department supports two PGY2 Oncology Residents, pictured here.

**WORKING TOGETHER,  
WE BECOME STRONGER**

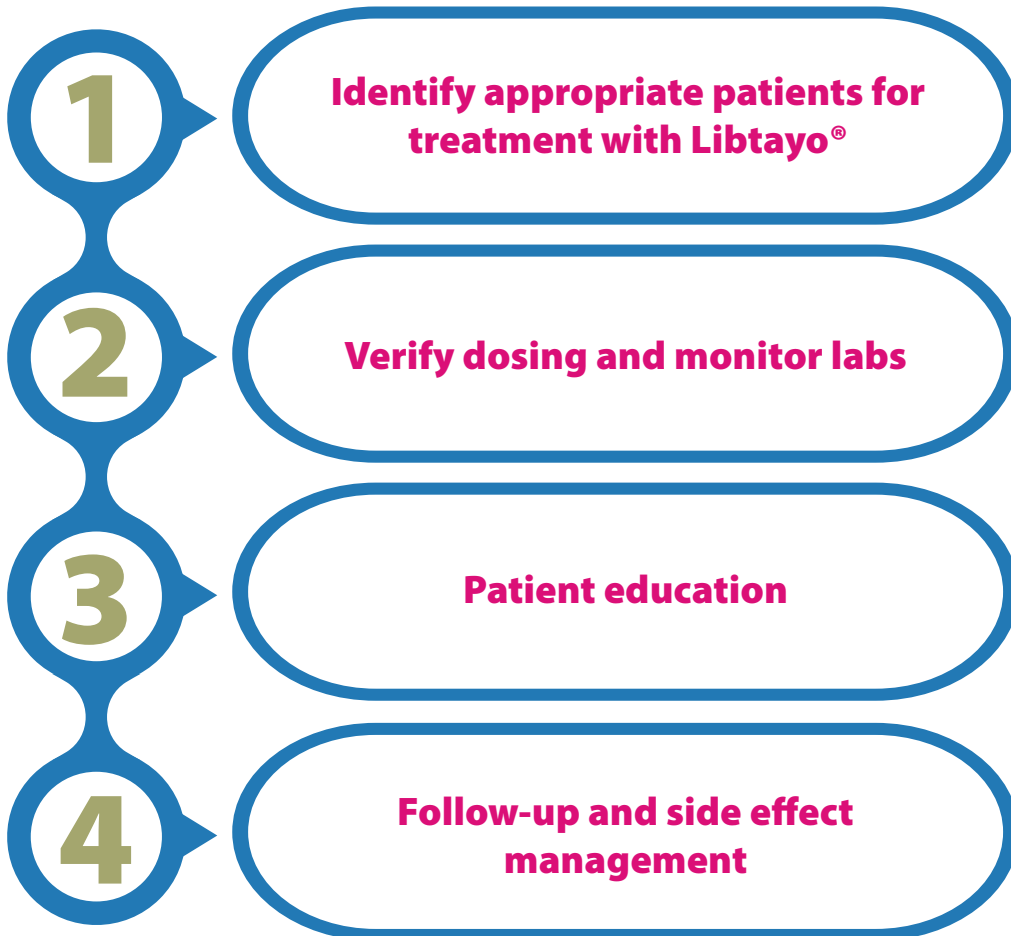




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# PQI PRINCIPLES:





## Helpful Online Resources

- [Cemiplimab-rwlc \(LIBTAYO®\) Patient Management](#)
- [Positive Quality Interventions](#)
- [NCODA Website](#)
- [NCODA Financial Assistance Tool](#)

### ON THE COVER:

- Justin Julius, Manager of Clinical Pharmacy Services at AHN, educates a patient on their new treatment.

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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October 2022