PQI IN ACTION

Positive Quality Intervention

NCODA

Zolbetuximab (Vyloy®) for Gastroesophageal Cancers

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 multi-disciplinary 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 Zolbetuximab (Vyloy®) for Gastroesophageal Cancers PQI and explores how the medically integrated teams at Georgetown University Lombardi Comprehensive Cancer Center (Georgetown), University of Miami Sylvester Comprehensive Cancer Center (Sylvester), and UCLA Health collaborate and utilize the information found in the PQI as part of their daily practice.

Zolbetuximab (Vyloy®) for Gastroesophageal Cancers PQI

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CLINICAL BACKGROUND:
ZOLBETUXIMAB (VYLOY®)

Zolbetuximab is a first-in-class chimeric immunoglobulin monoclonal antibody that binds to claudin 18.2 (CLDN18.2), a tight junction protein normally expressed in gastric mucosa but aberrantly expressed on the surface of gastroesophageal junction (GEJ) and gastric adenocarcinoma cells. It is indicated in adult patients in combination with fluoropyrimidine and platinum containing chemotherapy for first-line treatment of human epidermal growth factor receptor 2 (HER2)-negative, locally advanced unresectable or metastatic GEJ or gastric adenocarcinoma whose tumors are CLDN 18.2 positive.[1]

Its approval was based on two global, randomized phase 3 clinical trials: SPOTLIGHT and GLOW. The SPOTLIGHT trial enrolled 565 previously untreated patients with locally advanced unresectable or metastatic GEJ or gastric HER2-non amplified and CLDN 18.2-positive adenocarcinoma (defined as ≥75% of tumor cells showing moderate-to-strong membranous CLDN18 staining determined by central immunohistochemistry [IHC]) and randomized them to modified FOLFOX6 (mFOLFOX: 5-fluorouracil, leucovorin, and oxaliplatin) combined with either zolbetuximab or placebo.[2] Zolbetuximab was dosed as an 800 mg/m^2 loading dose followed by 600 mg/m^2 thereafter every 3 weeks. Zolbetuximab improved the primary endpoint of progression-free survival (PFS) compared to placebo with a median PFS of 10.6 vs. 8.7 months (HR 0.75, p=0.0066) and median overall survival (OS) of 18.2 months vs. 15.5 months (HR 0.75, p=0.0053).[2] The GLOW trial was a similar trial but randomized 507 patients to CAPOX (capecitabine, oxaliplatin) with zolbetuximab or placebo and demonstrated improvement in median PFS (8.2 months vs. 6.8 months, HR 0.69, p=0.0007) and median OS (14.4 months vs. 12.2 months, HR 0.77, p=0.0118) with zolbetuximab.[3]

The most common adverse reactions (≥15%) in combination with mFOLFOX or CAPOX: include nausea, vomiting, diarrhea, abdominal pain, constipation fatigue, peripheral sensory neuropathy, hypersensitivity reactions, pyrexia, and weight loss. In a combined analysis of the SPOTLIGHT and GLOW trials, the incidence of nausea decreased between cycles 1 and 2 of therapy (58% vs. 18%) as did the incidence of vomiting (43% vs. 15%).[4] Additional adverse reactions include decreases in appetite, neutrophil count, leukocyte count, hemoglobin, lymphocyte count, platelets, glucose, albumin, sodium, potassium, and magnesium. Increases in creatinine, glucose, AST/ALT, Alk phos, and phosphate may also occur.[1,2,3]

SPOTLIGHT TRIAL RESULTS: BOTH PRIMARY AND KEY SECONDARY OBJECTIVES MET[3]

01 **Median PFS: 10.6 mos (zolbetuximab) vs 8.7 mos (placebo) (HR = 0.751; *p* = .0066)**

02 **Median Overall Survival: 18.2 mos (zolbetuximab) vs 15.5 mos (placebo)(HR = 0.750; *p* = .0053)**

03 **OS benefits were sustained at 36 months: OS: 21% (zolbetuximab) vs 9% (placebo)**

GLOW TRIAL RESULTS: BOTH PRIMARY AND KEY SECONDARY OBJECTIVES MET[3]

01 **Median PFS: 8.2 mos (zolbetuximab) vs 6.8 mos (placebo) (HR = 0.687; *p* = .0007)**

02 **Median Overall Survival: 14.4 mos (zolbetuximab) vs 12.2 mos (placebo)(HR = 0.771; *p* = .0118)**

03 **PFS and OS benefits were sustained at 24 months: OS: 29% (zolbetuximab) vs 17% (placebo)**
PFS: 14% (zolbetuximab) vs 7% (placebo)

ZOLBETUXIMAB PATIENT PROFILE: HCP INSIGHTS

Patient selection for treatment with zolbetuximab requires careful evaluation of disease characteristics, biomarker status, and clinical stability. Across institutions, providers emphasized the importance of identifying claudin 18.2 positivity and ensuring patients are appropriate candidates for therapy based on performance status and gastrointestinal symptoms.

At Georgetown University Lombardi Comprehensive Cancer Center, Reetu Mukherji, MD, explained that patients with unresectable, locally advanced, or metastatic upper gastrointestinal cancers such as gastric or gastroesophageal junction tumors may be considered for zolbetuximab if they exhibit claudin 18.2 positivity. "We define this as moderate to strong staining in at least 75 percent of cells using the FDA-approved VENTANA assay," said Mukherji. She noted that patients who are not HER2-amplified would be eligible to receive frontline treatment with a platinum-based chemotherapy regimen in combination with zolbetuximab.

Mukherji shared that tolerance of treatment is an important factor in patient selection. "If I have patients who are very symptomatic, unable to keep food down, or already experiencing uncontrolled nausea and vomiting, that may be a consideration before starting zolbetuximab," she explained. "For most of my patients, there is some degree of dysphagia or tumor burden within the GI tract, so assessing baseline symptoms is key."

At the University of Miami Sylvester Comprehensive Cancer Center, Cindy Pabon, MD, described her evolving approach as data continues to emerge. "The people who benefit the most from zolbetuximab are those with metastatic or unresectable upper GI malignancies," Pabon said. "Although the studies are mainly in gastric cancer, I do extrapolate to esophageal cases if claudin 18.2 positivity is confirmed." Pabon added that while the approval is recent, some patients who missed the opportunity to receive zolbetuximab earlier may still be considered for later-line treatment when feasible.

Sasha Watson, PharmD, also from Sylvester Comprehensive Cancer Center, highlighted the clinical considerations from a pharmacy perspective. "The big side effect is nausea and vomiting, so we have to make sure the patient does not already have uncontrolled GI symptoms from the disease or prior therapy," Watson said. She emphasized that candidates should be clinically stable with good performance status. "The infusion can be quite long and add several hours to chemotherapy visits, so patients need to be able to tolerate extended appointments or additional visits if needed." Watson also reflected on the evolving treatment landscape. "It is an exciting time in gastroesophageal cancer, with multiple FDA-approved targets including claudin 18.2, HER2, and PD-L1. Sometimes we have to decide which to target first when a patient is positive for more than one."

At UCLA Health, Shirin Khorashadi, PharmD, APh, BCOP, described the collaborative approach to initiating therapy in her center. "The decision to treat with zolbetuximab is made by the physician," Khorashadi explained. "Once that decision is made, our team ensures that baseline evaluations are complete, including vitals, laboratory tests, liver function, renal function, and screening for infection and hepatitis B status."

CLAUDIN 18.2 TESTING AND BIOMARKER INTEGRATION

Testing for claudin 18.2 has become a crucial step in determining treatment pathways for patients with upper gastrointestinal malignancies. Providers emphasized the importance of early and comprehensive biomarker assessment to inform sequencing decisions and optimize outcomes. Dr. Mukherji explained that it is one of several biomarkers her team assesses when evaluating patients for targeted therapy. "I definitely want to know mismatch repair status, PD-L1, HER2, and claudin 18.2 status," she said. "While awaiting in-house testing we were using sendout labs like Neogenomics or CARIS, but we worked to expedite in-house testing. Now that it is in place, this is another way we can quickly test for CLDN18 expression," Mukherji noted.

Claudin 18.2 Testing and Biomarker Integration - continued

Dr. Pabon described a streamlined testing process that includes claudin 18.2 as part of a broader biomarker panel. "When pathology is reviewed at our center, we perform immunohistochemical testing for our key biomarkers—PD-L1 CPS, HER2, claudin 18.2, and mismatch repair proteins," said Pabon. This integrated approach allows for efficient decision-making when results return. "There are some characteristics that would take precedence over claudin positivity in treatment selection," she explained. "For instance, if a patient is mismatch repair deficient, we would prioritize immunotherapy, or if HER2 positive, HER2-directed therapy would come first. However, when those results are negative, claudin 18.2 positivity becomes the guiding factor." Pabon also highlighted that the institution's pathology department has validated the VENTANA assay, providing rapid turnaround of results, typically within a few days.

Minhee Kang, PharmD, BCPS, BCOP, the Oncology and Research Pharmacy Manager at Georgetown, emphasized that the pharmacy team verifies the accuracy and completeness of biomarker documentation before treatment initiation. "This includes confirming the diagnosis, reviewing treatment history, and ensuring that lab results support claudin 18.2 expression," Kang shared. Watson also described the pharmacy's critical role in cross-checking pathology reports before dispensing zolbetuximab. "The main thing I look for is the immunohistochemistry report for claudin 18.2 expression. We perform testing in-house, but also use external platforms like NeoGenomics depending on where the patient was originally diagnosed."

Watson added that while zolbetuximab is approved as first-line therapy for HER2-negative, treatment-naïve patients with metastatic gastric or gastroesophageal junction adenocarcinoma, some centers are evaluating its use beyond first-line settings. "There is definitely a gray area," she said. "We have patients who were diagnosed before the FDA approval and are now considered for zolbetuximab in later lines, even though it is only studied as first-line therapy."

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>
> – Reetu Mukherji, MD

MEDICALLY INTEGRATED PHARMACY

The implementation of Medically Integrated Pharmacy (MIP) practices within oncology care has transformed how patients experience and manage complex treatment regimens. With a growing emphasis on collaborative, patient-centered care, MIP structures aim to streamline communication, enhance medication safety, and improve treatment adherence, resulting in improvements across clinical outcomes. A defining strength of MIP is its multidisciplinary nature, where physicians, pharmacists, nurses, and pharmacy technicians work together seamlessly to provide comprehensive support. Across all participating institutions, collaboration among disciplines is essential to delivering effective and coordinated care for patients receiving zolbetuximab. Each team described how their multidisciplinary structures and MIP processes help ensure safety, communication, and timely treatment.

Dr. Mukherji emphasized the importance of a multidisciplinary approach across disease stages. "The field is quite complex, and we do not have strict guidelines for every scenario," she shared. "It is extremely valuable to review each case through a multidisciplinary lens, whether in the perioperative, neoadjuvant, or metastatic setting." She described regular meetings that include surgeons, radiation oncologists, and medical oncologists to evaluate treatment options. "We discuss which patients may benefit from surgery or radiation, even if the disease is technically metastatic," she explained. "It also allows us to educate each other about targeted therapies and immunothera-

Medically Integrated Pharmacy - continued

pies that may be new or less familiar to colleagues in other specialties." She noted that most of her cases are presented to the multidisciplinary team from the first patient encounter to ensure the entire care team is aligned.

At UCLA Health, Tamala Risher, Pharmacy Technician, highlighted the role of MIP workflows in bridging communication between providers, pharmacists, and patients. "The multidisciplinary team is important because everyone plays a key role in the patient's care," said Risher. "It is like passing the torch, each person does their part." She described how their MIP model follows a continuous process referred to internally as "the loop." "From the time the medication is prescribed, our clinical team ensures labs and authorizations are in place, financial assistance is assessed if needed, and all checks and balances are completed before therapy begins," Risher explained. "We make sure the loop is closed and every patient step is accounted for."

> "We make sure the loop is closed and every patient step is accounted for."
>
> – Tamala Risher

Dr. Pabon discussed how the team's collaboration extends across the patient's entire treatment journey. "We see patients at different moments throughout their cancer care," she said. "Some of us, like Sasha, are behind the scenes verifying doses and schedules, while others are in the treatment decision-making role, introducing therapy and ensuring patients understand their options." She emphasized that nurses and infusion

> "That collaboration is essential to the success of each patient's therapy."
>
> – Cindy Pabon, MD

staff play a critical role during treatment delivery, supporting patients both physically and emotionally. "After infusion, our triage nurses, social workers, and financial coordinators continue the process by addressing any challenges related to access, affordability, or understanding their medications," she shared. "That collaboration is essential to the success of each patient's therapy."

PHYSICIAN ROLE

Physicians play the central role in evaluating patients, developing treatment plans, and guiding multidisciplinary collaboration for those receiving zolbetuximab. At both Georgetown University Lombardi Comprehensive Cancer Center and the University of Miami Sylvester Comprehensive Cancer Center, Dr. Mukherji and Dr.Pabon specialize in gastrointestinal oncology, focusing on gastric, esophageal, and gastroesophageal junction cancers.

Their responsibilities include assessing biomarker profiles, determining treatment sequencing, and overseeing patient care throughout therapy. Both emphasized the importance of personalized treatment decisions and communication across the multidisciplinary team to ensure that each patient's therapy is coordinated, evidence-based, and aligned with clinical goals.

PHARMACIST ROLE

Pharmacists play a central role in ensuring the safe, effective, and coordinated delivery of zolbetuximab therapy. Their responsibilities span clinical, operational, and educational functions, beginning with verification of eligibility, diagnosis, treatment history, and claudin 18.2 expression before treatment initiation.

Pharmacists collaborate closely with the oncology team to confirm appropriate dosing, assess potential drug interactions, and manage supportive care for anticipated side effects such as nausea and vomiting. They also work with prior authorization and financial teams to ensure coverage and patient access. Within infusion and clinic settings, pharmacists provide guidance on preparation, stability, and administration, helping nursing staff implement proper premedications and infusion protocols.

Additionally, they maintain formulary oversight, contribute to treatment plan development within the electronic medical record, and educate colleagues, residents, and students on evolving therapies. Through this comprehensive involvement, pharmacists serve as a critical link between clinical decision-making, patient safety, and operational execution in the medically integrated oncology setting.

NURSING ROLE

Nurses are essential to the safe administration and monitoring of zolbetuximab, providing direct patient care and serving as a critical communication link within the multidisciplinary team. In the outpatient infusion setting, oncology nurses manage patient assignments, administer chemotherapy and immunotherapy, and oversee all aspects of infusion care, including port access and central line maintenance. Their role begins before treatment starts, verifying orders, preparing infusion stations, and reviewing premedication requirements to minimize nausea and infusion reactions.

Medically Integrated Pharmacy - continued

During administration, nurses monitor patients closely for gastrointestinal side effects and infusion-related symptoms, providing real-time intervention and reassurance. They also educate patients on what to expect from therapy, reinforce adherence to antiemetic regimens, and ensure follow-up communication after each cycle.

PHARMACY TECHNICIAN ROLE

Pharmacy technicians are integral to the success of zolbetuximab therapy, supporting both the clinical and operational aspects of care. Their responsibilities include coordinating prior authorizations, completing financial assistance applications, and facilitating communication between patients, physicians, and payers to ensure timely access to treatment.

Technicians are also involved in the preparation and mixing of zolbetuximab, adhering to strict aseptic and stability standards, and may oversee drug procurement, inventory management, and supply tracking to prevent delays in therapy. By managing these logistical and administrative processes, technicians help maintain treatment continuity, reduce financial and operational barriers, and enable pharmacists and clinicians to focus on direct patient care.

PQI PROCESS: STREAMLINING SAFE AND SUPPORTIVE ZOLBETUXIMAB THERAPY

Implementing zolbetuximab within a medically integrated care model requires structured coordination and the PQI framework provides guidance for the team. Each discipline plays a defined role in confirming eligibility, assessing readiness, and ensuring patient safety prior to treatment initiation.

The process begins with the provider confirming that the patient meets clinical criteria, as discussed earlier in the article. Dr. Mukherji noted, "You want to look at their performance status and some of their baseline symptoms. One of the first steps is confirming the patient is even eligible to receive combination chemotherapy." Providers also monitor baseline nausea or vomiting, ensuring these symptoms are well controlled before treatment begins to reduce the risk of early intolerance.

Once eligibility is confirmed, pharmacists and nurses collaborate to review the patient profile in detail. Kang described the coordination this requires: "Because zolbetuximab has a long infusion time, especially on cycle one day one, we have to coordinate closely with the nursing and provider teams. We review the progress note, confirm that performance status and labs are appropriate, and make sure everything is ready before therapy starts." Pharmacists also review all medications for potential interactions, including herbal supplements and over-the-counter agents, and verify that premedication plans are complete. "Even though zolbetuximab does not have a high risk of drug interactions, it is still important to review the patient's home medications and premedications," said Kang.

Nursing teams play an equally important role in patient assessment and infusion readiness. Casey Rafferty, BSN, RN, shared, "We make sure the patient's weight and body surface area are up to date, that there is a signed consent, and that the correct day and dose are scheduled. I also assess how they are doing mentally and physically, whether they are anxious about starting a new treatment, and if they have family support." This personalized evaluation ensures both physical and emotional preparedness.

Pharmacy and nursing collaboration extends to operational processes as well. Watson explained, "When insurance approves treatment and the patient is ready and clinically stable, our job is to make sure everything is in place — labs, orders, infusion times, supportive care medications, and coordination with the

> "It comes down to preparation and teamwork. Everyone has a role in making sure the patient is ready and safe."
>
> – Shirin Khorashadi, PharmD

PQI Process: Streamlining Safe and Supportive Zolbetuximab Therapy - continued

care team. It is all about making sure the patient and team are ready to go." Khorashadi summarized, "It comes down to preparation and teamwork. Everyone has a role in making sure the patient is ready and safe before the first infusion begins."

DOSING AND SCHEDULING CONSIDERATIONS

Establishing an accurate and coordinated dosing process is a central part of the zolbetuximab treatment workflow. Providers determine the starting dose of 800 mg/m² for the initial infusion, followed by subsequent doses of either 600 mg/m² every three weeks or 400 mg/m² every two weeks, administered in combination with fluoropyrimidine- and platinum-based chemotherapy. The medication must always be infused before chemotherapy on treatment days due to its sequence-specific requirements and emetogenic potential.[1]

Khorashadi shared, "The first dose is 800 mg/m², and subsequent doses are either 600 mg/m² every three weeks or 400 mg/m² every two weeks. Zolbetuximab is given first, prior to chemotherapy, and we start the infusion slowly, increasing the rate gradually as tolerated." She emphasized that infusion times vary, averaging a minimum of 3.5 hours for the initial dose and 2.5 hours for later cycles, with adjustments based on patient tolerance.

Pharmacists play a critical role in verifying the ordered dose, infusion sequence, and rate within the electronic health record. Kang described her clinic's system, "We use a double-check system where one pharmacist reviews eligibility and dose calculations and another verifies on the day of treatment. We created an Excel-based rate chart so pharmacists can automatically calculate the infusion rate based on the patient's body surface area and dose to ensure accuracy."

Scheduling also requires thoughtful coordination between clinical and operational teams due to the length of infusion and chair time. "Because of the long infusion time, especially for cycle one, we coordinate closely with the nursing team, scheduling team, and transportation support," Kang explained. "Patients often need to arrive early, and we make sure authorizations and antiemetic coverage are in place beforehand."

In practice, infusion rates and scheduling flexibility vary across sites. Watson noted, "We start conservatively with slower infusion rates, especially at the beginning, until we see how patients tolerate it. Some centers split zolbetuximab and chemotherapy over two days when chair time or patient tolerance requires it. It is important not to forget that zolbetuximab still needs all premedications, even when given separately."

VYLOY® (zolbetuximab-clzb): Dosing and Administration[1]

	VYLOY DOSE	INITIAL INFUSION RATE (FIRST 30 TO 60 MIN)	SUBSEQUENT INFUSION RATE
FIRST DOSE	800 mg/m²	100 mg/m²/hr	200-265 mg/m²/hr
SUBSEQUENT DOSES	600 mg/m² every 3 weeks	75 mg/m²/hr	150-265 mg/m²/hr
	400 mg/m² every 2 weeks	50 mg/m²/hr	100-200 mg/m²/hr

MANAGING NAUSEA, VOMITING, AND INFUSION REACTIONS

Because zolbetuximab is associated with both gastrointestinal and infusion-related reactions, early education, comprehensive premedication, and vigilant monitoring are key components of therapy. Teams emphasized the importance of preparation and communication between pharmacists, nurses, and providers, particularly during cycle one, when symptoms are most common.

Adverse reactions should be managed by reducing the infusion rate, temporarily interrupting, or permanently discontinuing zolbetuximab rather than by dose reduction.[1] Because zolbetuximab is highly emetogenic, antiemetic prophylaxis is essential. Institutions commonly follow a **four-drug regimen** that includes an **NK1 receptor antagonist, a 5-HT3 receptor antagonist, dexamethasone,** and **olanzapine prior to the first infusion**. Kang added, "At least for cycle one, day one, I recommend using the four-drug regimen since nausea and vomiting are most common during that first exposure."

Dr. Mukherji described her process: "On the day of infusion, patients receive four premedications 30 to 60 minutes before treatment. For delayed nausea at home, I tell patients to take dexamethasone daily, ondansetron twice daily for several days, and prochlorperazine as needed. I often add nightly olanzapine as well." She added, "If anything happens during the infusion, nurses contact me right away. We stop the infusion, give antiemetics, and once recovered, restart at a slower rate, only increasing again if tolerated."

Dr. Pabon explained that communication and layered support help manage nausea and build patient confidence. "The biggest issue with tolerance has been nausea, so counseling patients on how to use antiemetics appropriately is key. We have them take nightly olanzapine throughout treatment to reduce nausea at home, and on infusion day they receive fosaprepitant, dexamethasone, and ondansetron. We also maintain a GI triage nurse line so patients can reach us in real time with side effects or questions."

Pharmacists play a central role in reinforcing premedication and monitoring plans. Kang noted that their team integrated antiemetic protocols directly into order sets: "The EMR PowerPlan (order set) has the 5-HT3, NK1, and steroid prebuilt, but providers can check to add olanzapine. We also confirm that patients have all take-home antiemetics in hand before starting."

At the infusion chair, nurses closely monitor tolerance and assess for early signs of nausea, flushing, or infusion reactions as well as signs and symptoms that may be suggestive of a hypersensitivity reacton. Rafferty shared, "I like to weigh on the side of caution before increasing the infusion rate. It's important to make sure the patient has no nausea and knows to report anything that feels different right away." In one case, she recalled, "A patient began feeling nauseated about an hour into infusion. We stopped the medication, checked his vitals, and called Dr. Mukherji, who ordered olanzapine. Once he received it and stabilized, we restarted slowly. That first infusion ended up taking almost eight hours, so now we make sure all antiemetics are in stock before starting."

Infusion-related reactions, while less common, require structured monitoring and clear communication. Dr. Mukherji explained, "Our infusion nurses obtain vitals before, during, and after infusion to ensure there is no hemodynamic instability. They check in frequently during the first hour, and if anything arises such as flushing, tightness, back pain, they call me immediately. We stop the infusion, administer rescue medications, and if necessary, transfer to the emergency department."

Dr. Pabon added, "Our nurses go slower during that first exposure, especially the first hour. If the patient tolerates well, they can ramp up after. I haven't seen many infusion reactions, but if symptoms occur, we troubleshoot chemotherapy causes first before assuming it's zolbetuximab." Kang also noted, "We provide a hypersensitivity kit to the infusion unit so the team can respond immediately if needed. It's another safety net for patient care."

From the nursing perspective, vigilance and patient empowerment are key. "Every patient gets an emergency call button," said Rafferty. "I tell them to ring it for any new symptom including flushing, shortness of breath, back pain,

"If you start strong with antiemetics, patients typically continue doing well."

– Shirin Khorashadi, PharmD, APh, BCOP

Managing Nausea, Vomiting, and Infusion Reactions - continued

or even mild nausea. We take vitals before starting and at every titration point since infusion rates gradually increase based on tolerance."

Across all practices, proactive teamwork and established protocols allow early recognition and intervention for both nausea and infusion reactions. Dr. Mukherji summarized, "If the regimen works, I keep it consistent. After a few cycles, if patients are tolerating well, I may reduce the steroids or one antiemetic at a time. But the key is to stay ahead of symptoms, not to chase them."

PATIENT EDUCATION AND COUNSELING

Patient education plays a vital role in successful administration of zolbetuximab. Because nausea and vomiting are most common during the first infusion, anticipatory guidance and clear instructions on supportive care are essential for preparing patients and reducing anxiety. Providers and pharmacists collaborate to educate patients on what to expect before, during, and after treatment. Dr. Mukherji shared, "I tell patients that the first infusion will be a long day because we run it slowly, and that nausea is the most common issue we see. We set the expectation early and explain that the first two cycles are typically the hardest, but symptoms usually improve after that. I also walk them through all the premedications they'll receive and the additional medicines to take at home."

Dr. Pabon emphasized that multiple team members are involved in reinforcing patient understanding. "As much as we try to counsel patients on antiemetics, it can be confusing when they are starting chemotherapy and learning so much at once. That is why we include our advanced practice providers and nurses in additional teaching sessions. We review what to expect, provide written handouts in English or Spanish, and go over side effects. Our nurses reinforce that same education on treatment day while monitoring the first infusion."

Pharmacists play a central role in ensuring patients are prepared and medications are accessible. Kang explained, "For patients, we provide comprehensive education prior to each new cycle, explain the infusion process, and review what they can expect, including side effects such as nausea or hypersensitivity reactions. We also go over the importance of premedication with antiemetics, since patients may wonder why they are getting multiple medicines before treatment. It's important to explain what each drug does and what to do if something doesn't work well. They also need to know they can contact us right away if anything happens."

She added, "We have found that when patients are informed in advance, they tolerate therapy better and stay calm if side effects occur. If they aren't prepared, they can feel frightened or frustrated when symptoms arise. Consistent communication with nursing staff and the patient before each treatment makes a big difference."

Rafferty described how nursing education supports this consistency. "Our infusion center gives each new patient a binder that outlines their care team and details about their therapy. It includes a list of side effects, dietary guidance, and who to call when certain symptoms occur." Her team also utilizes the NCODA-led Patient Education Sheets. She said her team finds them easy to read and understand. She adds "During the first day, we review at-home antiemetics, confirm prescriptions were filled, and make sure patients know how to use them."

Watson shared, "Patient education is the biggest thing. I tell patients that nausea and vomiting are typically worst in the first cycle, and that everyone's experience is different. Some have none, some mild, and some severe. The key is knowing what to do. I tell them use your as-needed medications early and call us if they don't help. If needed, we can bring patients into the infusion center for IV antiemetics or hydration. I also remind them that nausea can occur during the infusion itself, so they should tell their nurse right away. The nurse can pause or slow the infusion and give rescue medications." She continued, "We don't want patients to go home and struggle silently. We can make adjustments including slower infusions, different premeds, or additional supportive care—to help them tolerate therapy and stay on treatment."

Patient Education and Counseling - continued

Khorashadi reinforced that proactive education prevents complications. "We warn patients about nausea and vomiting, and stress prevention rather than waiting to treat. We also talk about hydration and monitor electrolytes closely. Because zolbetuximab is often given with oxaliplatin, we counsel on neuropathy risk and signs of infection. Patients are encouraged to report fever, shortness of breath, or other new symptoms right away."

Across all sites, patient education is viewed as a shared responsibility among pharmacists, nurses, and physicians. The team's unified approach ensures patients understand the purpose of their medications, how to manage side effects, and when to reach out for support. As Dr. Pabon stated, "The most important part is anticipatory guidance before they begin. When patients know what to expect and when to call, it makes all the difference in how they experience treatment."

STAFF EDUCATION AND COORDINATION

Introducing a new therapy like zolbetuximab requires thoughtful planning and team education across departments. From protocol development to infusion preparation, success depends on clear communication and shared understanding among pharmacists, nurses, and providers.

Dr. Mukherji explained that education began well before the first patient received therapy. "When we brought zolbetuximab on board, I distributed the materials NCODA provided and held a meeting with our infusion nurses and pharmacists to review how the infusion should be administered, what to monitor, and how to manage reactions. We timed infusions carefully throughout the day and reviewed how to adjust rates when needed."

Kang shared that their site provides two structured in-service sessions for any new medication. "The first focuses on the clinical trial data and patient outcomes, while the second reviews drug mechanisms, preparation, and safety considerations. We also upload infusion instructions and safety guidelines to our electronic system so staff can access them easily at any time."

She emphasized that nurse education and communication are equally critical. "When staff are informed in advance, they are better prepared to manage side effects calmly and efficiently. We provide handouts and review what to do if a patient develops nausea or hypersensitivity, including rate adjustments and supportive care steps. Because our pharmacy and infusion areas are located on the same floor, communication is quick and seamless." She reinforced that a hypersensitivity kit is stored directly in the infusion unit. "Even though medications can be accessed through the automated system, having an emergency kit available saves time when seconds matter."

Watson described the logistical effort required to launch zolbetuximab across a large network. "When the drug was added to formulary, it was a major undertaking. We educated all infusion centers, created clear documentation within treatment plans, and coordinated with the manufacturer for supplemental nurse training. For the first several patients, I checked in with infusion teams regularly to see how infusions were going, whether pauses were needed, or if any bags expired before completion. It was important for pharmacists to understand the drug's stability and how to handle longer infusion times safely."

This collaborative preparation has helped streamline workflows and minimize delays. Regular communication, proactive education, and access to on-demand references have strengthened team confidence and ensured that every member understands their role in delivering therapy.

FINANCIAL NAVIGATION

Strong financial navigation ensures that every patient prescribed zolbetuximab has access to treatment without unnecessary delays. Risher explained, "Commercial patients are typically the easiest to assist because copay programs are available for on-label use. The more complex cases are often with Medicare patients, where additional approvals and support programs are required."

Risher emphasized the importance of vigilance throughout the process. "Once authorizations are in place, we move immediately to financial assistance to determine if patients need help. With oncology patients, time is critical. A few days' delay can affect care, so my advice is always to stay diligent and on top of each case."

Her approach involves persistence and resourcefulness. "I'm always researching new funding sources. I'll call foundations, check alternate funding sites, and even reach out directly to manufacturers to verify their assistance programs. Sometimes smaller grants can make a big difference for patients."

Despite proactive navigation, Risher noted that access challenges still occur when newer therapies are not yet fully recognized by insurers. "We've had to fight for coverage, submitting appeals and peer-to-peer requests to explain that a treatment wasn't available as a first-line option when the patient was initially diagnosed. These cases require strong advocacy and teamwork to ensure every patient receives timely access to care."

"With oncology patients, time is critical. A few days' delay can affect care, so my advice is always to stay diligent and on top of each case."

— Tamala Risher

CONCLUSION

The successful implementation of zolbetuximab highlights the strength of a coordinated multidisciplinary team. By addressing key challenges such as managing emetogenic risk, ensuring medication access, and aligning workflows, these teams improved both patient outcomes and practice efficiency.

NCODA's PQI serves as a valuable resource to guide other practices in establishing similar processes and ensuring consistent, high-quality care. Zolbetuximab represents not only a new treatment option but also the progress that can be achieved when oncology teams work together within a patient-centered model.

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Team Communication in Action

Collaboration across roles ensures safe, timely, and supportive zolbetuximab therapy.

Pharmacy Technician

"We stay diligent to prevent treatment delays and secure funding for every patient. Time is critical in oncology, so we stay on top of every authorization and resource."

– Tamala Risher

Physician

"Education before the first infusion helps patients feel prepared for a long day. Setting expectations up front makes all the difference."

– Reetu Mukherji, MD

COLLABORATION DRIVES SAFE AND TIMELY CARE

Nurse

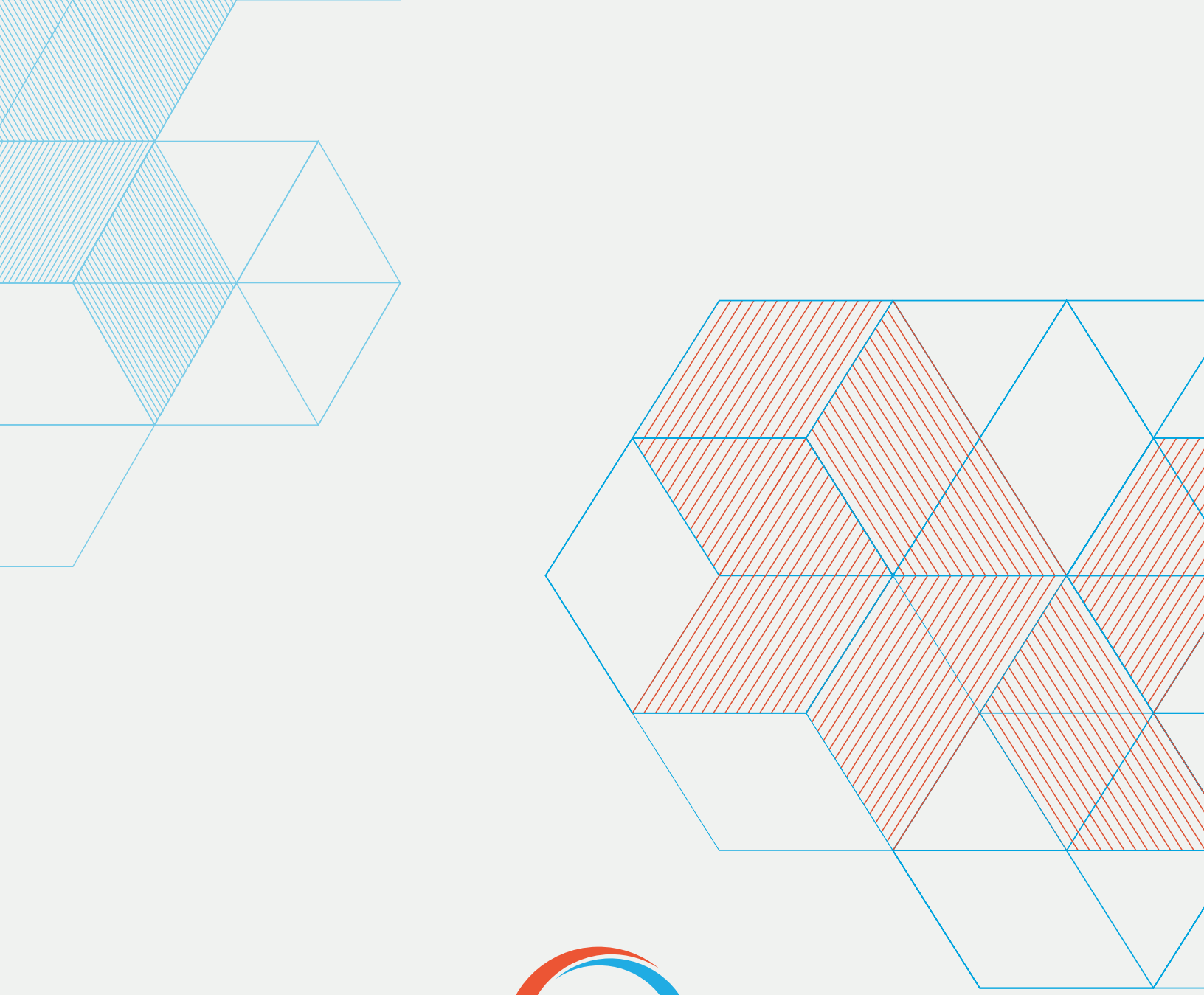
"I tell patients to ring the call bell at the first sign of nausea. Even small changes—like flushing or back pain—need quick attention so we can respond immediately."

– Casey Rafferty, BSN, RN

Pharmacist

"We double-check eligibility, dosing, and infusion rates for safety and consistency. Communication between pharmacy and nursing is essential for every first cycle."

– Minhee Kang, PharmD, BCPS, BCOP



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

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