# PQIIN ACTION





ENFORTUMAB VEDOTIN (PADCEV®)

MANAGEMENT FOR ADVANCED OR

METASTATIC UROTHELIAL CARCINOMA



### INTRODUCTION

In an effort to promote higher quality patient care NCODA created the NCODA Positive Quality Intervention (PQI) as a peer-reviewed clinical guidance resource for healthcare providers. By providing Quality Standards and effective practices around a specific aspect of cancer care, PQIs equip the entire multidisciplinary care team with a sophisticated yet concise resource for managing patients receiving oral or IV oncolytics. This PQI in Action is a follow up to the Enfortumab Vedotin (PADCEV®) Management for Advanced or Metastatic Urothelial Carcinoma PQI and explores how the Medically Integrated Teams at Seattle Cancer Care Alliance and Georgia Cancer Specialists incorporate PQIs as part of their daily workflow. This article will discuss how utilizing the Enfortumab Vedotin (PADCEV®) Management for Advanced or Metastatic Urothelial Carcinoma PQI elevates patient care.

Seattle Cancer Care Alliance (SCCA) is based in Seattle's South Lake Union neighborhood and is the only National Cancer Institute (NCI)-designated comprehensive cancer center in Washington state. SCCA has nine treatment centers in the greater Seattle region encompassing hematology/medical oncology, radiation oncology and infusion services, as well as network affiliations with hospitals in five states. Disease state clinics are set up inside of SCCA and each clinic has a designated disease specific clinical pharmacist in addition to the treating physicians, treatment coordinators, clinical nurse coordinators and advanced practice providers.

Georgia Cancer Specialists (GCS) is based in Atlanta, GA. GCS has 50 physicians that provide care in 26 Northside Hospital Cancer Institute locations across Metro Atlanta, North and Central Georgia. The practice offers medical oncology and hematology services and was the first private oncology practice to also provide a full range of support services for patients in Georgia, including nutritional counseling, pain management, wellness counseling, and home health coordination.

#### THE PARTICIPANTS

#### Seattle Cancer Care Alliance Seattle, Washington



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Medical Oncologist



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# DEFINING MEDICALLY INTEGRATED PHARMACY AND THE POSITIVE QUALITY INTERVENTION

edically Integrated Pharmacies (MIP) are a type of service model in which 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 oncologist's office that help to deliver timely and ongoing care as part of a single, multidisciplinary team. Complexity of cancer treatment has recently increased with a growing number of both oral and IV therapies which are delivered across an often-confusing, payer-driven healthcare system. Various treatment settings including community, institutional, and academic centers have made successful efforts to transition to this integrated service model to maintain continuous care of the patient and achieve the best possible clinical outcomes.

Empowered with innovative tools like the PQI, the 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 which provides concise, clinical guidance information to raise the standard of care across all the professional disciplines. In general, PQIs afford attention to any critical aspect of drug therapy that may be easily overlooked ("if you see 'x', remember



to do 'y"). In a world where new and novel treatments arise almost daily, healthcare professionals need an easy-to-use reference to enact the key clinical principles for each therapy. The PQI serves that need.

# THE ENFORTUMAB VEDOTIN (PADCEV®) MANAGEMENT FOR ADVANCED OR METASTATIC UROTHELIAL CARCINOMA PQI

dvanced uothelial carcinoma has remains an aggressive and generally incurable disease, even with advances in treatment.¹ Urothelial cancers are associated with resistance to chemotherapy and a minority of patients have a durable response to immunotherapy.¹ A cell adhesion molecule called Nectin-4 is highly expressed in this cancer type and is thought to play a role in tumor cell growth and proliferation.¹ Enfortumab vedotin-ejfv is a nectin-4 targeting antibody conjugated to the microtubule inhibitor monomethyl auristatin E (MMAE) and was granted accelerated approval by the FDA in December 2019 for the treatment of advanced or metastatic urothelial carcinoma. It is approved in patients who have previously received

a programmed death receptor (PD-1) or programmed death receptor (PD-L1) inhibitor, and a platinum-based chemotherapy in the neoadjuvant/adjuvant, locally advanced, or metastatic setting.<sup>2</sup> More recently, the FDA expanded that approval to include patients who are cisplatin-ineligible and have received at least one prior line of systemic treatment.<sup>2</sup>

The Enfortumab Vedotin (PADCEV®) Management for Advanced or Metastatic Urothelial Carcinoma PQI gives the multi-disciplinary team a concise resource for managing patients on enfortumab vedotin. The PQI is laid out in sections and begins with a Description followed by the Background, PQI Process, and Patient-Centered Activities, and

Supplemental Information sections. SCCA oncology clinical pharmacist Andew Ruplin, PharmD, authored the Enfortumab Vedotin PQI and shares, "I like the PQIs because we don't necessarily have standard operating procedures or an algorithm for every single thing at our center. In my PQI I didn't necessarily use algorithms, but I offer up suggestions that we use practically in our clinic, but that are also evidence based." GCS hematologist/oncologist Kristy McDonald, MD appreciates the PQI resource because it is more succinct than the package insert. "It is just easier to have this information together in one place, so you can better prepare the patients and better prepare the nursing staff. You know what to expect."

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Kristy McDonald, MD

# THE MEDICALLY INTEGRATED TEAM: A WINNING APPROACH FOR PATIENTS

CCA and GCS both take full advantage of the multidisciplinary team. The healthcare landscape has changed dramatically in the last 20 years and the clinician operating in isolation is now seen as undesirable.<sup>3</sup> Incorporating multiple perspectives in healthcare offers the benefit of diverse knowledge and experience, and a high-functioning team is an essential tool for building a more

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Petros Grivas MD, PhD

patient-centered, coordinated, and effective healthcare delivery system.<sup>3</sup> Teams offer the benefit of collective intelligence, expertise use, and diverse knowledge from various sources.<sup>4</sup> The oncology team plays a vital role in providing high quality patient care with positive outcomes. Pharmacy plays an important part of the team in both of our participating practices.

Petros Grivas, MD, PhD is a medical oncologist at SCCA, University of Washington and Fred Hutchinson Cancer Research Center, and clinical director of the Genitourinary Cancers Program at UW Medicine. He shares, "I cannot emphasize enough how important and vital the pharmacy team is in our practice. The pharmacist reviews the medications, reviews the orders in the electronic medical record (EMR), ensures that there are no drug-drug interactions, and ensures that there are no other considerations."

Dr. McDonald is a community oncologist and sees a wide variety of cancer types. She comments "we have new drugs coming out every month and it is hard to keep track of everything so having the pharmacy in our office with us is invaluable. It helps in learning about new medications, dosing schedules and side effect management. It is an extra level of safety for patients to have that expertise in the office."

### THE PQI DESCRIPTION AND BACKGROUND

he first two sections of the enfortumab vedotin PQI are the Description and Background. The Description gives the purpose of this PQI, which is to understand the management techniques and interventions when utilizing enfortumab vedotin. The Background lists the FDA approved indication, the mechanism of action, specific study information, and other information on enfortumab vedotin.

The Background discusses data from the pivotal phase II trial that took place in a heavily pre-treated population with an objective response rate of 44% including 12% complete responses. <sup>5,6</sup> According to Dr. Grivas, "enfortumab vedotin has been a very important tool in our armamentarium in the fight against advanced urothelial cancer. This agent has accelerated approval by the FDA as of December 2019. More recently at the ASCO GU 2021, enfortumab vedotin showed overall survival benefit compared to a taxane or vinflunine in a Phase III trial called EV-301." In the EV-301 trial enfortumab vedotin resulted in a 30% lower risk of death than chemotherapy, which indicates significantly longer overall survival. <sup>1</sup>

The PQI Background goes on to discuss adverse effects seen in the trials. The subsequent sections of the the PQI delve into these adverse effects and various management strategies-



Seattle Cancer Care Alliance located in Seattle, WA.

in much greater detail. Dr. Grivas shares that the pharmacists at SCCA not only help review orders for accuracy and things like drug-drug interactions but also assist in patient follow-up and management of side effects and toxicity.

### THE PQI PROCESS

he enfortumab vedotin PQI Process section consists of four steps. The first step is to confirm appropriateness of enfortumab vedotin using the EMR. Both SCCA and GCS have pharmacists reviewing orders in EMR prior to dispensing medications to patients. Prior to even that initial order review, pharmacist Douglas Hambrick, PharmD, BCOP is presenting new drugs at the practice's Quality, Research and Therapeutics meeting. He presents slides on the drugs that include information on safety, indications and other pertinent information. The committee decides if the medication will be added to the "formulary" and then Hambrick and another pharmacist build the order sets in the practice EMR. Hambrick shares that prior to dispensing enfortumab vedotin their pharmacists are actively reviewing orders and completing "a multitude of interventions to improve safety." The pharmacists are reviewing patient labs, any required testing, reviewing oncogenic drivers and ensuring that the medication is appropriate for the patient.

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RESIDENCY DIRECTOR PASSED ON TO ME,
'NO MEAT, NO TREAT.'"

Andrew Runlin PharmD

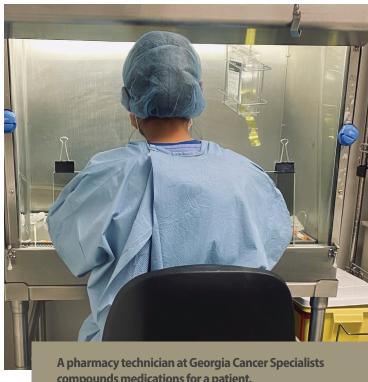
SCCA utilizes pre-built order sets, but Ruplin points out there are many nuances in therapy that make the pharmacist invaluable in reviewing these orders. He performs a comprehensive review of chemotherapy and non-chemotherapy antineoplastic treatments for his patients. He shares, "I do an extremely comprehensive review of everything about the patient. Everything from the oncology history of the patient to checking the pathology report. We have a saying that my residency director passed on to me, no meat, no treat." Ruplin also reviews the diagnosis, current medication trends, pre-medications, call parameters and labs. He says he reviews the infusion nurse's notes as well to determine if the patient had any difficulties during their past infusion.

The next step of the enfortumab vedotin PQI Process section is to review adverse events and interventions suggested. This step refers readers to the PQI Supplemental Information: Table 1. The following step is to review dose specific adjustments as required and refers readers to the PQI Supplemental information: Table 2. The adverse events covered in the PQI Table 1 are skin reactions, hyperglycemia, ocular toxicity, neuropathy, and diarrhea. SCCA Physician Assistant Jeannette Hammond, PA-C shares SCCA has a lot of experience with enfortumab vedotin in clincal trials and is now getting experience with it as standard of care. She says one of the most common toxicities with enfortumab vedotin is rash, "all different kinds of rashes. We are very intense in monitoring so we can manage patients quickly and appropriately."

Rash is an anticipated on-target toxicity of enfortumab vedotin because it targets Nectin-4, which is expressed in the skin.6 Skin reactions of any grade occurred in 54% of patients on enfortumab vedotin with a median onset for severe skin reactions of 0.8 months.<sup>2,5</sup> Ruplin says suggested interventions for skin reactions at SCCA include moisturizers and topical steroids as indicated, and possibly systemic steroids if the patient needs them. GCS pharmacists employ similar methods for treating skin toxicities. Hambrick shares their physicians grade the severity of the toxicity and manage based on that grade. This may include anything from topical preparations to referring the patient to dermatology. It also includes dose modifications and holds. GCS Pharmacist Rondalyn Smith, PharmD, BCACP, MBA says the patient can sometimes utilize moisturizers or topical steroid creams. Dose adjustments can be made according to Table 2 in the PQI.

Smith also comments that it is important to educate patients on hyperglycemia symptoms and the need for monitoring and reporting these, especially if the patient is diabetic. Dr. Grivas comments that based on the literature, there seems to be some association with a high BMI in patients who present with hyperglycemia. Ruplin explains SCCA draws labs prior to all treatments to make sure the patient's blood sugar is appropriate to treat the patient with enfortumab vedotin again. He says, "the recommendation is to not treat in the event

patients have a blood glucose greater than 250 mg/dl."This recommendation is also included in Table 2 in the PQI.<sup>5</sup>



compounds medications for a patient.

Ocular disorders including blurred vision and dry eye symptoms are another adverse event both teams have experience in managing. Ruplin shares, "I do talk about ocular toxicity a lot with patients. I do counsel patients that we can consider prophylactic artificial tears in case they get the dry eye symptom." Hammond normally lets patients know that dry eye is something that may come up and to check in ahead of time with their opthamologist if they are already established with one. Dr. McDonald also has experience in collaborating with a local opthamologist to follow patients. The median time to onset for ocular disorders was 1.9 months.<sup>2,5</sup>

The next selected adverse event listed on the PQI Table 1 is neuropathy. Peripheral sensory neuropathy was the most common reason for dose reduction of enfortumab vedotin.<sup>2,5</sup> Dr. Grivas shares, "we think about neuropathy in the patient population where they have prior platinum based chemotherapy and they are more senior patients with other medical issues." He adds that often dose holds and reductions may be required since there are no great therapeutic options for the neuropathy.

The third selected adverse event listed on the PQI table is diarrhea with 42% of patients having any grade of diarrhea. <sup>2,5</sup> Hammond talks about the GI side effects with patients up front because these side effects are usually treatable with

medications. She likes patients to be prepared in case the GI effects occur. Ruplin agrees and gives patients a firm recommendation so they know when they need to take action. His recommendation is based on the number and consistency of their stools.

The final step of the PQI Process is to review drug interaction considerations. Pharmacists at both GCS and SCCA perform this task prior to a patient starting therapy. GCS

pharmacist Kelsi Bates, PharmD explains that at the start of therapy GCS oncology pharmacists are reviewing everything that pertains to the patient in the EMR including lab values, tests that are necessary, and drug-drug interactions. "We have a drug-drug interaction checker built into our EMR that we can run." Enfortumab vedotin is metabolized via CYP3A4.<sup>4</sup>

# PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

he Patient-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. The enfortumab vedotin PQI Patient-Centered Activities section reviews patient education and symptom reporting. Both SCCA and GCS have a mix of pharmacists, nurses, and providers completing patient education. At GCS, as lead pharmacist Ellie Kamarjian, PharmD explains, initially the physician speaks to the patient on protocol or regimen changes. Following that interaction, a nurse will follow up and give the patient more detailed information. The pharmacy team also helps explain things to the patient and answers any drug specific questions. The patient is required to sign a consent and may also receive an additional chair-side chemo teach.

Angi Nicholson, RN is a clinical nurse coordinator at SCCA. Her role is to support two medical oncologists and Advanced Practice Providers with patient care, including patient education. She says she does whatever she can to support the patient and her job is "making the patient's journey through their treatment as easy as possible." She feels it is important to review the most common side effects with patients and give the patient some anticipatory guidance on how they may feel while on the medication.

Ruplin also educates patients at SCCA. He shares, "I find that many times the team sees an extreme value in having a pharmacist talk to the patient about treatment. Many times people think about the pharmacist as educating patients on oral treatments, like in a community pharmacy, but I talk to patients across my clinic on intravenous chemotherapy and oral chemotherapy. It is great because we have 30, sometimes 45 minutes to talk one on one specifically about their treatment."

The first patient-centered activity on the PQI is to advise

patients that skin toxicities for enfortumab vedotin are likely to manifest as dry skin, pruritis, and/or maculopapular rash.<sup>2,5</sup> Severe skin toxicities (10%) incidence included symmetrical drug-related intertriginous and flexural exanthema (SDRIFE), bullous dermatitis, exfoliative dermatitis, and palmar-planter erythrodysesthesia.<sup>2,5</sup>

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Andrew Ruplin, PharmD

The next patient-centered activity on the PQI is to advise patients to self-monitor for peripheral sensory neuropathy and motor neuropathy. Ruplin explains, "I like to discuss the exact sensation with the patients, so I explain they may have tingling, burning, or numbness and particularly in the hands and feet." He adds he lets patients know this is a side effect that will not necessarily get better if they do not tell the team

they are experiencing neuropathy. Hammond also educates patients on neuropathy. She shares that in general, "I let patients know that sometimes we don't have the right dose right away. I let them know some people need a dose reduction, so it does not feel so shocking if it happens."

Dr. Grivas sums up patient-centered activites by stating that managing the potential side effects of the medication requires close collaboration of the provider team and the pharmacy team. He says, "it is important to clarify with patients that it is critical to report any side effects immediately, don't wait."

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IMMEDIATELY, DON'T WAIT."

Petros Grivas, MD, PhD

## SUPPLEMENTAL INFORMATION: SELECTED ADVERSE EVENTS, INTERVENTIONS, AND DOSE ADJUSTMENTS

he final section of the enfortumab vedotin PQI is Supplemental Information. As mentioned previously, this section contains two tables on Selected Adverse Events and Suggested Interventions and Dose Adjustments for Adverse Events. Hammond appreciates the PQI and the tables because "these types of things are an easy reference and it has all of the information you need. I always like to know what the relative risks are, so knowing the percentage of patients in which certain adverse events may be significant." Kamarjian also comments on the value of the tables in this section. She says, "I think the tables are very helpful from a practical perspective because they give you what to look out for and potential resolution."

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Ellie Kamarjian, PharmL

#### Selected Enfortumab Vedotin Adverse Events and Suggested Interventions<sup>4</sup>

Event	Severity/Incidence	Suggested Intervention	Comments
Skin Reactions	54% (any grade)	Fragrance-free moisturizers/ointments  Topical steroids and antihistamines as	Median time of onset for severe skin reactions was 0.8 months (range $0.2-5.3$ ) <sup><math>\tau</math></sup>
		indicated	Patients in EV-301 with grade 3 rash did not require treatment interruption if symptoms were manageable <sup>3</sup>
		Systemic steroids as indicated	
Hyperglycemia	11% (any grade)¹ regardless of known hyperglycemia at baseline	Blood glucose test prior to infusion – a basic metabolic panel suffices	BMI and elevated A1c correlated to a higher incidence of grade 3/4 hyperglycemia1
	68% of patients with baseline hyperglycemia did not experience worsenin	Does not need to be fasting	Patients with baseline A1c ≥ 8% were excluded from EV-201
			Patients with baseline A1c ≥ 6.5% should be referred to an appropriate provider for glucose management
Ocular Toxicity	Ocular disorders including blurred	Consider prophylactic artificial tears1	Median time to onset for ocular disorders was 1.9 mon-
	vision – 46%	Consider topical ophthalmic steroids after	ths (range 0.3 – 6.2)
	Dry eye symptoms – 36%	ophthalmic exams <sup>1</sup>	
Neuropathy	49% (any grade).	Recommend dose reduction as initial strategy The median time to onset of grade $\geq 2$ was 3.8 m (range: $0.6 - 9.2$ )	The median time to onset of grade $\geq 2$ was 3.8 months
	Peripheral sensory neuropathy was the most common reason for dose reduction		(range: 0.6 – 9.2)
		Consider use of gabapentin or duloxetine	At the last follow-up in EV-201, 19% had complete resolution and 26% had partial improvement. 76% had resolution or ongoing grade 1 neuropathy
Diarrhea	42% (any grade)	Recommend anti-diarrheal medications for patient as required	Grade 4 diarrhea that resolves to grade ≤2 within 72 hours with supportive management does not require treatment interruption

PQI Table 2: Dose Adjustments for Adverse Events<sup>1</sup>

Administration	IV infusion over 30 minute	s on days 1, 8, 15 of a 28-day cycle until progression/toxicity	
Starting dose	1.25 mg/kg up to 125 mg*		
First dose reduction	1 mg/kg up to 100 mg*		
Second dose reduction	0.75 mg/kg up to 75 mg*		
Third dose reduction	0.5 mg/kg up to 50 mg*		
D 1/1	No dose adjustment is required for renal dysfunction		
Renal/hepatic dysfunction considerations	No current studies in moderate to severe hepatic dysfunction – consider avoiding use Mild hepatic dysfunction does not require an upfront dose reduction		
Adverse Event	Grade/Severity	Dose Modification	
Hyperglycemia	Blood glucose > 250 mg/dL	Withhold until ≤ 250 mg/dL, then resume at same dose level	
Peripheral neuropathy	2	Withhold until grade ≤ 1, then resume at same dose level. If recurrence, withhold until Grade ≤ 1, then resume and reduce one dose level	
	≥ 3	Permanently discontinue	
	3	Withhold until grade ≤ 1, then resume at same dose level or consider reducing by one dose level	
Skin reactions	4 or recurrent 3	Permanently discontinue	
	3	Withhold until grade ≤ 1, then resume at same dose level or consider reducing by one dose level	
Other non-hematologic toxicities	4	Permanently discontinue	
Hematologic toxicity	3 or Grade 2 thrombocytopenia	Withhold until grade ≤ 1, then resume at same dose level or consider reducing by one dose level	
	4	Withhold until grade ≤ 1, then resume and reduce one dose level or discontinue treatment	

## THE MEDICALLY INTEGRATED TEAM: PROVIDING SAFE AND INNOVATIVE TREATMENT

CODA member practices vary in size, type and geographical area. Something can be learned from each practice, and we find unique ways of providing top-notch patient-centered care across multiple practice settings. Oncology pharmacy technicians are an extremely valuable part of the multi-disciplinary team and can serve in a myriad of capacities in oncology clinics. GCS pharmacy technician Nashan Franklin mixes IV chemotherapy for patients. She works with the medications on a day to day basis and is able to offer tips on compounding. She shares one of the most important things to remember when compounding enfortumab vedotin is to try to keep the medication from bubbling up. She says she realized that if you instill the water too quickly it will foam up and it is important to let it rest after reconstituting.

In addition to compounding functions SCCA has pharmacy technicians in the role of Pharmacy Billing Coordinator. Michelle Lentz, PhT and Serenity Robinson, CPhT fulfill this role. They are both licensed pharmacy technicians and obtain prior authorizations for high cost infusion and oral antineoplastic drugs. Lentz explains the benefit of having

pharmacy staff perform this function is that "we are familiar with drug names and therapeutic classes. We have a better understanding than a staff member that may work at a call center or hub that just goes off what is input into an enrollment form." Robinson adds "I have a background in infusion so I am aware of how the drugs are made for the patients. It is good to work with the clinical pharmacist because they can answer questions about clinical information when submitting a prior authorization."

Nicholson describes one more unique and beneficial aspect of SCCA for patient-centered care, the ACE clinic. ACE stands for Acute Care Evaluation and functions as their very own Urgent Care Clinic inside of their infusion center. They first opened this clinic during the early COVID-19 days as a way for patients reduce their risk of exposure. Nicholson shares, "it has been such a great resource for patients." The ACE clinic is able to offer lab services, hydration therapy and other supportive care that does not require hospitalization and is an innovative option for patients. The medically integrated team is making a difference daily in the lives of patients.

# CONCLUSION: NCODA, THE MEDICALLY INTEGRATED TEAM AND ENFORTUMAB VEDOTIN PQI: OPTIMIZING PATIENT OUTCOMES

he Medically Integrated Team provides value to patients. Dr. Grivas sums up the value of pharmacy as part of this team, "pharmacy is so important in education, both in community outreach and internal education. I think it is important to outline the central role pharmacy plays in patient care, research, and education." Hammond agrees and adds "I love more education and am so appreciative of our pharmacy team here. They are great problem solvers and they have so much knowledge. We have a lot of new drugs we are dealing with in bladder cancer and it is nice to all be working together." The Enfortumab Vedotin (PADCEV®) Management for Advanced or Metastatic Urothelial Carcinoma PQI provides the Medically Integrated Team with an easy to use, compact clinical resource guide when treating patients on enfortumab vedotin. It helps the team ensure they are managing side effects properly and providing patients with the tools and education

to improve clinical outcomes. Pairing the Medically Integrated Team with the Enfortumab Vedotin (PADCEV®) Management for Advanced or Metastatic Urothelial Carcinoma PQI meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.



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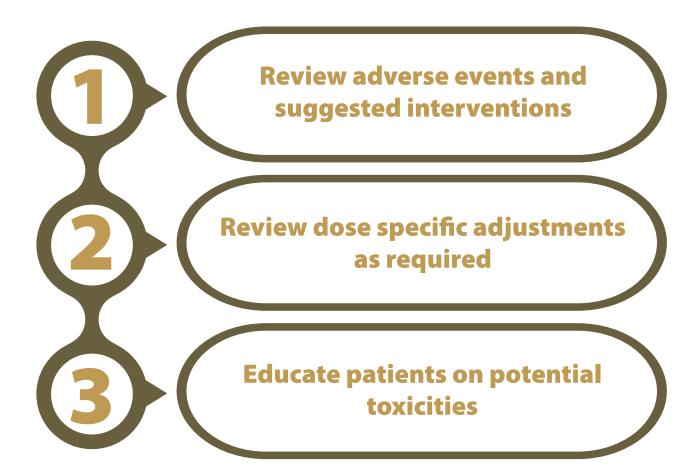
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#### **ON THE COVER:**

Georgia Cancer Specialists Lead Oncology Pharmacist Ellie Kamarjian, PharmD reviews medication orders for a patient.

### **PQI PRINCIPLES:**





### **Helpful Online Resources**

- **NCODA Website**
- Oral Chemotherapy Education Sheets
- Are you interested in authoring a PQI?
- Positive Quality Interventions
- Enfortumab Vedotin PQI
- Are you interested in taking part in a PQI In Action?

#### 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.



