

PQI IN ACTION



**ENFORTUMAB VEDOTIN (PADCEV®)
MANAGEMENT FOR ADVANCED OR
METASTATIC UROTHELIAL CARCINOMA**



**NCODA'S POSITIVE QUALITY
INTERVENTION IN ACTION**

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 Management for Advanced or Metastatic Urothelial Carcinoma** PQI and explores how the medically integrated teams at City of Hope and Baptist MD Anderson Cancer Center incorporate PQIs as part of their daily workflow. This article will discuss how utilizing the **Enfortumab Vedotin Management for Advanced or Metastatic Urothelial Carcinoma** PQI elevates patient care.

City of Hope (COH), formally Cancer Treatment Centers of America (CTCA), unites shared vision, values and commitment to high-quality compassionate care that puts patients first. City of Hope Comprehensive Cancer Centers are located in Atlanta, GA, Chicago, IL and Phoenix, AR. In addition, COH offers convenient outpatient care centers in the Chicago and Phoenix areas. COH prides itself on pioneering the whole-person treatment approach to cancer treatment and applying this standard to every patient. This PQI in Action highlights members of the COH practices in Atlanta, GA and Chicago, IL.

Baptist MD Anderson Cancer Center brings together one of the largest and most respected cancer centers in the nation and one of Northeast Florida's top ranked hospital systems to provide comprehensive and compassionate cancer care to patients in Jacksonville, Florida and its surrounding areas. The Baptist MD Anderson Cancer Center has a central location in downtown Jacksonville, steps away from Baptist Medical Center, and 2 additional outpatient centers located near Baptist Medical Center South and Baptist Medical Center Clay, offering services more convenient and close to home for many patients. Baptist MD Anderson Cancer Center prides itself on servicing every aspect of cancer care, from diagnosis to survivorship, and providing much needed emotional, spiritual and financial support every step along the way. This PQI in Action highlights members of the Baptist MD Anderson Cancer Center's central location in Jacksonville, Florida.

THE PARTICIPANTS

City of Hope Chicago, IL



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Oncology Nurse Practitioner



Megan Kranz, PharmD, BCPS, BCOP
Clinical Oncology Pharmacist



Cynthia Chilson, CPhT
Oncology Pharmacy Technician

DEFINING MEDICALLY INTEGRATED PHARMACY AND THE POSITIVE QUALITY INTERVENTION

The implementation of pharmacists as part of the medically integrated team continues to add value as the complexity of cancer treatment evolves. As the care of patients with cancer continues to be challenged with high-cost therapies, medication shortages, regulatory requirements, and dwindling reimbursement, the oncology pharmacist is heavily relied on to provide support for the clinical team to improve overall cancer care and quality of life.¹ Oncology pharmacists also play a key role in the education of patients and other health care providers, as they continue to be the experts on medication and side effect management. In addition, pharmacy technicians and other pharmacy team members contribute essential roles in the care of these patients. These roles include but are not limited to accurate ordering and inventory procurement of drugs, safe handling and mixing of chemotherapy and other drug therapies and ensuring financial aid and billing are secure and accurate. Sarah Griffis, ARNP, FNP-C finds significant value in having a clinical oncology pharmacist on her team at Baptist MD Anderson. Griffis comments “I cannot imagine doing my job here without a pharmacist by my side. Our pharmacist, Megan, is instrumental as a patient resource and our patients benefit tremendously from the extra time and attention she provides during patient counseling.” Cynthia Chilson, CPhT, also of Baptist MD Anderson adds “The pharmacists play a vital role in checking our orders prior to mixing and providing a final check of the finished product before it goes to the patient. Our location is steps away from the patient who will receive the medication, ensuring timely delivery of the product.”

Dr. Ajaz Khan who chairs the Department of Medicine at City of Hope expresses that his pharmacy team gives a unique layer of safety to the oncology patients at COH. Khan comments “Having the pharmacists, technicians and entire care team onsite truly gives a speed to care delivery in the fact that everything is done right here, with no waiting for drug delivery or long turnaround of labs.” Khan continues as he comments on the pharmacist role, “Having the pharmacist



Cynthia Chilson, CPhT completes the mixing process of enfortumab vedotin for a patient at the Baptist MD Anderson Cancer Center.

on the team, from a safety standpoint, significantly improves communication and reduces potential errors that can arise. When I walk out of my office door, the pharmacists are right there and we can discuss doses, treatment protocols, lab values, etc.”

“HAVING THE PHARMACISTS, TECHNICIANS AND ENTIRE CARE TEAM ONSITE TRULY GIVES A SPEED TO CARE DELIVERY IN THE FACT THAT EVERYTHING IS DONE RIGHT HERE, WITH NO WAITING ON DRUG DELIVERY OR LONG TURNAROUND OF LABS.”

Ajaz Khan, MD, MBA, CPE

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

Locally advanced or metastatic urothelial carcinoma is an aggressive and lethal malignancy that predominantly affects individuals of advanced age.² The treatment options for these patients, especially those who are cisplatin-ineligible, are limited. Antibody-drug conjugates (ADCs), which offer a combination of chemotherapy linked to immunotherapy, are targeted to attach to specific antigens that are highly expressed on tumor cells.³ ADCs empower selective delivery of highly potent drugs to tumor cells while sparing healthy cells, attenuating the main clinical obstacle of traditional chemotherapy, thus providing a broad therapeutic window.³

The **Enfortumab Vedotin Management for Advanced or Metastatic Urothelial Carcinoma PQI** provides

a precise and concise overview of the approved indications for enfortumab vedotin and guides clinicians on how to counsel and manage side effects that patients may experience during treatment. The Description and Background sections of the Enfortumab Vedotin (PADCEV®) PQI include the purpose of the PQI and important trial information that led to the current FDA approvals.

Enfortumab Vedotin (PADCEV®) is an antibody-drug conjugate directed at nectin-4, a cell adhesion protein molecule, that is highly expressed in urothelial carcinoma.^{2,4} Composed of a fully human monoclonal antibody and monomethyl auristatin E, this highly specific targeted agent binds to nectin-4 to facilitate targeted delivery of monomethyl auristatin E, resulting in cell-cycle arrest and apoptosis via microtubular inhibition.^{4,5} Currently, enfortumab vedotin is approved by the FDA for two indications. The first is for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma in patients who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a cisplatin-containing chemotherapy.^{4,6} Additionally, enfortumab vedotin is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.^{4,6}

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Baptist MD Anderson Cancer Center, located in Jacksonville, FL, offers exceptional care to cancer patients and their families, including research, prevention programs, and education, all in one location.

The PQI Background displays the trial information, including response rates and side effects experienced by the patients. In cohort 1 of the pivotal open-label phase II trial EV-201, patients with metastatic urothelial carcinoma who had previously received both a platinum-containing chemotherapy regimen and a PD-1/PD-L1 checkpoint inhibitor were evaluated.⁷ Results in this cohort 1 demonstrated ORR of 44% (95% CI, 35.1%-53.2%), including 12% complete responses.⁷ Grade 3 or higher treatment-related adverse events led to dose reductions (32%) or discontinuation of therapy (12%).⁷ Cohort 2 of the EV-201 trial evaluated patients who had previously been treated with a PD-1 or PD-L1 checkpoint inhibitor therapy and were ineligible for a cisplatin-containing regimen.⁸ In this cohort of patients, ORR was 52% (95% CI, 41%-62%) with 20% of patients having a complete response.⁸ Grade 3 or higher treatment-related adverse events in this group averaged 55%.⁸ The phase III EV-301 trial further concluded the benefit of enfortumab vedotin compared to chemotherapy after treatment with cisplatin-containing regimens followed by immunotherapy (median OS, 12.88 vs 8.97 months; hazard ratio 0.70; 95% CI, 0.56-0.89; P=0.001).⁹ The incidence of grade 3 or higher adverse events in this EV-301 trial was similar in both patient groups, 51.4% with enfortumab vedotin compared to 49.8% with chemotherapy.⁹

THE PQI PROCESS: A LOOK AT ADVERSE EVENT MANAGEMENT, DOSE REDUCTIONS AND DRUG INTERACTIONS

The Enfortumab Vedotin PQI Process is a sequence of steps to follow when starting a patient on this therapy, taking all key patient factors into consideration. Two supplemental tables are also included for guidance on interventions for specific levels of adverse events and also how to dose adjust for these adverse events.¹⁰ Khan at COH Chicago sees enfortumab vedotin as a likely option in his patients who fail other lines of treatment. “The decision to move to enfortumab vedotin is simple once the patient has failed other lines of treatment. It is also important to consider that these patients are usually older in age and sometimes have lower performance status. Eligible patients that I have treated on this drug had few adverse events, usually lab abnormalities, which I was able to dose reduce, allowing the patient to continue on treatment just fine.”

Upon receiving an order of enfortumab vedotin, confirm diagnosis and previous lines of treatment to ensure appropriateness of drug. Once confirmed, verify that the dosage and administration listed in the EMR are correct for the patient. The starting dose of enfortumab vedotin is 1.25 mg/kg up to 125mg, based on the actual body weight of the patient.⁴ The calculated dose is then mixed in D5W, NS or LR to a final diluted concentration of 0.3 to 4 mg/mL.⁴ The final mixed product is then administered over 30 minutes on days 1, 8, 15 of a 28-day cycle until disease progression.⁴

Once on therapy, if the patient experiences adverse events, follow the suggested interventions in the first supplemental table in the PQI. Megan Kranz, PharmD, BCPS, BCOP, of Baptist MD Anderson, comments that “We have experienced a few patients needing dose reductions after 3-4 cycles, but typically patients tolerate enfortumab vedotin well.”

ENFORTUMAB VEDOTIN ADVERSE EVENTS AND SUGGESTED INTERVENTIONS

Event	Severity/Incidence	Suggested Intervention	Comments
Skin Reactions	54% (any grade) ¹	Fragrance-free moisturizers/ ointments Antihistamines, topical and systemic steroids as indicated	Median time of onset for severe skin reactions was 0.8 months (range 0.2 – 5.3). ¹
Hyperglycemia	11% (any grade) ¹ regardless of known hyperglycemia at baseline 68% of patients with baseline hyperglycemia did not experience worsening	Blood glucose test prior to infusion – a basic metabolic panel suffices Does not need to be fasting	BMI and elevated A1c correlated to a higher incidence of Grade 3/4 hyperglycemia. ¹ Patients with baseline A1c \geq 6.5% should be referred to an appropriate provider for glucose management ¹
Ocular Toxicity	Ocular disorders including blurred vision – 46% ¹ Dry eye symptoms – 36% ¹	Consider prophylactic artificial tears ¹ and consider topical ophthalmic steroids after eye exams ¹	Median time to onset for ocular disorders was 1.9 months (range 0.3 – 6.2) ¹
Neuropathy	49% (any grade). ¹ Peripheral sensory neuropathy was the most common reason for dose reduction	Recommend dose reduction as initial strategy Consider use of gabapentin or duloxetine	The median time to onset of grade \geq 2 was 3.8 months (range: 0.6-9.2). 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 ²
Diarrhea	42% (any grade) ¹	Recommend as needed anti-diarrheal medications	Grade 4 diarrhea that resolves to grade \leq 2 within 72 hours with supportive management does not require treatment ⁴

References noted on chart refer to the references within the Enfortumab Vedotin PQI.

If dose reductions are necessary due to adverse events, follow the suggested dose reductions in the second supplemental chart in the PQI. Bob Luschen, PharmD, BCOP, Clinical

Coordinator of the Inpatient Pharmacy Department at COH Atlanta, expresses the importance of monitoring these patients while on therapy. Luschen states “For many of these

patients, enfortumab vedotin is their last option. Because of this, early intervention with appropriate services and/or dose reductions or dose interruptions, will allow us to maximize their time with this treatment.” Luschen continues, “We are very fortunate here at COH to provide onsite services such

as physical therapy and supportive care services, to tailor the care of the entire patient. Early intervention to begin some of these alternative services to overcome adverse events, can help significantly in keeping patients on a therapy and increasing their likelihood of a significant response.”

ENFORTUMAB VEDOTIN DOSE ADJUSTMENTS FOR ADVERSE EVENTS

Administration	IV infusion over 30 minutes 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*	
Renal/hepatic dysfunction	No dose adjustment is required for renal dysfunction No current studies in moderate to severe hepatic dysfunction – consider avoiding	
Adverse Event	Grade/Severity	Dose Modification
Hyperglycemia	Blood glucose > 250 mg/dL	Hold until ≤ 250 mg/dL, then resume at same dose level
Peripheral neuropathy	2	Hold until Grade ≤ 1, then resume at same dose level or reduced by one level
	≥ 3	Permanently discontinue
Skin reactions	3	Hold until Grade ≤ 1, then resume at same dose level or reduced by one level
	4 or recurrent 3	Permanently discontinue
Other non-hematologic toxicities	3	Hold until Grade ≤ 1, then resume at same dose level or reduced by one level
	4	Permanently discontinue
Hematologic toxicity	3 or Grade 2 thrombocytopenia	Hold until Grade ≤ 1, then resume at same dose level or reduced by one level
	4	Hold until Grade ≤ 1, then resume at same dose level or reduced by one level
Pneumonitis	Grade 2	Hold until grade ≤ 1 for persistent or recurrent grade 2, consider dose reduction by one level
	Grade ≥ 3	Permanently discontinue

*Based on actual body weight. Dose is capped for patients ≥100 kg

Khan sees true benefit in the supplemental tables of the PQI stating, “You will have patients that have read about the drug and come prepared with questions about insurance, side effects and duration of therapy. Having this PQI handy can be very helpful for us as practitioners to answer these patient questions.”

The final piece of the PQI process is to monitor for potential drug-drug interactions. Enfortumab vedotin is metabolized via CYP3A4, and concomitant use of an antibody-drug conjugate containing MMAE and dual P-gp and strong CYP3A4 inhibitors should be considered.⁴ Dose adjustment is typically not required but may result in increased inhibition.⁴ Therefore, it is important to review current medications that patients are taking before starting enfortumab vedotin for these interactions, as well as, check for drug-drug inte-

ractions if starting any new medications while the patient is being treated with enfortumab vedotin.

“FOR MANY OF THESE PATIENTS, ENFORTUMAB VEDOTIN IS THEIR LAST OPTION. BECAUSE OF THIS, EARLY INTERVENTION WITH APPROPRIATE SERVICES AND/OR DOSE REDUCTIONS OR DOSE INTERRUPTIONS, WILL ALLOW US TO MAXIMIZE THEIR TIME WITH THIS TREATMENT.”

Bob Luschen, PharmD, BCOP

PATIENT-CENTERED ACTIVITIES: HOW TO RELAY THE MOST IMPORTANT INFORMATION TO THE PATIENT

With the patient always at the center, the PQI Process section is followed by Patient-Centered Activities. This section contains key information for the patients when they begin treatment with enfortumab vedotin. The two most common adverse reactions to warn patients about are skin reactions (54%) and neuropathy (49%).⁴ For skin reactions, advise patients that skin toxicities for enfortumab vedotin are likely to manifest as dry skin, pruritis and/or maculopapular rash.⁴ For neuropathy, advise patients to self-monitor for peripheral sensory and motor neuropathy, with sensory neuropathy (44%) more common than motor neuropathy (14%).^{4,7} In addition to these patient-centered activities, NCODA has a PQI available to assess Chemotherapy Induced Peripheral Neuropathy, which provides additional guidance in identifying and treating this adverse event. The Patient-Centered Activities section also provides a link to the NCODA Financial Assistance Tool. Financial toxicity, especially when patients become heavily treated and fail several treatment options, becomes a real burden. Carey Milewski, Revenue Cycle Supervisor at COH Atlanta, states “Collaborating

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Erica Marchese, PharmD, MHA, BCPS, BCOP and Ajaz Khan, MD, MBA, CPE prepare to speak to a patient about their infusion therapy in clinic.

efficiently with the pharmacy team to assist with drug approvals or precertifications of drugs like enfortumab vedotin is vital to allow these patients quick access to the drug. In the event that financial assistance is needed, the NCODA financial assistance tool is a great resource to guide our team to additional assistance.”

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ASSISTANCE TOOL](#)

THE MEDICALLY INTEGRATED ONCOLOGY TEAM: THE IMPORTANCE OF COLLABORATION AND PUTTING PATIENTS FIRST

Every team member that plays a part of treating the oncology patient can impact the quality of care that patient receives. When EMR systems are connected and everyone can all function as one team, this process is made easier and safety and quality care likely follow. Megan Kranz, clinical oncology pharmacist at Baptist MD Anderson, describes how pharmacists collaborate as part of this team. “Pharmacists here play an integral part in linking aspects of patient care. Because we are able to see the patients on the clinic side and then

again on the infusion side, we are sort of the 'glue' that links everything together.” She continues on to discuss the counseling they provide. “As the drug experts, we are able to provide extensive patient counseling on oral and IV medications. In addition to side effects, we also discuss the logistics of each infusion treatment, such as how long the treatment will be, what the regimen cycle looks like, and how long they will be expected to be in clinic and on which days.” At COH, the nurses play more of a role in the infusion clinic counseling that Kranz describes above.

Liz Green, BSN, OCN, states “By the time the patient gets to me in the infusion clinic, they have already had initial counseling on what they are getting and why – but I will reiterate all of the key details. I ensure they are aware of side effects, what to expect while they are in the chair, what to expect 1-2 days after treatment, etc. I am the reinforcer of all of this information.” These patients often receive so much information and it can be very overwhelming, so reinforcing the information to these patients or their caregivers is very important.

“IN ADDITION TO SIDE EFFECTS, WE ALSO DISCUSS THE LOGISTICS OF EACH INFUSION TREATMENT, SUCH AS HOW LONG THE TREATMENT WILL BE, WHAT THE REGIMEN CYCLE LOOKS LIKE, AND HOW LONG THEY WILL BE EXPECTED TO BE IN CLINIC AND ON WHICH DAYS.”

Megan Kranz, PharmD, BCPS, BCOP

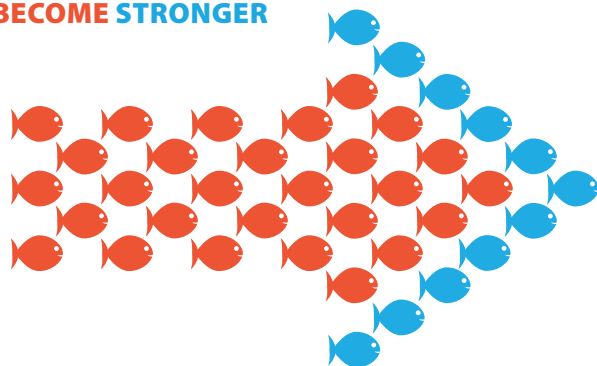
CONCLUSION: NCODA, THE MEDICALLY INTEGRATED TEAM AND BRIDGING THE GAP WITH THE ENFORTUMAB VEDOTIN PQI

As pharmacy team members continue to serve as essential members of the medically integrated teams in oncology clinics, it is vital to equip them with valuable resources. Marchese of COH Chicago strives to incorporate pharmacists into their care teams. “One of my jobs is to get our pharmacists to practice at the top of their license and integrate them into the medical teams. One of the ways I achieve this is to make them more visible to the team. We now have a pharmacist sitting in all 3 of our oncology clinics and they take an active role in contributing to the oncology team, most importantly by being available as a resource, educating the patients and improving the quality of the workflow of the clinic operations, such as escalating any billing issues or precerts, so patients receive what they need in a timely manner.”

The **Enfortumab Vedotin PQI: Management for Advanced or Metastatic Urothelial Carcinoma** provides the medically integrated team with a precise and concise reference document when treating patients with enfortumab vedotin. Griffis and Kranz both view the PQI as a valuable resource to utilize when treating patients with enfortumab vedotin.

Kranz comments “our providers and mid-levels would benefit from using this as a quick and easy guide for trial information and side effects.” Griffis adds, “The tables that address adverse events and dose reductions would be the most helpful to me.” Empowering the team with the tools to effectively educate, counsel and treat oncology patients with advanced or metastatic urothelial carcinoma meets NCODA’s Guiding Values of being Patient-Centered and Always Collaborative.

**WORKING TOGETHER,
WE BECOME STRONGER**



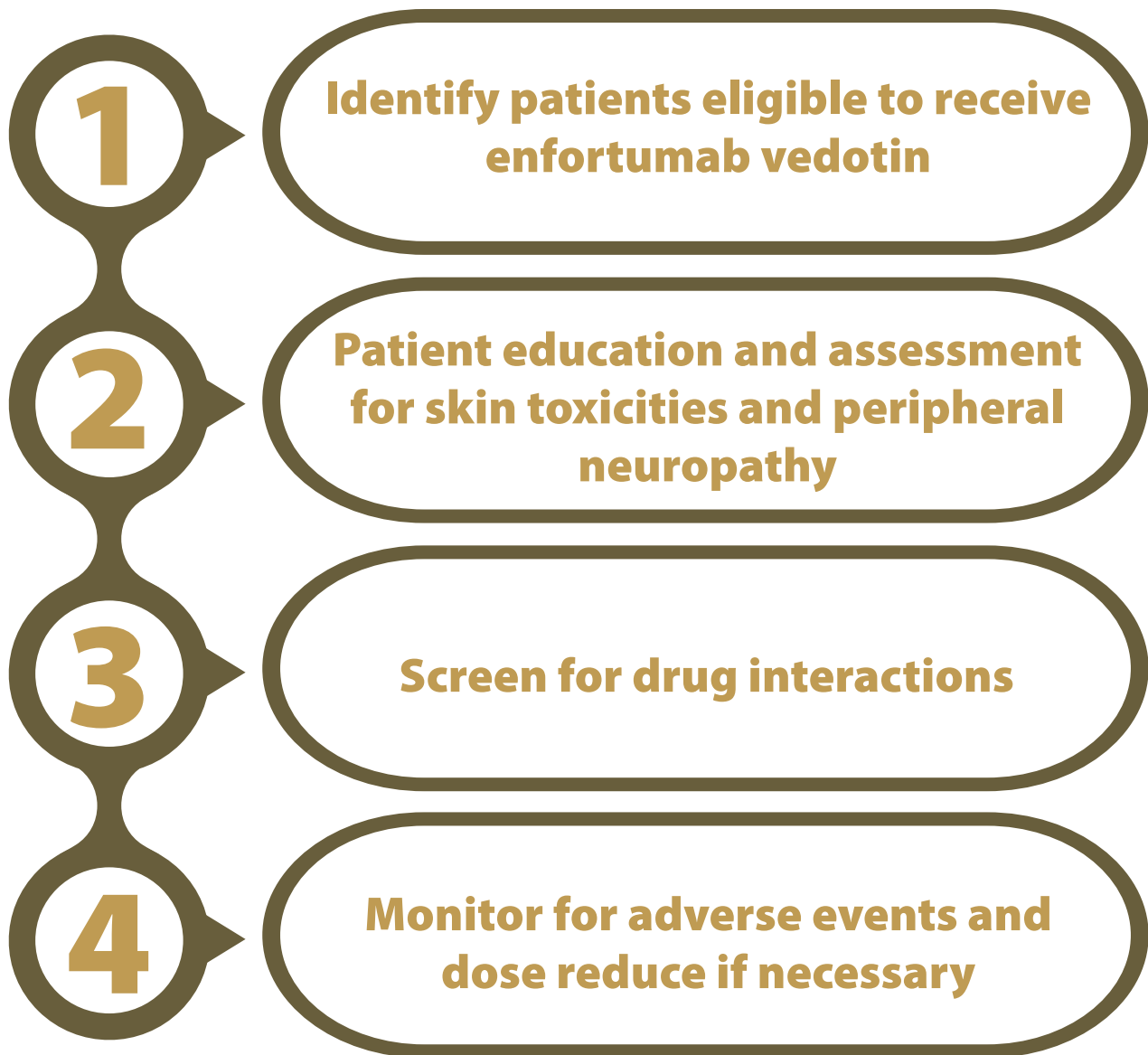
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ON THE COVER:

- Ajaz Khan, MD and Erica Marchese, PharmD, MHA, BCPS, BCOP discuss enfortumab vedotin therapy in clinic.

PQI PRINCIPLES:





Helpful Online Resources

- [NCODA Website](#)
- [Oral Chemotherapy Education Sheets](#)
- [Positive Quality Interventions](#)
- [Enfortumab Vedotin PQI](#)
- [Are you interested in authoring a 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.



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