



Hydration
Station

Tisotumab vedotin-tftv (Tivdak[®]) Management

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 information, and other guidance, PQIs equip the entire multidisciplinary care team with a comprehensive yet concise resource for managing patients receiving oral or IV oncolytics.

This PQI in Action is a follow up to the [Tisotumab vedotin-tftv \(Tivdak®\) Management PQI](#) and explores how the medically integrated teams at Mitchell Cancer Institute and Johns Hopkins collaborate and utilize the information found in the PQI as part of their daily practice. This article will discuss how utilizing the Tisotumab vedotin-tftv (Tivdak®) Management PQI elevates patient care.



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Quality Intervention

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TREATMENT LANDSCAPE FOR CERVICAL CANCER

GLOBALLY cervical cancer is the fourth most common cancer in women.¹ In the United States, cervical cancer is relatively rare, ranking as the 20th most prevalent cancer because of HPV vaccination and effective screening through pap smears.² Almost all cervical cancers are caused by high-risk human papillomaviruses (HPV), making it a mostly preventable and potentially curable disease when diag-

nosed early.^{1,3} Yet, disparities still exist across the cervical cancer care continuum, leading to differences in recurrent or metastatic cervical cancer burden across the US.⁴ Five-year survival rates are 91% for localized cervical cancer and 61% for regional cancer. Once the cancer has metastasized, 5-year survival rates plummet to 19%.²

WHAT THE GUIDELINES SAY

Treatment of recurrent or metastatic

cervical cancer typically consists of chemotherapy with or without bevacizumab. In patients with PD-L1 positive tumors, immunotherapy is preferentially added to this combination. However, patients with disease progression on or following initial treatment have limited treatment options in the subsequent line setting(s) with historically low response rates.⁵

TIVDAK®: INDICATION AND CLINICAL DATA

TIVDAK INDICATIONS, MECHANISM OF ACTION, AND CLINICAL TRIAL DATA

TIVDAK (tisotumab vedotin-tftv) is an antibody-drug conjugate (ADC) indicated for the treatment of patients with recurrent or metastatic cervical cancer that have progressed on or after chemotherapy.⁶ It contains a monoclonal antibody targeted against tissue factor, a protein expressed in large amounts on many solid tumors, including cervical cancer. Tissue factor contributes to cancer-promoting angiogenesis, progression, and metastasis. The monoclonal antibody component is connected to a microtubule-disrupting chemotherapy agent called monomethyl auristatin E (MMAE), which interferes with cell division. Once the monoclonal antibody

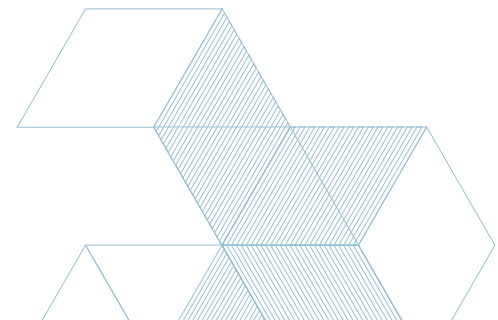
binds to tissue factor, the ADC is internalized into the cell and the MMAE is released, leading to tumor cell death.⁷

Tivdak was approved for recurrent or metastatic cervical cancer in the subsequent line setting based on the results of the innovaTV 301 clinical trial. In this study, patients received either Tivdak monotherapy 2 mg/kg every three weeks or investigator's choice of chemotherapy (topotecan, vinorelbine, gemcitabine, irinotecan, or pemetrexed). After a median follow-up of 10.8 months, the primary outcome of median overall survival was significantly longer in the Tivdak group compared to the chemotherapy group (11.5 mo vs 9.5 mo, $p=0.0038$). Median progression-free survival was extended by about one and a half months (4.2 mo vs 2.9 mo, $p<0.0001$) and objective response rate

was also improved in the Tivdak group compared to chemotherapy (17.8% vs 5.2%, $p<0.0001$). The most common ($\geq 25\%$) adverse events (AEs) included decreased hemoglobin, peripheral neuropathy, conjunctival adverse reactions, nausea, fatigue, AST/ALT increase, epistaxis, alopecia, and hemorrhage. The incidence of grade 3 AEs was less in the Tivdak group compared to the chemotherapy group (52% vs 62.3%).⁸

TIVDAK IN THE NCCN GUIDELINES®

Tivdak is a category 2A NCCN® preferred therapy for second-line or subsequent therapy treatment of locoregional recurrent, stage IVB, or recurrent cervical cancer with distant metastases.⁵



THE MEDICALLY INTEGRATED TEAM AND TIVDAK

TIVDAK is expertly delivered by the Medically Integrated Team, ensuring patients receive comprehensive and coordinated care. The Medically Integrated Team can improve management of patients on therapies like Tivdak in several ways including improved communication, managing regimen changes, quicker therapy initiation, increased patient satisfaction, financial assistance, cost avoidance, and producing less waste.¹⁰

Tivdak has a boxed warning for ocular toxicity, requiring special monitoring and prevention strategies throughout treatment.⁶ In phase I/II studies, 60% of patients with cervical cancer who were treated with Tivdak experienced ocular toxicities like conjunctivitis, dry eye, ulcerative keratitis, blepharitis, and keratitis. It is thought that these eye toxicities are related to expression of tissue factor in the eye.¹¹ The medically integrated team becomes especially critical for medications like Tivdak that require intensive monitoring.

Providers at both Mitchell Cancer Institute and Johns Hopkins say that having a pharmacist adds great value in ensuring patients receive the highest quality care. Mary Lucy Mattei, WHNP-BC, nurse practitioner at Mitchell Cancer Institute emphasizes that “having a pharmacist adds another layer of safety and confidence that we are doing the right thing for the patient.”

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— Mary Lucy Mattei, WHNP-BC, Nurse Practitioner

Amy Brown, RN, nurse manager in the inpatient gynecology unit at Johns Hopkins understands the breadth of medication knowledge that pharmacists can bring to the table. “The

PharmD has such a tremendous amount of knowledge about medicines, because GYN oncology physicians are, in my opinion, surgeons first. With all the new drugs coming out, we rely a lot on that pharmacy piece.”

NCODA offers multiple tools to aid the Medically Integrated Pharmacy (MIP) practice in managing oncolytics. This toolbox contains a Patient Survey that is practice-customizable, a Cost Avoidance and Waste Tracker tool, a Financial Assistance database, Treatment Support Kits, IV Chemotherapy Education sheets, and of course the Positive Quality Intervention clinical resource documents.

THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

BRITTNEY Carden, PharmD, specialty pharmacy manager at Mitchell Cancer Institute comments on the value of the PQI. Although her institution has a whole team dedicated to gynecologic oncology, she thinks the PQI is useful for those practicing in an oncology setting that manages a wide variety

of cancers or who don't have as much support. “For a practice where, medical oncologists are having to manage Tivdak eye toxicities, it could be more difficult because they are not prescribing it as much. The PQI diagram is very helpful and the PQI is an easy resource for them to follow.”

Brown notes that the PQI is useful for

nurses in the inpatient setting, where they don't necessarily give Tivdak, but they see the side effects from many medications that are severe enough to require hospitalization. She says, “I think it is so important that the nurse knows all this information to provide education to the patients. The more information nursing has concerning toxicities, the

The Positive Quality Intervention: a Valuable Clinical Resource - continued

more we can drive home how serious this is. If you say to someone, 'Hey, your eyesight is at risk, your eyesight depends on your complying with this,' this is something that's got to be driven home."

Joyce Hamba, CRNP, nurse practitioner at Johns Hopkins notes that the PQI is also useful because "It compresses everything into less documentation. We

like having the side effects listed and the interventions right next to each without going into the prescribing information online every time."

This article will explore the benefits of PQI utilization as a core standard of the MIP and how adoption can benefit any practice. Mitchell Cancer Institute and Johns Hopkins have each found successful ways to incorporate the PQI

clinical resource. These practices position their Medically Integrated Teams in a way to ensure appropriate treatment, increase compliance, and maximize clinical outcomes. We will explore their practice settings, how implementing the Tisotumab vedotin-tftv (Tivdak®) Management PQI benefits their staff and patients, and how they advance patient care on a daily basis.

MEDICALLY INTEGRATED PHARMACY: ELEVATING CARE

AS cancer treatment continually grows in complexity containing IV, oral and combination regimens, MIP continues to offer an invaluable option for patient care. The MIP and multidisciplinary staff has unparalleled access to patient information and means of direct communication with other members of the team. The pharmacy members of the team also have direct access to communication with patients and can easily report information back to the providers. This model greatly reduces fragmentation of care.

Hamba sums up how an interdisciplinary team improves the experience for their patients by providing comprehensive care for the patient. She shares "we all bring different strengths and different worldviews or medical views to the team. It is the safest way to conduct the complex care that is needed for patients undergoing cancer treatment. Everyone brings something to the table."

Sally Nakla, PharmD, inpatient pharmacist at Mitchell Cancer Institute, notes that having an integrated team improves communication and decreases

wait times for patients at their institution. She says, "The benefit is that we're all under one roof. We can contact whoever we need in terms of if we need to talk to the doctor about labs or if we should hold a drug. We have a messaging system, so we have everything written down. That communication reduces the time the patient has to wait for their drug to be mixed and administered to them."

"We all bring different strengths and different worldviews or medical views to the team. It is the safest way to conduct the complex care that is needed for patients undergoing cancer treatment."

- Joyce Hamba, CRNP, Nurse Practitioner

Putting the Tisotumab vedotin-tftv (Tivdak®) Management PQI INTO ACTION

POSITIVE Quality Interventions (PQIs) are designed to operationalize and standardize practices to achieve positive clinical outcomes. The Tisotumab vedotin-tftv (Tivdak®)

Management PQI is written in sections, beginning with a Description and ending with Patient-Centered Activities and References. Following the description, the background section gives pertinent historical data and information, clinical

trial experience, and the focus of the intervention. Regarding Tivdak, the background discusses Tivdak mechanism of action, FDA approval, and important clinical trial and adverse effect information.

THE PQI PROCESS: SUPPORTING THE PATIENT FOR OPTIMAL CARE

THE next section of the Tisotumab vedotin-tftv (Tivdak®) Management PQI is the PQI Process. This section lays out the intervention in step by step points, contains clinician directed guidance, and critical clinical criteria that can benefit the entire team. The first step of the Tisotumab vedotin-tftv (Tivdak®) Management PQI includes confirming that the patient is an appropriate candidate for Tivdak based on information from the Electronic Medical Record (EMR). Jennifer Pierce, MD, gynecologic oncologist at Mitchell Cancer Institute, highlights important points about the cervical cancer population. She first mentions that it's important to understand where patients are in their treatment journey when they become a candidate for Tivdak. She says "This is a patient who, with the addition of immunotherapy to first line cancer treatment, has up to a 10% chance of cure. It is not high. So now the introduction of Tivdak is on the heels of telling this patient they were not cured, and they will probably be on some type of cancer treatment for the rest of their life, which is now significantly shorter."

She also brings up some factors that likely led to their diagnosis that could impact treatment compliance, especially for a medication like Tivdak. She says, "Cervical cancer patients are unique. There is a component of their interaction with the healthcare system which has resulted in their cervical cancer. You have to remember that 99% of cervical cancer is curable between a combination of vaccination and screening and follow-up of that abnormal screen. And so this is a patient who largely, for many different reasons, whether it's trust, history of trauma, their own interactions with the health system that were negative, or lack of access, resources, etc. has not had those things and therefore ended up with a diagnosis."

Brown agrees that due to Tivdak's ocular toxicities, you have to consider the patient's ability to comply with all the monitoring requirements needed to prevent these toxicities. She says, "You need to have a compliant patient for this treatment." These clinical practice pearls highlight all the more reason to incorporate medically integrated pharmacy to ensure that patients stay compliant with their treatment.

The next step of the process includes ensuring the patient has an eye exam prior to treatment and that eye drop prescriptions have been sent. Tivdak requires eye exams prior to every cycle for the first nine cycles and the use of multiple different types of eye drops (Table 1)⁶. Incorporating ophthalmologists as part of the interdisciplinary team is a key strategy for ensuring optimal patient safety. Pierce says that in addition to counseling patients, she also educates her local ophthalmologists on the ocular toxicity monitoring requirements, including what to look for and how often patients need eye exams. She says, "From there, we let them manage any ophthalmologic side effects higher than grade one." As far as eye drop access, having a medically integrated pharmacy allows practitioners to send patients to pick up their eye drops immediately after they've been counseled on Tivdak side effects. This ensures that the patient is less likely to forget to pick up their prescription and also that they receive another layer of education from the dispensing pharmacist.

The vasoconstrictor and corticosteroid eye drop prescriptions need to be

The PQI Process: Supporting the Patient for Optimal Care- continued

Table 1. Eye Care Requirements⁶

Ophthalmic Exam (visual acuity and slit lamp)	Prior to starting treatment and prior to each dose for the first 9 cycles
Topical corticosteroids eye drops	Administer 1 drop in each eye 10 minutes prior to infusion and continue for additional 2 times at home on day 1. Continue 1 drop per eye 3x per day on days 2 and 3 after infusion as well.
Topical ocular vasoconstrictor eye drops	Administer 3 drops in each eye 10 minutes prior to infusion.
Topical lubricating eye drops	Administer in each eye daily for the duration of therapy and for 30 days after the last dose of therapy. However, eye care providers may prescribe different frequency of lubricating eye drops due to baseline eye exam.
Cooling eye packs/pads	Start cooling the eyes ~10 mins prior to infusion and continuing for a total of 60 minutes. Rotate cooling pads as needed.
Contact Lens	Patients should be instructed to avoid wearing contact lenses throughout therapy.

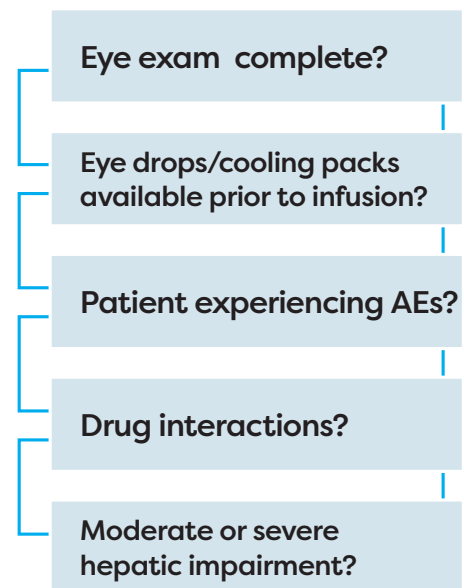
administered 10 minutes prior to each Tivdak infusion. The next step of the PQI process includes checking with the nurse that the patient has brought all eye drops into the clinic. Similar to a pre-medication for nausea, the eye drops are included in the EMR treatment plan at both Mitchell Cancer Institute and Johns Hopkins to ensure that the nurse is able to witness and document administration prior to the infusion. Carden explains how a MIP can additionally prevent delays in Tivdak treatment, “It is so convenient. Even today, two patients didn’t have their steroid drops and were able to come here and pick them up. Their treatment was not delayed.”

Another important part of this step includes ensuring that cooling patches or pads are available in the clinic as these packs must be placed on the eyes 10 minutes prior and for the 60-minute duration of the Tivdak infusion. Nakla mentions that nurses are responsible, but infusion pharmacists can reinforce

this piece by checking in with them prior to dispensing the medication. “We make sure that is something that is happening because we do have a lot of new nurses. We are also constantly educating.”

The next steps include reviewing the order for any necessary dose adjustments, looking for drug interactions, avoiding use of Tivdak in moderate or severe hepatic impairment, and reviewing for adverse events (AEs) and any necessary AE management. Sheetal Patil, PharmD, clinical oncology pharmacist at Johns Hopkins, highlights the importance of how pharmacists can best support the medically integrated team. “Drug-drug interactions are my biggest key. Holistically, I think some of our team members may not be considering what other drugs are playing a factor into an adverse effect.” Outside of the first bullet, each part of the PQI process needs to be revisited with every dose of Tivdak (Figure 1).

Figure 1. PQI Process for Tivdak



PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

THE Patient-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. The Tisotumab vedotin-tftv (Tivdak®) Management PQI Patient-Centered Activities suggests providing the patient with an IV Chemotherapy Education (IVE) sheet. IVE sheets are an NCODA-led initiative that provide information about IV chemotherapy drugs and their side effects to both cancer patients and caregivers. In 2019 the Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards were published to provide standards for medically integrated dispensing of oral anticancer drugs and supportive care medications.¹² Standard 1.2 of the ASCO/NCODA Standards reads:

Prior to initiation of an oral anticancer drug, a formalized patient education session should occur with an experienced clinical educator such as a nurse, physician, pharmacist, nurse practitioner, or physician assistant. The discussion should include drug name (generic and brand), drug dose, schedule, potential adverse effects and how to properly manage them, fertility (where applicable), treatment goal, duration of therapy, and financial and affordability considerations.¹²

Although these standards were published with oral therapies in mind, the main principles of education also apply to IV therapies, especially when more involved monitoring is needed.

The next steps include educating the patient on how to administer the eye drops, providing a checklist for patients to remind them about the dosing of their eye drops, and ensuring that the

patients understand the importance of eye exams and reporting problems with their eyes. The patient-centered activities section also includes a bullet that suggests providing the patient with the Eye Care Guide for Patients from the [Tivdak website](#).¹³ This resource includes important information about eye exams, a helpful table for when to use the eye drops, and a calendar to help patients track eye drop administration. Hamba likes this resource because it helps her go through the checklist of potential side effects. She says, “These are relatively new drugs and I want to make sure that I’m not missing anything.” She says that most of her patients are very compliant with taking care of their eyes while on Tivdak, noting “a lot of our patients understand that most tissues can regenerate, for example if you have a dermatologic tissue, your skin can regenerate. But with the eyes, you must be very vigilant. I have not met any patient who either misses their ophthalmology appointments or who does not follow the very stringent instructions.”

Mattei also likes to print the Eye Care Guide for Patients from the Tivdak website when educating patients. She notes that at Mitchell Cancer Institute, the patient is often educated multiple times on eye care. Her initial visit reviews important eye care education. She says, “Patients usually receive double education from Brittney and me. The ophthalmologists are educating them as well.”

Brown agrees that repetition is key to driving these educational points home. She says, “Medication compliance is huge and often it is a matter of education. Patients need to hear things ten times, ten different ways. If you can have a pharmacist explain it, even

better.”

Eye toxicities are not the only potential side effects of Tivdak. The next step in the Patient-Centered Activities discusses educating patients on adverse events that should be reported to the care team and when to reach out. Both Mattei and Pierce mentioned that they

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– Amy Brown, RN

were surprised at the type and severity of neuropathy that Tivdak can cause. Pierce says, “I think the big one that flew under the radar for me was neuropathy. This is motor and sensory and has real implications for people’s mobility and independence. If someone lives in a trailer or camper, there is a real issue with them needing to be in a wheelchair.”

Rashes, mouth ulcers, nose bleeds, and hair loss are other adverse events that providers at Mitchell Cancer Institute encounter with Tivdak. Mattei noted that one patient experienced a sunburn-like rash on her face, in the areas where the ice packs were not placed during the infusion. With the next infusion, they had the patient place ice on the area that had developed redness previously and it did not return. It is im-

Patient-Centered Activities: Keeping the Focus on Patients - continued

portant to note that severe cutaneous reactions, including severe or life-threatening Stevens-Johnson syndrome can occur with Tivdak.¹⁴

Mattei closely follows her patients, which helps her improve her education visits in the future. “You can educate on potential side effects all day long, but not fully understand until you see it. It is helpful to see these patients each cycle,

so we know what is happening. We are trying to intervene ahead of time. I can tell them with confidence “this is absolutely going to happen.” She has also learned little tricks to help manage side effects. For example, nosebleeds occurred in up to 33% of patients in Tivdak clinical trials.¹⁵ Mattei says that covering the bridge of the nose with ice packs (in addition to the eyes) helps prevent these nosebleeds in her patients.

The last steps of the patient-centered activities include encouraging the patient to notify the team of any new medications started by outside providers and to advise females of reproductive potential to use adequate contraception.

FINANCIAL ASSISTANCE: A BENEFIT OF MIP AND THE MULTIDISCIPLINARY TEAM

In addition to close follow up and detailed education, MIP renders the practice able to provide excellent customer service, unmatched patient care, and help with finding funding so the patient can afford to receive the medication.

Pierce notes that medication affordability is a real barrier to compliance in her area of the country and highlights how a MIP pharmacy can help overcome this. “Our pharmacy is very well capacitated to help patients interact with and achieve patient assistance programs and gain access to medications that they otherwise would find very cost prohibitive. Patient affordability, especially in lower Alabama, is the number one cause of noncompliance.”

Although the retail specialty pharmacy is geared towards financial assistance related to oral medications, Nakla notes that the infusion pharmacy plays a large role in ensuring that the patient receives timely infusions when receiving free medication through patient assistance. She says, “We keep up with it. That way if a patient comes in, we always have the drug in house. We have it shipped prior to the patient coming so they are not delayed in therapy, and that involves our financial services, our technicians out in the front.”

Patil mentions that at Johns Hopkins, “we are doing a lot of double checks throughout multiple points of the drug use process.” The many layers of dou-

ble checks not only ensure medication safety, but also prevent expensive medication waste. This includes pharmacist review of the order for accuracy at two points in the process, nurse assessment of the patient prior to treatment, three separate pharmacist checks during the medication preparation, and barcode scanning of the orders to ensure that medications are made correctly and received safely. She says, “we have manual eyes as well as digital tools to help us with that.” Medically Integrated Pharmacies can play a key role in ensuring the patient receives timely and affordable access to medications regardless of whether its administered IV or oral.

“Our pharmacy is very well capacitated to help patients interact with and achieve patient assistance programs and gain access to medications that they otherwise would find very cost prohibitive. Patient affordability, especially in lower Alabama, is the number one cause of noncompliance.”

- Jennifer Pierce, MD, MPH, FACOG

CONCLUSION: NCODA, THE MIP AND PQI: OPTIMIZING PATIENT OUTCOMES

ALL team members agree that the MIP model and the PQI Clinical Resource are valuable to the team and to patients. Every day the MIP team can make a difference in the life of patients.

The team can continually learn something new or can begin a process that optimizes care. The PQI fosters this through appropriate patient identification, selection, increased speed to therapy, reduced cost, and hospitalization.

The ultimate goal of the PQI is to ensure that medications reach our patients in the most effective and safest way. Je-vaugh Anderson, CPhT, pharmacy technician at Johns Hopkins sums it up best when describing his number one priority in preparing medications for patients. “There is a face behind the label. This is someone’s life I am impacting; safety is 100% important.”

The PQI provides the MIP program with an easy to use, compact clinical resource guide when discovering the right

patient and dispensing Tivdak. It helps the team ensure they are providing patients with the tools and education to improve clinical outcomes. Pairing Medically Integrated Pharmacy with the Tisotumab vedotin-tftv (Tivdak) Management PQI meets NCODA’s Guiding Values of being Patient-Centered and Always Collaborative.

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

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