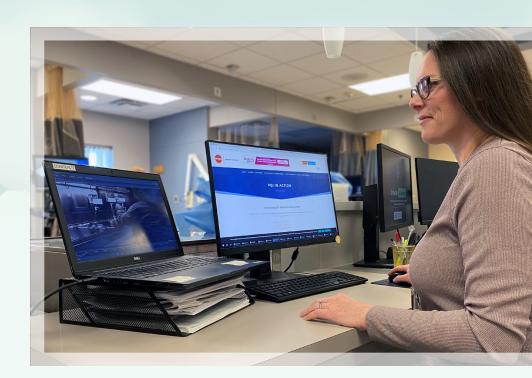
PQI IN ACTION



SACITUZUMAB GOVITECAN (TRODELVY®): MANAGEMENT OF NEUTROPENIA AND DIARRHEA



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 Sacituzumab govitecan (TRODELVY®): Management of Neutropenia and Diarrhea PQI and explores how the medically integrated teams at New England Cancer Specialists and Lake Regional Health System incorporate the information found in the PQIs as part of their daily workflow. This article will discuss how utilizing the Sacituzumab govitecan (TRODELVY®): Management of Neutropenia and Diarrhea PQI elevates patient care.

New England Cancer Specialists (NECS) is a private medical group practice with four offices in Maine and New Hampshire. NECS's oncologists and hematologists represent nearly 50% of the cancer specialists in Maine. Because they are a private entity, they are able to work with any hospital or primary care physician in the country. Their long-standing partnership with the Dana-Farber Cancer Institute provides patients with a dual advantage - access to the latest clinical trials and treatment advancements while still being able to receive care in their own neighborhood. NECS operates under the Oncology Medical Home model, so patients have access to comprehensive in-house services such as imaging, financial support, specialty pharmacy and much more right within the practice. NECS is an ASCO Quality Oncology Practice Initiative (QOPI)-certified practice, meaning patients can be assured they are receiving the highest quality of cancer care.

Lake Regional Health System's Cancer Center provides state-of-the-art services to patients throughout the Lake of the Ozarks region in southern Missouri. Personalized treatment plans and supportive care services such as cancer navigators, nutrition support, and the availability of oncology resources support patients from diagnosis to survivorship. Lake Regional Cancer Center is accredited by the Community Hospital Cancer Program from the Commission on Cancer of the American College of Surgeons. This commendation assures patients that Lake Regional Health System Cancer Center is providing the best in cancer diagnosis and treatment.



THE PARTICIPANTS

MIP, THE PQI, AND SACITUZUMAB GOVITECAN: PROACTIVE MANAGEMENT OF COMMON SIDE EFFECTS TO IMPROVE OUTCOMES

acituzumab govitecan is an antibody drug conjugate (ADC) indicated for multiple cancers, including locally advanced or metastatic urothelial cancer, triple negative breast cancer, and hormone receptor (HR)-positive, HER2-negative breast cancer.¹ All ADCs combine a targeted monoclonal antibody with a cytotoxic drug to allow for more selective, tumor-directed treatment.² Sacituzumab govitecan's monoclonal antibody portion targets Trop-2, a protein that's overexpressed in most epithelial cancer cells. Trop-2 is found in high amounts in both urothelial and breast cancers.³ The attached cytotoxic drug (or payload) is SN-38, a topoisomerase inhibitor derived from irinotecan. Once sacituzumab binds to Trop-2, sacituzumab is internalized and the cytotoxic SN-38 payload is delivered to the tumor. This allows for much more efficient delivery of the medication to the tumor, but sacituzumab govitecan can still affect healthy bystander cells as well.² This results in sacituzumab govitecan's well known side effect profile.

The most common side effects that lead to sacituzumab govitecan dose reduction or discontinuation include neutropenia (64% all grades, 49% grade 3-4), diarrhea (64% all grades, 11% grade 3-4), and nausea/vomiting (64% all grade, 3% grade 3-4). Sacituzumab govitecan also holds a boxed warning for severe or life-threatening neutropenia or diarrhea.¹ Proactive management of these side effects can prevent early discontinuation of sacituzumab govitecan.⁴

Amanda Magnoli, ANP-BC, AOCNP, Nurse Practitioner at NECS notes that although side effects such as diarrhea, neutropenia, and fatigue do occur, they have been able to manage them proactively. "We have not really had anyone report that they had to be evaluated urgently due to acute side effects. I think it just goes to show how well we are managing patients up front with appropriate premeds and giving them the tools at home to use to manage their side effects and Janna, our team nurse, completes a lot of education with them."

Sacituzumab govitecan can be dispensed by the Medically Integrated Team, and thus offers patients more comprehensive care. Both New England Cancer Specialists (NECS) and Lake Regional Health System mainly use sacituzumab govitecan for breast cancer. Yoni Resnick, PharmD, clinical pharmacist at New England Cancer Specialists says the breakdown of sacituzumab govitecan usage in their practice is "about three quarters in the breast cancer space and one quarter in the bladder, urothelial carcinoma space." Dr. Shahid Waheed, MD, FACP, medical oncologist at Lake Regional Health System says, "mainly what I have used this for is breast cancer."

Triple negative breast cancer (TNBC) is a characteristically more aggressive breast cancer type and Black women are dis-

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Amanda Magnoli, ANP-BC, AOCNP

proportionately affected by it. Black women are twice as likely to be diagnosed with TNBC and 30% more likely to die from it due to lower rates of surgery and chemotherapy.7 Several factors contribute to these disparities including diagnosis at a more advanced stage and lower access to quality care, among others.^{7,8} In a sub-analysis of the ASCENT study, patients who self-identified as Black experienced efficacy and safety outcomes consistent with those observed in the overall ASCENT study population.9,10 The benefits typically offered by the Medically Integrated Team model could extend to mitigation of inequities in access to high-quality cancer.¹¹ Resnick notes that community oncology practices can provide that same level of care that academic cancer centers provide, but at a more convenient location. He says, "our practice is fiercely proud of our community roots and view the community practice of oncology as the lower cost, higher quality site of care for patients, given the choice." Targeting inequities in access to care would allow those that have historically experienced healthcare disparities

to retain clinical outcomes closer to those seen in controlled clinical trials.

NCODA offers multiple tools to aid the Medically Integrated Team in managing oncolytics. This toolbox contains a Patient Survey that is practice-customizable, a Financial Assistance database, Treatment Support Kits, IV Chemotherapy Education sheets, and of course the Positive Quality Intervention clinical resource.

THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

anna Dyer, RN, Nurse at NECS comments on the value of the PQI. "We do utilize it in our practice. It is helpful in terms of following up on treatment-related decisions and being able to look at that, and especially knowing what the plan is going to be going

forward with the neutropenia or diarrhea. So being able to refer back to this for up-to-date clinical information is really important. And it gives us more guidance without having to always bother our clinical pharmacist or nurse practitioner."

CLICK HERE TO VIEW PQI

Even though they haven't needed to

dose reduce sacituzumab govitecan for side effects yet, Kristen Eblen, PharmD, clinical pharmacist at Lake Regional

"IT IS HELPFUL IN TERMS OF FOLLOWING UP ON TREATMENT-RELATED DECISIONS AND BEING ABLE TO LOOK AT THAT, AND ESPECIALLY KNOWING WHAT THE PLAN IS GOING TO BE GOING FORWARD WITH THE NEUTROPENIA OR DIARRHEA. SO BEING ABLE TO REFER BACK TO THIS FOR UP-TO-DATE CLINICAL INFORMATION IS REALLY IMPORTANT. AND IT GIVES US MORE GUIDANCE WITHOUT HAVING TO ALWAYS BOTHER OUR CLINICAL PHARMACIST OR NURSE PRACTITIONER."

Janna Dyer, RN



Lake Regional Health System provides excellent multidisciplinary care to patients.

Health System especially likes the PQI for this purpose. She says, "We have never had to dose reduce, but I love the PQI for what to do when we need to dose reduce, so I will refer to that when it comes up. We have been lucky so far." She mentions that they are excited to incorporate the PQI as a resource, "especially the sections on neutropenia, the ANC cut-offs, and dosage adjustments."

This article will explore the benefits of PQI utilization as a core standard of the MIP and how adoption can benefit any practice. New England Cancer Specialists and Lake Regional Health System 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 tolerability, and maximize clinical outcomes. We will explore their practice settings, how implementing the **Sacituzumab govitecan (TRO-DELVY®): Management of Neutropenia and Diarrhea PQI** benefits their staff and patients, and how they advance patient care on a daily basis.

MEDICALLY INTEGRATED PHARMACY: ELEVATING CARE

s 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.

Both NECS and Lake Regional Health System have IV clean rooms on-site with experienced pharmacy technicians mixing both hazardous and non-hazardous medications for the team's patients. Resnick mentions that having a pharmacy presence on-site ensures consistency and safety, including compliance with pharmacy regulations like USP 797 and 800. He notes, "if we didn't have a pharmacy presence who were knowledgeable and capable, those kinds of things would fall by the wayside." He also mentions the vital role that pharmacy technicians play in balancing inventory management with timely care. He says, "our technicians order all the drugs on a daily basis. It's an incredible responsibility that they have to make sure that the drug is in stock for patients for the next one, two, or three days, but at the same time, find that balance of not having too much on the shelf. And knowing which drugs are more common that they can order more often, which drugs are rare that they should wait to order until the last possible minute. To ensure we are not sitting on medication that's going to go unused for some kind of lesser used drugs. So it's critical for everybody's experience in the clinic, both patients and staff, to have a robust high quality group of pharmacy technicians in a compliant intravenous room setting to do that role within the practice."

Providers and nurses alike find great value in having a clinical pharmacist integrated within their team. At NECS, Magnoli highlights the numerous ways that pharmacists contribute by saying, "having a pharmacist involved in patient care ensures that the quality of care that's given in our clinic is consistent and safe and is in accordance with all our national guidelines. Yoni and our other pharmacists give us data-driven information so that we can make evidence-based treatment options for the management of different diseases, and how to manage different adverse reactions and symptoms from the cytotoxic drugs that we give. They also play a key role in educating our providers, nurses, patients, and caregivers on multiple levels. And he really plays a critical part in developing institutional guidelines and practice-based decisions. That's a key thing. And I think on a day to day basis, our pharmacists are involved in all aspects of a patient's care. From the recommendations that are made in in the office pre- and post-treatment, and at the chairside in our infusion room, in policymaking and practice improvement. And the pharmacists really know the safety, efficacy and also importantly, the financial and pharmacological effects of each drug that we give, and not having a pharmacist involved in patient care is just not great care. It's really important."

Dyer echoes this sentiment by saying, "Having a clinical pharmacist on staff for us, you can't put a price tag on that. It's the safest thing for the patients and for the healthcare team."

At Lake Regional Health System, Eblen says that having an integrated pharmacy has really cut down on wait times for patients. "Now that there is a pharmacist down here in the cancer center, that person is talking with the patients about their home medications, running interactions with their new chemo versus what they're on at home. We're double checking the doses, cross-referencing the NCCN guidelines, and we're able to build the order sets down here." This provides a level of reassurance for the rest of the team. When asked about the biggest value of the medically-integrated pharmacist, Eblen says, "I would say provider and nurse comfort level. They're just more confident that the order sets are correct. One of them told me a few months ago, 'It helps me sleep at night, knowing that you're down here confirming everything'."

"THEY'RE [PROVIDERS AND NURSES] JUST MORE CONFIDENT THAT THE ORDER SETS ARE CORRECT. ONE OF THEM TOLD ME A FEW MONTHS AGO, 'IT HELPS ME SLEEP AT NIGHT, KNOWING THAT YOU'RE DOWN HERE CONFIRMING EVERYTHING!"

Kristen Eblen, PharmD

PUTTING THE SACITUZUMAB GOVITECAN (TRODELVY®): MANAGEMENT OF NEUTROPENIA AND DIARRHEA PQI INTO ACTION

he PQI is a peer-reviewed clinical guidance document that provides Quality Standards and effective practices around a specific aspect of cancer care. The Medically Integrated Pharmacy team is in a unique position to ensure appropriate treatment, improve tolerability, and maximize clinical outcomes. Positive Quality Interventions (PQIs), an NCODA Quality Standard, are designed to operationalize and standardize those practices to achieve these positive clinical outcomes. The **Sacituzumab govitecan (TRODELVY®): Management of Neutropenia and Diarrhea 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 main focus of the intervention. Regarding sacituzumab govitecan, the background discusses mechanism of action, common side effects leading to dose reduction or discontinuation, and genetic variations that increase side effect risk.⁴

Kerri Roettgen, RN, Infusion Nurse at Lake Regional Health System loves having a pharmacist directly in the infusion center to provide guidance and education on medications like sactizumab govitecan. "Kristen [Lake Regional Health System's pharmacist] adds so much to our team. If we have any questions, she's available to us all the time. She educates us and the patients so we know what to expect. What order to give medications, what to watch for. She's invaluable. It's like a safety net." Roettgen said her favorite parts include, "what to look for, like how often they're having nausea, vomiting, diarrhea, when to dose reduce or discontinue treatment, that is very helpful. And how to manage side effects."

"KRISTEN [LAKE REGIONAL HEALTH SYSTEM'S PHARMACIST] ADDS SO MUCH TO OUR TEAM. IF WE HAVE ANY QUESTIONS, SHE'S AVAILABLE TO US ALL THE TIME. SHE EDUCATES US AND THE PATIENTS SO WE KNOW WHAT TO EXPECT. WHAT ORDER TO GIVE MEDICATIONS, WHAT TO WATCH FOR. SHE'S INVALUABLE. IT'S LIKE A SAFETY NET."

Kerri Roettgen, RN

PQI PROCESS

he next section of the Sacituzumab govitecan (TRODELVY®): Management of Neutropenia and Diarrhea 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 Sacituzumab govitecan (TRODEL-VY®): Management of Neutropenia and Diarrhea PQI mentions UGT1A1 testing. UGT1A1 testing is not required prior to sacituzumab govitecan administration.⁴ It's not common for institutions, including NECS and Lake Regional Health System, to order this test up front. The next step of the PQI includes many steps to take for the prevention and management of neutropenia. These steps include important information about lab monitoring, ANC cut-offs, guidance for GCSF use, and alternative approaches to managing neutropenia.

Both providers at NECS and Lake Regional Health System use growth factor as secondary prophylaxis if a patient's therapy is delayed due to neutropenia. Magnoli says, "for neutropenia, we normally can give growth factor on day eight, if they've proved to not be able to hold up their counts to 1,500 /mm³ or higher ANC on day one or 1,000/mm³ or higher on day eight. We could also use a short-acting growth factor given at multiple day injections to get their counts up to par." When asked about Lake Regional Health System's strategy for managing neutropenia, Waheed says, "we use standard drugs for neutropenia, we have short-acting or long-acting white cell growth factors. Now there are a lot of biosimilars, so it depends upon what contract we have in the pharmacy." Eblen adds that they use "exclusively biosimilars for pegfilgrastim unless insurance dictates that a specific product needs to be used. In cases that pegfilgrastim wasn't approved by insurance, we would try for filgrastim for three days."

Magnoli mentions that in addition to growth factor, they

also use the dose reduction recommendations for neutropenia based on the sacituzumab govitecan package insert and PQI. She says, "I don't believe we've had to discontinue the drug permanently because of unmanageable side effects with TRODELVY®. We've really done some dose modification and heavy supportive care."

The last step of the PQI Process includes numerous options for the prevention and management of diarrhea. Important bullets include appropriate use of antidiarrheals, management of cholinergic reactions, and dietary interventions for diarrhea. The PQI incorporates a useful dose adjustment table for grade 3 or 4 diarrhea:

Neutropenia Grade	Occurrence	Dose Modification
Grade 4 Neutropenia > 7 days	First	25% dose-reduction
OR		Administer GCSF
Grade 3-4 Neutropenia	Second	50% dose-reduction
OR		Administer GCSF
At time of scheduled treatment, Grade 3-4 neutropenia which	Third	Discontinue treatment
delays dosing by 2-3 weeks for recovery to Grade < 1		Administer GCSF
At time of scheduled treatment	First	Discontinue treatment
Grade 3-4 neutropenia which delays dosing beyond 3 weeks for recovery to Grade < 1		Administer GCSF

Nonhematologic toxicity:	Occurrence	Dose Modification
Grade 4 non-hematologic toxicity of any duration OR	First	25% dose-reduction
Any Grade 3-4 nausea, vomiting or diarrhea due to treatment		
that is not controlled with anti-emetics and antidiarrheal agents OR	Second 50%	50% dose-reduction
Other Grade 3-4 non hematologic toxicity persisting > 48 hours despite optimal medical management OR	Third	Discontinue treatment
At time of scheduled treatment, Grade 3-4 nonneutropenic he- matologic or non-hematologic toxicity, which delays dose by 2-3 weeks for recovery to Grade < 1		
In the event of Grade 3-4 non-neutropenic hematologic or non-hematologic toxicity, which does not recover within 3 weeks to Grade < 1	First	Discontinue treatment

NECS uses a variety of these strategies in their practice to keep patients on track with their treatment. Magnoli says, "For diarrhea, we usually initially manage with loperamide, but if not effective, we can add a transition out to diphenoxylate/atropine plus or minus colestipol and if refractory

to those drug regimens, we could treat with octreotide. In my clinical experience with using TRODELVY®, I have not had to use octreotide for diarrhea. Our patients haven't had that much diarrhea. And obviously, if they have anticholinergic effects with cycle one, then we would add in atropine to the premedications. But again, we haven't had to do that." She emphasizes that atropine isn't a standard premedication used upfront and "we only add in atropine if the cholinergic effects were exhibited."

Lake Regional Health System has not had too many issues with sacituzumab govitecan-induced diarrhea yet, but they use a similar approach when treating diarrhea. They use "Mostly Imodium[®]. Sometimes Lomotil[®] if it's severe. And sometimes we do use atropine," says Waheed. Eblen agrees. She says, "that's our step therapy. Loperamide at home or here if needed, and atropine after that."

Octreotide is often an inconvenient option for patients because it requires the patient to self-inject the medication

multiple times a day.¹² Resnick offers a potential solution that can increase patient convenience. "We've reached for octreotide, but not in a short-acting three times a day subcutaneous fashion, but rather a long-acting release (LAR). We've had really good success with it in terms of efficacy, but also kind of equally important from an operational standpoint, insurance authorization." He notes that while they haven't had to use this for sacituzumab govitecan yet, it's been helpful for other medications that have caused chemotherapy-induced diarrhea. Although data for the use of octreotide LAR in chemotherapy-induced diarrhea is still evolving, monthly injections may offer an alternative for patients who can't or won't do the more frequent injections.

PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

he Sacituzumab govitecan (TRODELVY®): Management of Neutropenia and Diarrhea PQI Patent-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. The Patient Centered Activities suggests providing the patient with an Intravenous Chemotherapy Education (IVE) sheet. IVE sheets

CLICK HERE TO VIEW OCE SHEET

are NCODA-led initiatives that provide information about IV chemotherapy and targeted therapy 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.¹³ 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.¹³

These standards also extend to IV therapies where many of



Both NECS and Lake Regional Health System provide standard pre-medications prior to each infusion as per the sacituzumab govitecan package insert, with no major issues noted for either nausea or infusion reactions.

components of MIP can help prevent premature discontinuation of sacituzumab govitecan due to side effects.

Patient-centered activities in the PQI also touch on the importance of making sure that the patient is well equipped for side effect management. These activities include ensuring the patient has appropriate antidiarrheals and nausea medications available, empowering the patient to manage side effects as they arise, and discussing red flags that warrant calling the clinic.

Nursing education and an established monitoring plan helps NECS stay on top of side effects that may arise early in treatment. Dyer says that each patient "recieves a phone call after cycle 1, day 1 to check in and make sure they are feeling ok. They always have direct access to the nursing triage. They come in on day 8 for their infusion as well. They know the side effects to look out for. We give them a lot of education on that, especially in terms of neutropenia. Our patients contact us frequently, they don't have a problem reaching out. So I'd say the biggest thing is having open communication with them and knowing our number and how to reach us."

Lake Regional Health System has a similar method for catching side effects before they become a problem. Waheed says, "the infusion nurse who was in charge of infusing the sacituzumab govitecan gives them a call the next day to make sure that they are doing ok, are there any symptoms, etc. If there are any issues, then we have navigators. We have a breast navigator, lung navigator, etc. The navigators can coordinate the management of any side effects, either with me, or with one of the PAs or NPs." Roettgen also emphasizes the importance of keeping the line of communication open with patients. She says, "they always have our phone number. business hours, and they have an after-hours number. And we give them a list of things to look out for, such as fever, diarrhea, and nausea. If it's more than 12 to 24 hours, call us. Dizziness, just not feeling themselves, we always have them call."

More subjective side effects like fatigue can be more difficult to manage. Dyer says, "I would say one of the things that as a nurse is hardest to manage is the fatigue from people because there is not a lot that we can do other than rest, but also light exercise, keep moving. So I think that might be nursing-wise one of the hardest side effects that people have to manage because a lot of times we are in the metastatic setting and you're on chronic treatment and it's one of those side effects that there is not a great answer for." Magnoli jumps in to say, "we also use our inner community, the physical therapy (PT) offices, to help with fatigue as well. We have different PT programs that are specifically designed for cancer patients undergoing treatment or post-treatment, kind of this cancer rehab, pre-hab. Just this general maintenance so they don't become deconditioned."

Sacituzumab govitecan can also cause infusion reactions and nausea. With a 35% incidence of all-grade hypersensitivity/ infusion-related reactions and a high emetogenicity, it's important to use appropriate pre-medications.^{1,14} Both NECS and Lake Regional Health System provide standard premedications prior to each infusion as per the sacituzumab govitecan package insert, with no major issues noted for either nausea or infusion reactions. It's common for institutions to use diphenhydramine as the standard H1-blocker to prevent infusion reactions, but this can cause significant sedation, especially in the elderly population. At NECS, Resnick made a move to swap out the sedating first-generation H1-blockers for the less sedating, second generation H1-blockers. He says, "something that we instituted a couple years ago is that we don't do any intravenous diphenhydramine any longer for premedication for drugs that require H1-blockade for prevention of infusion reactions. We've transitioned entirely to the use of oral non-sedating H1-blockade, so we use cetirizine 10 mg. This was one of the first big clinical changes that I instituted when I got to NECS a bunch of years ago and it has gone smooth."

COST CONTAINMENT: A BENEFIT OF MIP AND THE MULTIDISCIPLINARY TEAM

n 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 the medication.

CLICK HERE TO VIEW FINANCIAL ASSISTANCE TOOL Patients may be eligible to use the TRODELVY[®] Savings Program and NCODA offers a Financial Assistance Tool for members that links to available resources.

NECS and Lake Regional Health System both make efforts to contain medication-related costs, which ultimately saves the institution and patient money. Proper preparation, administration and staff education on both is important to eliminate waste. The Medically Integrated Pharmacy is in an ideal position to provide this proper technique and staff education. Resnick mentions an important point when mixing sacituzumab govitecan. "The vials say that they have 180 mg in them and the reconstitution instructions say to reconstitute that powder with 20 mL to create a 10 mg/mL solution because that means there is actually 200 mg in the vial and not 180 mg like the vial says". Each vial contains overfill to compensate for liquid loss during preparation and after reconstitution, the total resulting volume delivers a concentration of 10 mg/mL.¹⁰ "I would just emphasize making anyone who is preparing the drug aware of that. Attention to that little detail is important to avoid any billing, dosing, or preparation concerns."

Another way to minimize medication waste is to ensure good technique in reconstituting sacituzumab govitecan. Gale Nations, CPhT, Pharmacy Technician at Lake Regional Health System offers her expertise by mentioning that you should "inject your diluent in slowly because once it foams, it can take a while for it to settle down. And it is really hard to dilute if it is sitting in foam because it likes to stay in that foam. And it won't be in the diluent, so just be careful with that." She notes it can take up to 30 minutes to make sacituzumab govitecan, so ensuring proper technique helps prevent treatment delays and potential medication waste.



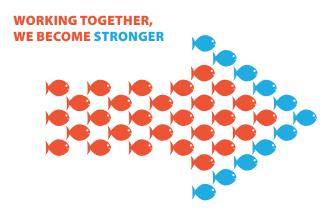
CONCLUSION: NCODA, THE MIP AND PQI: OPTIMIZING PATIENT OUTCOMES

Il 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.

PQI in Action articles like this one are also a valuable way to share knowledge and improve care. Waheed notes the importance of providing resources that highlight other institution's practices so that they can continue to evolve and grow. When asked about resources that would be helpful, he says to NCO-DA, "if you have any template with other practices that are doing something different than what I have talked about it, we can implement those here also."

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 and by improving strategies to enhance tolerability for the patient and their Medically Integrated Teams.

Resnick emphasizes, "we do everything that we do within the practice with the goal of patient care in mind, using the available resources that are out there to promote that quality." The PQI provides the medically integrated team program with an easy to use, compact clinical resource guide when discovering the right patient and dispensing sacituzumab govitecan. It helps the team ensure they are providing patients with the tools and education to improve clinical outcomes. Pairing Medically Integrated Pharmacy with the **Sacituzumab govitecan (TRODELVY®): Management of Neutropenia and Diarrhea PQI** meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.



REFERENCES

- Trodelvy [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2023. https://www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy_trodelvy_pi.pdf.
- Pandey P, Gogia A. Sacituzumab govitecan: A narrative drug review. Cancer Res Stat Treat. 2023;6(4):562. doi:10.4103/crst.crst_290_23.
- Sakach E, Sacks R, Kalinsky K. Trop-2 as a Therapeutic Target in Breast Cancer. Cancers. 2022;14(23):5936. doi:10.3390/cancers14235936.
- Martin, Rebecca. Positive Quality Intervention: Sacituzumab govitecan (Trodelvy): Management of Neutropenia and Diarrhea. Accessed January 18, 2024. https://www.ncoda.org/wp-content/uploads/pqis/ Sacituzumab-govitecan-Trodelvy%C2%AE-Management-of-Neutropenia-and-Diarrhea_PQI_NCODA.pdf.
- Eno V. NCODA Announces the defining of the Medically Integrated Dispensing Pharmacy. NCODA. Published January 27, 2020. Accessed October 23, 2023. https://www.ncoda.org/medically-integrated-dispensing-pharmacy/.
- Wimbiscus B. Medically Integrated Dispensing: An Alternative to How Oral Drugs Get Dispensed. AJMC. Published March 14, 2019. Accessed October 23, 2023. https://www.ajmc.com/view/medically-integrated-dispensing-an-alternative-to-how-oral-drugs-get-dispensed.
- 2022 Cancer Facts & Figures Cancer for African American/Black People | More Black Women Die from Breast Cancer Than Any Other Cancer. Accessed January 26, 2024. https://www.cancer. org/research/acs-research-news/facts-and-figures-african-american-black-people-2022-2024.html.

- Clarke S, Chin SN, Dodds L, George SHL, Badal S. Racial disparities in breast cancer preclinical and clinical models. Breast Cancer Res BCR. 2022;24:56. doi:10.1186/s13058-022-01551-x.
- Bardia A, Hurvitz SA, Tolaney SM, et al. Sacituzumab Govitecan in Metastatic Triple-Negative Breast Cancer. N Engl J Med. 2021;384(16):1529-1541. doi:10.1056/NEJMoa2028485.
- Gilead MI: trodelvy-ascent-subanalysis-in-black-study-population. Accessed January 26, 2024. https://www.askgileadmedical.com/docs/ trodelvy/trodelvy-ascent-subanalysis-in-black-study-population.
- Kanter GP, Parikh RB, Fisch MJ, et al. Trends in Medically Integrated Dispensing Among Oncology Practices. JCO Oncol Pract. 2022;18(10):e1672-e1682. doi:10.1200/OP.22.00136.
- Benson AB, Ajani JA, Catalano RB, et al. Recommended Guidelines for the Treatment of Cancer Treatment-Induced Diarrhea. J Clin Oncol. 2004;22(14):2918-2926. doi:10.1200/JCO.2004.04.132.
- Dillmon MS, Kennedy EB, Anderson MK, et al. Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCO-DA Standards. J Clin Oncol. 2020;38(6):633-644. doi:10.1200/ JCO.19.02297.
- Ettinger, David S., Berger, Michael J., Agarwal, Rajiv. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines). Antiemesis. Version 1.2024. Accessed January 26, 2024. Published online December 13, 2023. https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf.

PQI PRINCIPLES:



ON THE COVER

• NCODA partners with oncology practices to develop clinical resources to optimize patient care.

Practice panelists' comments reflect their experiences and opinions and should not be used as substitutes for medical judgment.

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