PQIIN ACTION



VENETOCLAX (VENCLEXTA®) FOR THE TREATMENT OF ACUTE MYELOID LEUKEMIA



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 **Venetoclax (VENCLEXTA®) for the Treatment of Acute Myeloid Leukemia PQI** and explores how the medically integrated teams at Sutter Health's Comprehensive Cancer Center, UW Carbone Cancer Center, and Cancer Specialists of North Florida incorporate the information found in the PQIs as part of their daily workflow. This article will discuss how utilizing the **Venetoclax (VENCLEXTA®) for the Treatment of PQI** elevates patient care.

Sutter Health's Comprehensive Cancer Center in Berkeley, California is one of 13 cancer centers across Northern California, offering nationally recognized cancer care specialists and cutting-edge treatments. The Comprehensive Cancer Center is accredited by the American College of Surgeons Commission on Cancer (CoC), which recognizes programs that provide multidisciplinary patient-centered and high-quality care. Patients receiving care from Sutter Health's Comprehensive Cancer Center can expect extensive cancer care, evidence-based treatment and support all the way from diagnosis to survivorship

UW Carbone Cancer Center (UWCCC) Rockford, part of the University of Winsconsin Health Systems and formally Swedish American Regional Cancer Center, sevices patients located in the northern part of the state of Illinois. As one of the top 25 hospitals in the annual U.S. News and World Report's "America's Best Hospitals" list, the UWCCC is committed to fighting cancer through groundbreaking research and top-notch care. UWCCC is an integral part of the UW School of Medicine and Public Health, uniting scientists and physicians in order to translate discoveries into beneficial new treatments.

Cancer Specialists of North Florida (CSNF) has an impressive 13 neighborhood locations located throughout Northeast Florida, including the largest cancer practice in Jacksonville. CSNF offers the same state-of-the-art offerings as large institutions, but with the convenience of close proximity to home. The physician-owned and operated practice gives CSNF the freedom to quickly adapt to the ever-changing landscape of cancer care. Their in-house dispensing pharmacy (Florida Specialty Pharmacy), access to clinical trials, convenient laboratory services, and highly committed staff make CSNF one of the only all-inclusive cancer care institutions in the area.

THE PARTICIPANTS

Sutter Health's Comprehensive Cancer Center Berkeley, CA



Rajesh Behl, MD Medical Oncologist



Amanda Chee, PharmD, CSP Clinical Pharmacist



Thanh Trinh, PharmD, BCOP Clinical Pharmacist



Carrie Heron, RN Discharge Nurse Navigator



Lisa Tran, CPhT Pharmacy Technician

UW Carbone Cancer Center Rockford, IL



Deer Cheung, PharmD Pharmacist



Heather Maynard, CPhT Medication Access Specialist





Bijoy Telivala, MD Medical Oncologist



Erin McPherson, PharmD Pharmacist

MID, THE PQI, AND VENETOCLAX: NEW TREATMENT OPTIONS FOR THOSE INELIGIBLE FOR INTENSIVE CHEMOTHERAPY

cute myeloid leukemia (AML) is a type of blood cancer that makes a large number of abnormal blood cells. These abnormal blood cells are typically immature white blood cells that crowd out healthy white blood cells, red blood cells, and platelets. This results in infection, anemia, and easy bleeding. AML is the most common type of acute leukemia in adults and can quickly worsen if not treated.¹

The standard treatment for AML is intensive induction chemotherapy, followed by consolidation therapy that consists of high-dose chemotherapy, stem cell transplant, or both.² However, patients greater than 65 years old are frequently ineligible for or have disease that is refractory to standard chemotherapy due to comorbidities, pre-existing myelodysplasia, and higher incidence of drug resistance and unfavorable cytogenetics.³ Hypomethylating agents (decitabine or azacitidine) or low-dose cytarabine are frequently used instead.^{2,3} However, monotherapy with these agents is associated with low response and survival rates.^{3–5}

Venetoclax (VENCLEXTA®) is an oral BCL-2 inhibitor. BCL-2 is a protein that resists apoptosis and is found in large amounts on AML cells. Inhibition of BCL-2 restores apoptosis and treats AML.⁶ Use of venetoclax alone is associated with a modest response, but combining treatment with hypomethylating agents or low-dose cytarabine increases response.^{7,8}

VIALE-A was a phase III, placebo-controlled trial of 431 patients with AML who were ineligible for standard induction chemotherapy due to comorbidities or age \geq 75 years. The combination of venetoclax 400 mg once daily plus azacitidine 75 mg/m2 IV for 7 doses of a 28 day cycle increased overall survival compared to azacitidine alone (14.7 months versus 9.6 months, p<0.001).⁹ VIALE-C was a phase III, placebo-controlled trial of 211 patients with previously untreated AML who were ineligible for intensive chemotherapy. The combination of venetoclax 600 mg once daily plus cytarabine 20 mg/m² subcutaneously on days 1 to 10 of a 28 day cycle demonstrated clinically meaningful benefits in response rate and overall survival.¹⁰

Bijoy Telivala, MD, Medical Oncologist at CSNF confirms that venetoclax's place in AML is best suited for use in combination with other agents. He says, "Venetoclax has revolutionized the way we treat AML. As a single agent, it doesn't do much. The biggest bang for your buck is when you combine it with a hypomethylating agent like azacitidine or decitabine, and the improvement in response and survival is pretty significant."

Venetoclax is FDA-approved for use in combination with azacitidine, decitabine, or low-dose cytarabine for the treatment of newly diagnosed AML in adults 75 years or older, who have comorbidities that preclude use of intensive induction chemotherapy.⁶

Venetoclax can be dispensed by the Medically Integrated Team, and thus offers patients more comprehensive care. NCODA defines Medically Integrated Dispensing (MID) as a dispensing pharmacy within an oncology center of excellence that promotes a patient-centered, multidisciplinary team approach. The MID is an outcome-based collaborative and comprehensive model that involves oncology healthcare professionals and other stakeholders who focus on the continuity of coordinated, quality care and therapies for cancer patients.¹¹ The MID model can improve management of patients on therapies like venetoclax in several ways including improved communication issues, measuring adherence, managing regimen changes, quicker therapy initiation, increased patient satisfaction, financial assistance, cost avoidance, and producing less waste.¹²

Dr. Telivala muses on what makes MID so beneficial to his team. "You don't want immediate care that is wrong. And you don't want appropriate care which takes weeks and months to happen. You want the combination at best. The biggest benefits [of MID] are the quality of care, the appropriateness of care, the speed at which care is provided, and communication. Oncology is a world where all those are needed in real time."

THE BIGGEST BENEFITS [OF MID] ARE THE QUALITY OF CARE, THE APPROPRIATENESS OF CARE, THE SPEED AT WHICH CARE IS PROVIDED, AND COMMUNICATION. ONCOLOGY IS A WORLD WHERE ALL THOSE ARE NEEDED IN REAL TIME."

Bijoy Telivala, MD

NCODA offers multiple tools to aid the MID 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, Oral Chemotherapy Education sheets, and of course the Positive Quality Intervention clinical resource documents.

THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

arrie Heron, RN, discharge nurse navigator at Sutter Health's Comprehensive Cancer Center comments on the value of the PQI. "It highlights

the important things that the patient and family might need to know. And it also helps guide my education and what I should be focused on. We coordinate care for solid tumor and hematology patients. It is helpful to have reminders of what is important for patient education."

<u>CLICK HERE</u> <u>TO VIEW THIS PQI</u>

Deer Cheung, PharmD, Pharmacist at UW Carbone Cancer Center also notes that the PQI helps her focus patient education on the most important points. "I think the PQI does a good job of laying out all of the information that would be pertinent without overwhelming the patient. By utilizing the PQI, it keeps you on track, so that the pharmacist doesn't offer the patient too much information that becomes overwhelming. It's very digestible, which I think helps in a time where patients are likely very overwhelmed with the amount of information they're receiving. Just because this is only one small aspect of the rest of their care."

This article will explore the benefits of PQI utilization as

"IT'S VERY DIGESTIBLE, WHICH I THINK HELPS IN A TIME WHERE PATIENTS ARE LIKELY VERY OVERWHELMED WITH THE AMOUNT OF INFORMATION THEY'RE RECEIVING. JUST BECAUSE THIS IS ONLY ONE SMALL ASPECT OF THE REST OF THEIR CARE."

Deer Cheung, PharmD, UW Carbone Cancer Center



Dr. Bijoy Telivala reviews labs for a patient starting venetoclax therapy at Cancer Specialists of North Florida.

a core standard of the MID and how adoption can benefit any practice. Sutter Health's Comprehensive Cancer Center, UW Carbone Cancer Center, and Cancer Specialists of North Florida have each found successful ways to incorporate the PQI clinical resource. All three of 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 Venetoclax (VENCLEX-TA®) for the Treatment of Acute Myeloid Leukemia PQI benefits their staff and patients, and how they advance patient care on a daily basis.

MEDICALLY INTEGRATED DISPENSING: ELEVATING CARE

s cancer treatment continually grows in complexity containing IV, oral, and combination regimens, MID continues to offer an invaluable option for patient care. The MID and multidisciplinary staff have 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.

Amanda Chee, PharmD, Clinical Pharmacist at Sutter Health's Specialty Pharmacy thinks that some of the greatest benefits of MID include improved communication and quicker patient access to medication. "We have multiple ways to connect with the clinic. Whether we go downstairs to the clinic, call them, or message them through the electronic health record, our responses feel rather instantaneous. Effective communication helps our patients get answers right away so they can receive their medications as quickly as possible."

"OUR ONSITE PHARMACY HAS PLAYED A HUGE ROLE IN GETTING PATIENTS SET UP WITH THEIR MEDICATIONS AND ORAL CHEMO. HAVING A DIRECT LINE OF COMMUNICATION AND HAVING SOMEONE ONSITE HAS BEEN THE GREATEST ASPECT OF THAT."

Carrie Heron, RN, Discharge Nurse Navigator

MID also helps provide patients with a plan of care in a timely manner. Heron says, "Our onsite pharmacy has played a huge role in getting patients set up with their medications and oral chemo. Having a direct line of communication and having someone onsite has been the greatest aspect of that."

Venetoclax is a bit unique in that even though it's an oral medication, sometimes it has to be started in the inpatient setting. This might be due to concern for tumor lysis syndrome (TLS) or simply because they need to start treatment



UW Carbone Cancer Center, formally Swedish American Regional Cancer Center, provides comprehensive cancer treatment to patients throughout the Rockford area and Northern Illinois.

urgently after being diagnosed in the inpatient setting. MID greatly improves the transition from inpatient to outpatient care. Thanh Trinh, PharmD, BCOP, at Sutter Health's Comprehensive Cancer Center knows this well as a clinical pharmacist who works in the inpatient setting. "When my patient is about to leave the hospital, I contact the specialty pharmacist so that they can begin help with prior authorization and financial assistance as needed. When the patient is discharged from the hospital, we want them to have their medication in hand to reduce the likelihood that a dose will be missed."

PUTTING THE VENETOCLAX (VENCLEXTA®) FOR THE TREATMENT OF ACUTE MYELOID LEUKEMIA 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, increase compliance, 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 Venetoclax (VENCLEXTA®) for the Treatment of Acute Myeloid Leukemia 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 venetoclax, the background discusses the need for AML treatment options in patients ineligible for intensive chemotherapy, indication, and published data leading to approval.

The background also discusses pertinent adverse effects, tumor lysis syndrome (TLS) monitoring, and drug interaction management. $^{\rm 13}$

Rajesh Behl, MD, Medical Oncologist at Sutter Health's Comprehensive Cancer Center doesn't see as much TLS in the AML setting compared to CLL. He says that is the rationale behind the short venetoclax ramp-up. "But we do take tumor lysis precautions and we give the required treatment, especially for those at risk, who have a very high white count for example. But for the most part we have not had issues. We are aware of the issues and we tell the patient that there is a dose ramp-up and that they will be getting supportive medications for possible TLS, which

will be monitored with labs, etc."

The PQI includes a link to a TLS risk tool to aid providers in determining appropriate TLS prevention measures based on indication and white blood cell count. <u>CLICK HERE</u> TO VIEW PQI TLS RISK <u>TOOL</u>

What is more common is a reduction in blood counts. Certain blood counts are already low in AML due to the disease, however venetoclax can further reduce them. Heron says she does see a fair number of patients requiring dose reductions due to blood counts. "What I see is based on counts. Sometimes just the days are reduced, not the dose. I think physicians typically dose reduce in days before cutting the dose." Behl adds, "Especially those patients who have attained remission, we often reduce the duration of venetoclax. We sometimes even dose reduce and keep the patient on venetoclax. This is a very standard practice in my institute. We often have patients who are only getting, say, five days of venetoclax per cycle instead of 28 days, or even 14 days, so we are very

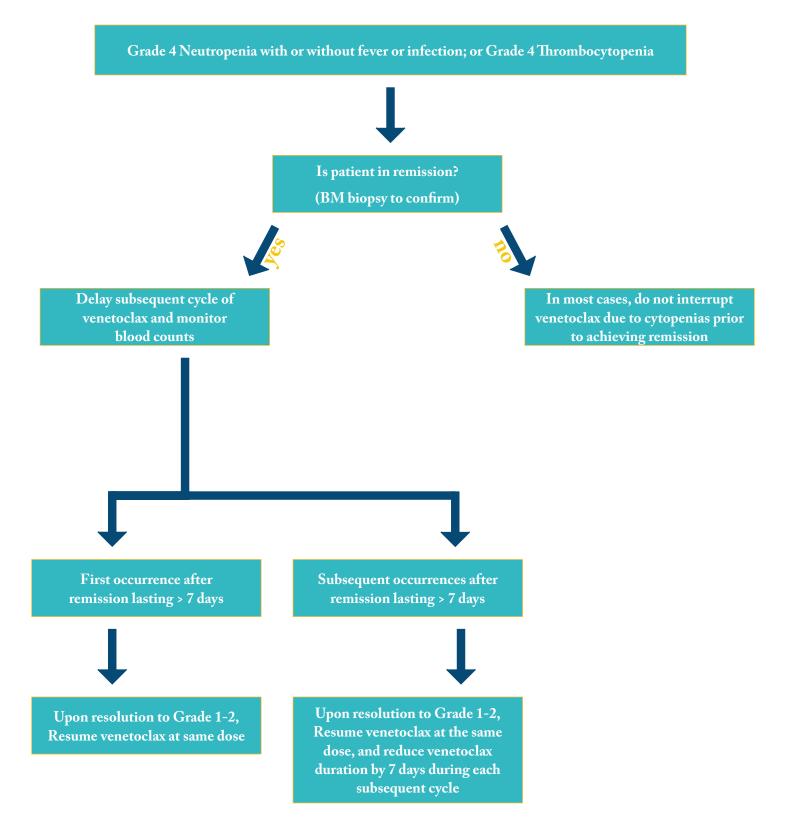
"WE HAVE HAD PATIENTS WHO ARE ON SEVERAL YEARS OF MAINTENANCE REGIMENS, THE OLDER PATIENTS WHO ARE ENJOYING AN EXCELLENT QUALITY OF LIFE WHILE BEING IN REMISSION."

Rajesh Behl, MD

quick to reduce the number of days. And we have had patients who are on several years of maintenance regimens, the older patients who are enjoying an excellent quality of life while being in remission."

Sometimes providers need to hold venetoclax. Dr. Telivala says "It's different for everyone. There's no one rule fits all. So when the blood counts go low, you always think, 'Is it the leukemia coming back or is it the drug?' Because it could be either. Whether I hold it depends on the numbers [of the blood counts]. Some people bounce back quickly and some don't."

VENETOCLAX DOSE MODIFICATION CHART



THE PQI PROCESS: A TEAM EFFORT

he next section of the Venetoclax (VENCLEX-TA®) for the Treatment of Acute Myeloid Leukemia 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 Venetoclax (VENCLEXTA®) for the Treatment of Acute Myeloid Leukemia PQI includes confirming that the dose and ramp-up schedule are appropriate for the indication.

The first three to four days of venetoclax include a short ramp-up dosing to decrease the risk of developing TLS. This is different than the ramp-up schedule for chronic lymphocytic leukemia (CLL). Patients are instructed to take 100 mg on the first day, 200 mg on the second day, and 400 mg on the third day. Whether they continue with 400 mg indefinitely or increase to 600 mg daily starting on day four depends on which chemotherapy they are receiving with it. Dr. Telivala says, "Very few people use the 600 mg dose with low-dose cytarabine."

| Venetoclax Ramp-Up Schedule in AML | | | | |
|------------------------------------|--------------------------------------------------------------------------------|--|--|--|
| Day 1 | 100 mg | | | |
| Day 2 | 200 mg | | | |
| Day 3 | 400 mg | | | |
| Day 4 and beyond | 400 mg with hypomethylating agent <i>or</i> 600 mg with low dose cytarabine | | | |

If they are worried about blood counts or TLS risk, sometimes providers will do a longer ramp-up based on their clinical judgement. Erin McPherson, PharmD, pharmacist at CSNF says, "Sometimes we'll see them do a little slower taper. They might keep them at 100 mg or 200 mg for a week or two and see how they're doing on that lower dose before they titrate up."

The venetoclax ramp-up schedule, TLS lab monitoring, potential need for IV hydration, and infusion days of the different chemotherapies can be quite confusing for patients. Pharmacists and nurses at SSutter Health's Comprehensive Cancer Center develop calendars to help patients keep track of all their appointments. Heron says, "The calendar is one part of having the layout of knowing what days they are



Amanda Chee, PharmD, CSP, discusses a venetoclax regimen for a patient.

taking medications, which medications, and when they need to come to the center.. We generally will see these patients pretty frequently, especially in the beginning. Once weekly, sometimes more if needed." She goes on to say "We can upload to the patient's calendar. So if they are in the treatment room, care team members can access it and print it out. It's helpful for us too, because we are tracking all of our patients. And so that it is a good reference for us as well." Patients find the calendars helpful, even after they are established on a stable dose. They are especially helpful for patients who are on a cyclic venetoclax regimen, for example if they've been dose reduced by decreasing the number of days on venetoclax. Chee says, "They love it. They usually want it every month."

The PQI process continues with drug interaction management, determining necessity of cytoreduction prior to starting venetoclax, TLS management, and assessment of response.

McPherson finds the PQI especially helpful for lab monitoring and drug interaction management as a dispensing pharmacist. She says "That [the PQI] would definitely be helpful to know for drugs that have different labs we need to be checking besides the normal baseline thing, and different interactions. Also, if for some reason it's not in our system to flag yet, or just which parameters stand out for different drugs that need to be checked versus others. When we have a stack of 20 new chemo prescriptions to check, the PQI NCODA offers is easier than trying to read through the package insert and figure out what you need to check on each one and make sure you don't miss something for each different chemo." When asked what she likes most about the PQI, Trinh says "The whole thing, but mainly the drug interactions. It's easy to look at." In the inpatient setting, she checks for drug interactions on a daily basis, and loves that an integrated system allows other pharmacists to see her notes regarding rationale for venetoclax dose reductions. "It's great to have everything on one platform."

Dr. Telivala emphasizes the importance of managing drug interactions. He says, "A lot of these AML patients are on anti-fungal medications and depending on what they are, you need to adjust the [venetoclax] dose. It's important to do that, because if you don't, they have much more prolonged cytopenias and other trouble. If you have drug interactions, be proactive and reduce the dose if you can. It saves the patients money, saves the health system costs, and avoids these prolonged neutropenias." He also points out that monitoring for response is different with venetoclax-based regimens compared to induction chemotherapy. "Usually with induction chemotherapy, we did a bone marrow biopsy at around day 14 to look at response. When you are on azacitidine or decitabine plus VENCLEXTA®, you need to wait a good month because that is when you see what is going on or what is not going on."The PQI also details this nuance so that patients don't receive this procedure too early.

| Coadministered Medication | Ramp Up Dose Modification | Steady Daily Dose Modification | |
|--------------------------------------|-----------------------------------------------|--------------------------------|--|
| | Day 1: 10 mg | | |
| Posaconazole | Day 2: 20 mg | 70 | |
| | Day 3: 50 mg | 70 mg | |
| | Day 4: 70 mg | | |
| Other Strong CYP3A4 Inhibitors | Day 1: 10 mg | 100 | |
| | Day 2: 20 mg | | |
| | Day 3: 50 mg | | |
| | Day 4: 100 mg | | |
| | At least a 50% dose reduction is advised | | |
| Moderate | A modified ramp up schedule can be considered | | |
| CYP3A4 | Day 1: 50 mg | 200 mg | |
| Inhibitors and Pgp Inhibitor | Day 2: 100 mg | | |
| | Day 3: 200 mg | | |

PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

he Patent-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. The Venetoclax (VEN-CLEXTA®) for the Treatment of Acute Myeloid Leukemia PQI Pa-

<u>CLICK HERE</u> TO VIEW OCE SHEET

tient Centered Activities suggests providing the patient with an Oral Chemotherapy Education (OCE) sheet. OCE sheets are NCODA-led initiatives that provide information about oral chemotherapy and hormone therapy 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.¹⁴ 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.¹⁴

The pharmacists at UW Carbone Cancer Center frequently use the OCE sheets as part of their counseling session. Heather Maynard, CPhT, medication access specialist at UW Carbone Cancer Center says, "We use the OCE information for every drug that we counsel on for oncology drugs." Cheung mentions how the OCE sheets allow patients to take charge of their own care. "Your [NCODA's] oral chemotherapy education is really helpful for when we're counseling. I love the way that it is laid out. You can even fill in the dose and the schedule for the patient. It goes through really pertinent information in an easy way to format and it gives some ways in which the patient can triage some of their side effects at home, which empowers the patient to take their health care into their own hands. I utilize the oral chemotherapy education sheets from NCODA quite a bit and I think they are really helpful."

The Patient Centered Activities section also discusses important TLS prevention and adverse event counseling points. Chee notes, "The biggest side effect that I always talk about is tumor lysis syndrome. I'm able to break it down so that they really understand what that is." She goes on to explain how she describes TLS to patients and how all the waste products (uric acid, potassium, etc.) from destroyed cancer cells are floating in your body and need to be excreted. "And that's when I explain the importance of the water bottle and how it's going to hydrate them and flush out everything. I also talk about nausea, vomiting, diarrhea, fatigue, increased risk of infection, and protecting the immune system. I even talk about edema because I know some of my patients experience that sometimes. So I really emphasize that if they're able to weigh themselves every day and they gain more than five pounds in a week, then they can bring that up to the doctor."

Patients at Sutter Health's Comprehensive Cancer Center experience continued support from their oncology team, even after they are on a stable dose. Lisa Tran, CPhT, pharmacy technician at Sutter Health's Comprehensive Cancer Center says, "I do monthly follow-ups with the patient, making sure that they're not experiencing any side effects or missing any doses of the medication. If they did or have any questions, I refer to the pharmacist." Those who fill at non-MID pharmacies would unfortunately miss out on this benefit, which could potentially impact adherence.

FINANCIAL ASSISTANCE: A BENEFIT OF MID AND THE MULTIDISCIPLINARY TEAM

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

Both pharmacy technicians at Sutter Health Specialty Pharmacy and UWCCC find that venetoclax can be relatively easy to get approved. Tran notes, "I haven't encountered any major hiccups of getting venetoclax for patients. We recently had a patient who had no insurance. Given the patient's financial situation, we were able to work with the manufacturer to obtain free drug and the patient was able to start treatment."

Maynard describes the benefits that might be lost if a patient has to go through a pharmacy that doesn't have MID. "Things fall through the cracks. They don't get their medication on time. A lot of specialty pharmacies [without MID] will call one time, and if the patient is not available, it's kind of on them [the patient] to get back to them. We're continually following up with the patient to see what's going on." She also mentions that UWCCC will help patients with financial assistance, even when patients aren't filling their medications through them. "As far as their copay, it's up to the pharmacies to leave it up to the patient to sign up for a copay card, or to try to find any copay assistance. I've had nurses from the cancer center reach out and say, 'Could you just sign this patient up for a copay card? I know you're not filling for them.' Or 'At least tell me if there's copay assistance available through the foundations for them because certain pharmacies will just not do that." McPherson mentions that an integrated system gives the prior authorization team access to not only office staff and physicians, but pharmacists as well. "Sometimes the pharmacists can help them figure out based on the notes in the chart what the answers to their questions are. So it doesn't leave everything to rely on the physician to answer the questions. If we can answer the questions for them, then we can get the medications to the patient quicker if they can get the authorization approved."

Maynard agrees that system integration improves turnaround time and eases the burden on other staff. "They get their prescriptions a lot quicker through us. I have access to all the chart notes, all the labs. I can pull all of that myself. If it's an outside group doing the prior auth, they would have to ask for chart notes and labs to be sent over. Then it's being kicked back to the nursing staff and sometimes that can take several days. And so it's a satisfier for patients as far as time, and then also for the staff, because the nursing staff is not having to do that. We're doing that for them."

Sutter Health's Comprehensive Cancer Center, UWCCC, and CSNF all have dedicated staff to help patients with financial assistance. For facilities that may be less familiar with the resources available for medication assistance, the PQI has a financial assistance program tool that lists currently available programs for each medication.

CLICK HERE TO VIEW FINANCIAL ASSISTANCE PROGRAM TOOL

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

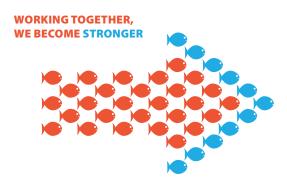
Il team members agree that the MID model and the PQI Clinical Resource are valuable to the team and to patients. Every day the MID team can make a difference in the life of patients.

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 and by improving adherence techniques for the patient and their Medically Integrated Teams.

Dr. Behl loves that the MID pharmacy is concise, and that the integration improves communication, adherence, and resolution of issues. He says, "Patients can collect many of the medications when they come in, either for follow-up appointments or their treatment visits. Secondly, the pharmacists are closely integrated with the physicians, so they are able to communicate a lot faster. And they are also on the Epic system, so communication is far more rapid through either secure chat or My Health Online. And so resolution of the problem is almost instantaneous." He thinks the PQI is useful even for physicians that specialize in hematology. "It's still nice to have it because even we are overwhelmed with information and it's nice to have supporting data."

PQI in Action articles like this one are a valuable way to share knowledge and improve care. Chee looks forward to reading the PQI in Action articles because "I like to see what other people and practices are doing, because at the end of the day I think all our goals are similar. It's going to be patient care. So that's what I find very valuable."

The PQI provides the MID program with an easy to use, concise clinical resource guide when discovering the right patient and dispensing venetoclax. It helps the team ensure they are providing patients with the tools and education to improve clinical outcomes. Pairing Medically Integrated Dispensing with the Venetoclax (VENCLEXTA®) for the Treatment of Acute Myeloid Leukemia PQI meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.



REFERENCES

- Acute Myeloid Leukemia Treatment NCI. Published November 24, 2023. Accessed December 24, 2023. <u>https://www.cancer.gov/</u> types/leukemia/patient/adult-aml-treatment-pdq.
- Pollyea, Daniel A., Altman, Jessica K., Assi, Rita. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines). Acute Myeloid Leukemia, Version 6.2023. Accessed December 24, 2023. <u>https://tinyurl.com/2xcnscxd</u>. Published online October 24, 2023.
- Griffioen MS, de Leeuw DC, Janssen JJWM, Smit L. Targeting Acute Myeloid Leukemia with Venetoclax; Biomarkers for Sensitivity and Rationale for Venetoclax-Based Combination Therapies. Cancers. 2022;14(14):3456. doi:10.3390/cancers14143456.
- Burnett AK, Milligan D, Prentice AG, et al. A comparison of lowdose cytarabine and hydroxyurea with or without all-trans retinoic acid for acute myeloid leukemia and high-risk myelodysplastic syndrome in patients not considered fit for intensive treatment. Cancer. 2007;109(6):1114-1124. doi:10.1002/cncr.22496.
- Dombret H, Seymour JF, Butrym A, et al. International phase 3 study of azacitidine vs conventional care regimens in older patients with newly diagnosed AML with >30% blasts. Blood. 2015;126(3):291-299. doi:10.1182/blood-2015-01-621664.
- 6. VENCLEXTA [Prescribing Information]. Updated June 2022. Accessed December 24, 2023. <u>https://tinyurl.com/4jtnkdve</u>.
- Souers AJ, Leverson JD, Boghaert ER, et al. ABT-199, a potent and selective BCL-2 inhibitor, achieves antitumor activity while sparing platelets. Nat Med. 2013;19(2):202-208. doi:10.1038/nm.3048.

- Konopleva M, Pollyea DA, Potluri J, et al. Efficacy and Biological Correlates of Response in a Phase II Study of Venetoclax Monotherapy in Patients with Acute Myelogenous Leukemia. Cancer Discov. 2016;6(10):1106-1117. doi:10.1158/2159-8290.CD-16-0313.
- DiNardo CD, Jonas BA, Pullarkat V, et al. Azacitidine and Venetoclax in Previously Untreated Acute Myeloid Leukemia. N Engl J Med. 2020;383(7):617-629. doi:10.1056/NEJMoa2012971.
- Wei AH, Montesinos P, Ivanov V, et al. Venetoclax plus LDAC for newly diagnosed AML ineligible for intensive chemotherapy: a phase 3 randomized placebo-controlled trial. Blood. 2020;135(24):2137-2145. doi:10.1182/blood.2020004856.
- Eno V. NCODA Announces the defining of the Medically Integrated Dispensing Pharmacy. NCODA. Published January 27, 2020. Accessed October 23, 2023. <u>https://tinyurl.com/yndm9anh</u>.
- Wimbiscus B. Medically Integrated Dispensing: An Alternative to How Oral Drugs Get Dispensed. AJMC. Published March 14, 2019. Accessed October 23, 2023. <u>https://tinyurl.com/ykjfpwds</u>.
- Carulli, Alison. Positive Quality Intervention: Venetoclax (VEN-CLEXTA®) for the Treatment of Acute Myeloid Leukemia. Accessed December 24, 2023. <u>https://tinyurl.com/3t2yb7hk</u>.
- 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.

ON THE COVER:

Lisa Tran, CPhT, communicates the completion of a venetoclax prescription for a new AML patient.

PQI PRINCIPLES:

Identify AML patients eligible to receive venetoclax therapy

Review labs to assess TLS status is appropriate for therapy initiation

Ensure dosing of venetoclax is appropriate based on regimen

Screen for drug interactions and adjust dosing and ramp up therapy as needed

Counsel patient on side effects, dosing and titration schedule, importance of hydration

Monitor for adverse events and dose reduce or modify as needed

4

5



| NICO | | | |
|------|-------------|---------|--|
| INCO | DA V | Vebsite | |
| | | | |

Venetoclax (VENCLEXTA®) for the Treatment of AML PQI

Oral Chemotherapy Education Sheet for Venetoclax (VENCLEXTA®)

NCODA Dose Modification Charts for Venetoclax Treatment and Venetoclax TLS Risk Assessment Tool

NCODA Financial Assistance Tool

NOTES:

| |
|------|
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

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

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.



