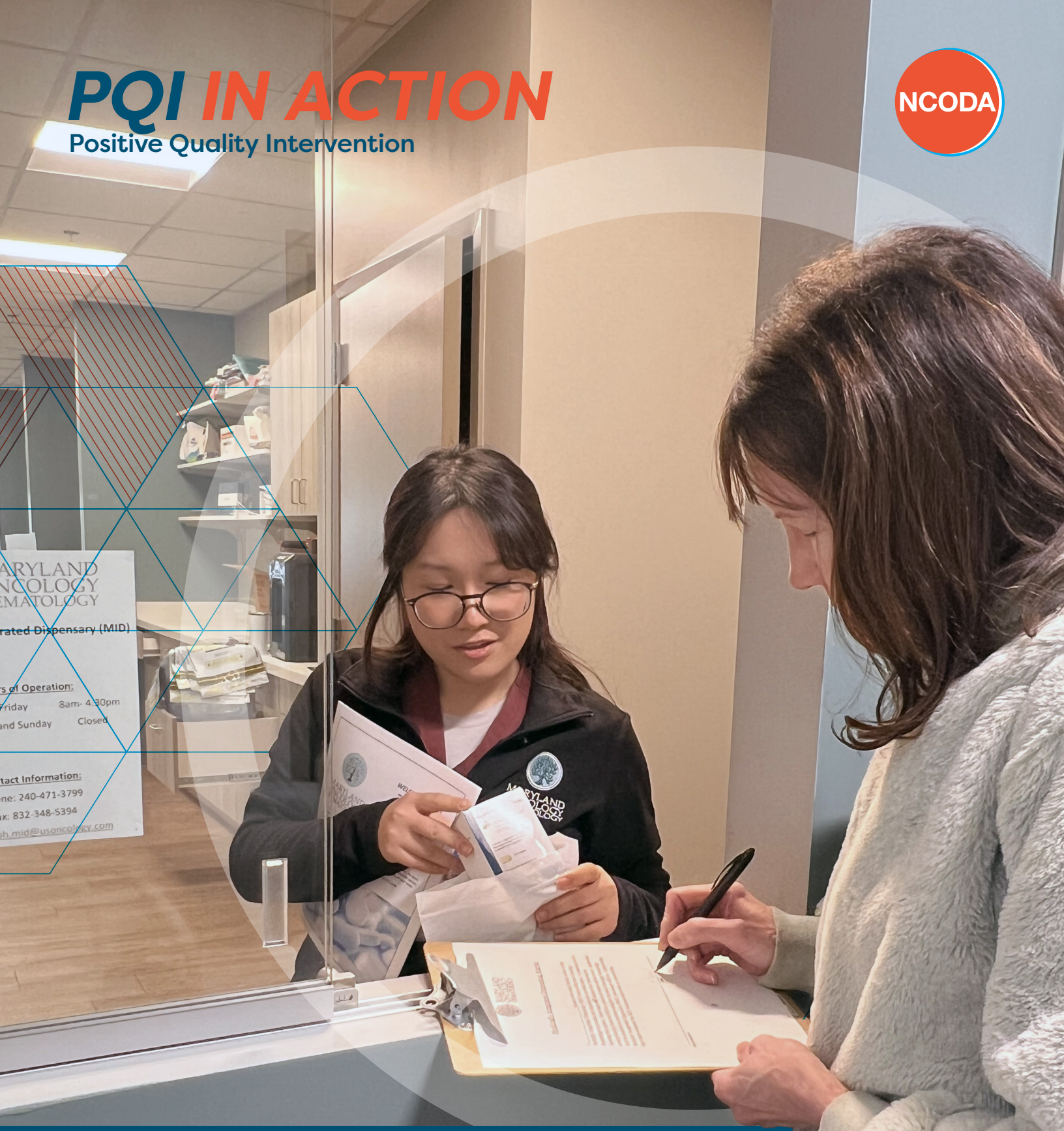
PQI IN ACTION

Positive Quality Intervention

NCODA



Optimizing Venetoclax Treatment of Acute Myeloid Leukemia

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, and package insert 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 Optimizing Venetoclax Treatment of Acute Myeloid Leukemia and explores how the medically integrated teams at Maryland Oncology Hematology, Willamette Valley Cancer Center, and Rocky Mountain Cancer Center collaborate and utilize the information found in the PQI as part of their daily practice. This PQI in Action focuses on the use of venetoclax in combination with a hypomethylating agent (HMA; azacitidine or decitabine).

Scan or click here to access Venclexta® Positive Quality Intervention

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INTRODUCTION TO AML PATIENTS INELIGIBLE FOR INTENSIVE CHEMOTHERAPY

ACUTE Myloid Leukemia (AML) is uncommon, comprising about 1% of all cancer cases, with the average age at diagnosis being 69 years.[1] Consequently, older patients are less likely to tolerate intensive chemotherapy and are more prone to experiencing side effects from treatment due to a higher prevalence of co-morbidities, reduced overall health status, and a decreased capacity to metabolize chemotherapy.[2] Luckily, more recent advances in molecular targeting have yielded encouraging outcomes in AML treatment, opening the door to new, more tolerable treatment strategies. In this older and more treatment-sensitive patient subgroup, venetoclax paired with a hypomethylating agent (HMA; e.g. azacitidine or decitabine) represents an effective, guideline-recommended strategy[3], which will be discussed in more detail below.

VENETOCLAX: INDICATIONS[4]

IN April 2016, venetoclax was initially approved for use in adults with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). However, since this PQIiA will focus exclusively on AML, details regarding CLL/SLL will not be covered further.

In October 2020, venetoclax gained its second approval, this time for use in combination with azacitidine, decitabine, or low-dose cytarabine (LDAC) in newly diagnosed adult AML patients who are 75 years or older, or who have other health conditions that prevent them from undergoing intensive induction chemotherapy.

VENETOCLAX MECHANISM OF ACTION AND AML CLINICAL TRIAL DATA

Venetoclax is an oral drug that selectively inhibits BCL-2, a protein that prevents cell death that is highly expressed in both CLL and AML.[4] By attaching directly to the BCL-2 protein, venetoclax aids in reactivating the cell death process.[4]

The above labeled AML indications for venetoclax in combination are based on data from the Phase 3 VIALE-A[5] and VIALE-C[6,7] trials. In VIALE-A, untreated AML patients who were not candidates for intensive chemotherapy were assigned to receive venetoclax plus azacitidine (n=286) or placebo plus azacitidine (n=145). The median overall survival (mOS), the primary endpoint, was significantly longer for patients in the venetoclax group when compared to the placebo group at 14.7 months vs 9.6 months, respectively (HR 0.66; 95% CI: 0.52-0.85; p<0.001). Furthermore, the complete remission (CR) rate was also higher in the venetoclax group at 37% versus 18% in the placebo group (p<0.001).[5]

The VIALE-C trial,[6] which also enrolled untreated AML patients ineligible for intensive chemotherapy, randomized patients to venetoclax with LDAC (n=143) or placebo with LDAC (n=68). While there was no notable difference in median OS between the venetoclax group and placebo groups in the primary analysis,[6] a subsequent analysis showed a longer mOS of 8.4 months for the venetoclax group compared to 4.1 months for the placebo group (HR, 0.7; 95% CI, 0.5-0.99; p = 0.04) after six additional months of follow-up.[7] In addition, the CR or complete response with incomplete blood count recovery (CR/Cri) favored those patients who received venetoclax-LDAC vs. placebo-LDAC - 48% vs 13%, respectively (p<0.001).[7]

WHAT THE NCCN GUIDELINES® SAY[3]

The combination of venetoclax and azacitidine is a preferred category 1 regimen for patients who are not suitable for intensive chemotherapy. Venetoclax given concurrently with decitabine (category 2A recommendation) is listed as another potential treatment option.

In terms of safety, it is recognized that venetoclax given with HMAs may cause extended periods of low blood cell counts even once remission is achieved.[3,8] As such, NCCN® advises pushing through cycle 1 despite any low blood counts, while providing aggressive supportive care (including transfusion support), until disease response can be determined.[3,9] A bone marrow biopsy should be performed between days 21 and 28, and the panel stresses postponing growth factor support until after this procedure has been completed.[3,10]

ELEVATING PATIENT CARE THROUGH MEDICALLY INTEGRATED PHARMACY (MIP)

COLLABORATION within the multidisciplinary team is critical for optimizing patient outcomes, particularly when managing complex therapies for the treatment of AML such as hypomethylating agents and venetoclax. Specifically, Dr. Luke Fletcher from Willamette Valley Cancer Center, highlights, "interactions and teamwork between a pharmacist and an oncologist are absolutely imperative with hypomethylating and venetoclax administration."

Dr. Fletcher explains that pharmacists play a crucial role in managing drug-drug interactions and ensuring appropriate dosing, particularly for acutely ill patients with low blood counts. Their expertise is invaluable for navigating challenges such as infectious disease (ID) prophylaxis and minimizing interactions that could compromise care. Equally, nurses and pharmacy technicians are integral to the team, providing hands-on care, monitoring, and operational support that drive the success of treatment plans. This seamless collaboration ensures that each patient receives the safest and most effective care possible. Mohit Narang, MD, medical oncologist and a founding partner of Maryland Oncology and Hematology (MOH), shared that his practice decided to start their own MIP to "provide a better quality of care and better compliance for patients."

> "Interactions and teamwork between a pharmacist and an oncologist are absolutely imperative with hypomethylating and venetoclax administration."
>
> -Luke Fletcher, MD

BENEFITS OF MIP FOR PATIENTS PRESCRIBED VENETOCLAX

THE Medically Integrated Pharmacy (MIP) model offers substantial benefits for patients on venetoclax, creating an efficient and patient-centered approach to care. Karen Ho, CPhT, from Maryland Oncology Hematology, emphasizes the impact, stating, "If we can make the process of getting patients their medications easier and quicker for both the prescriber and the patient, it creates a much more streamlined and focused care experience." The ability to access the Electronic Medical Record (EMR) is a key advantage, allowing the pharmacy team to view patient history, labs, and medication records, which non-integrated specialty or Pharmacy Benefit Manager (PBM) pharmacies cannot easily achieve. Melissa Shimanek, PharmD, BCACP, from Rocky Mountain Cancer Centers (RMCC), highlights this, noting, "Having access to the EMR and being able to see the full picture of the patient—labs, messages, concerns—is incredibly helpful."

The multidisciplinary panel contributed to a list of benefits to patients filling their venetoclax prescriptions using MIP. Figure 1 highlights their collective insights.

FIGURE 1: BENEFITS OF PATIENTS FILLING VENETOCLAX PRESCRIPTIONS USING MIP

01	Streamlined and quicker access to medications for patients and prescribers.
02	Direct messaging and collaboration between pharmacists and physicians, enhancing trust and communication.
03	Access to EMR, including labs, patient history, and clinical notes for comprehensive care.
04	Reduced medication waste through accurate prescription management.
05	Avoidance of treatment delays by expediting prior authorizations and refills.
06	Coordination of care across the multidisciplinary team for improved patient outcomes.
07	Proper management of risks associated with tumor lysis syndrome (TLS) and infections.
08	Regular follow-ups, including clinical check-ins, adherence monitoring, and patient education.
09	Pharmacy technicians' critical role in handling prior authorizations, refill calls, and patient assistance.
10	Enhanced medication adherence through close patient support and monitoring.

VENETOCLAX PATIENT ASSESSMENT AND TREATMENT CONSIDERATIONS

THE Optimizing Venetoclax Treatment of Acute Myeloid Leukemia PQI highlights processes that can be implemented to minimize delays when treating AML with combination venetoclax and HMA therapy. It reviews the optimization of venetoclax treatment initiation and ongoing patient management. Upon AML diagnosis and the decision to initiate venetoclax therapy, the team pharmacist and physician will collaborate to manage tumor lysis syndrome (TLS) and infection risk. The physician will then determine if the patient should start treatment as an inpatient or outpatient.

Dr. Fletcher explains that one of the primary considerations when deciding whether to start a patient on venetoclax and azacitadine as an inpatient or outpatient is the pace of their disease. "Is the disease progressing rapidly or more slowly? Are they a proliferative AML or more dysplastic, such as those with an antecedent myelodysplastic syndrome?" He explains that for patients with rapidly rising white counts, there is a heightened risk of TLS, making it essential to cytoreduce these patients prior to starting treatment. In

Venetoclax Patient Assessment and Treatment Considerations- continued

such cases, inpatient treatment is often safer. However, Dr. Fletcher notes that the vast majority of patients, provided their counts are not rapidly rising, can be safely treated in an outpatient setting. He points out that outpatient care is generally preferred when feasible, as it allows patients to remain in their own surroundings and sleep in their own beds during treatment initiation. He adds that another critical factor in determining treatment location is the level of patient support, such as having someone available to transport them to appointments and transfusions.

When treating patients with AML using venetoclax, Dr. Narang emphasizes a tailored approach, considering both physiological and chronological age, as patients' health can vary widely regardless of actual age. Frailty plays a critical role, with more frail individuals often requiring inpatient care. Additionally, he too, says the strength of the patient's support system, including whether they live alone or have adequate assistance, significantly impacts treatment planning. Lastly, the patient's blood counts are a key factor, with lower counts typically necessitating hospitalization to manage care effectively.

The PQI Process highlights recommended points of collaboration between the pharmacist and provider regarding TLS, dosing schedule and reviewing monitoring requirements as shown in Figure 2.

FIGURE 2: THE PHARMACIST WILL COLLABORATE WITH THE PROVIDER TO:

01 **Manage the risks of TLS and infection by recommending appropriate prophylaxis (e.g., antihyperuricemics, antiemetics, antimicrobials, and other supportive care).**

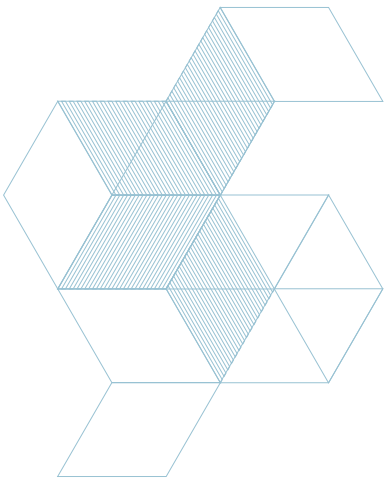
02 **Determine whether the patient should start treatment as an inpatient or outpatient accounting for TLS risk and necessary monitoring, transfusion threshold, ease of hospital access, etc.**

03 **Establish a dosing schedule and recommend dose adjustments to account for potential drug interactions.**

04 **Review the monitoring requirements, including the timing of bone marrow biopsy (BMB) and various laboratory tests such as complete blood cell count (CBC), blood chemistry, etc.**

Dr. Fletcher emphasizes the critical role of pharmacist collaboration, noting that pharmacists and oncologists must work closely to manage drug-drug interactions, supportive care, and dosing. AML patients often present with low counts and require multiple supportive medications, such as antifungals, which frequently interact with venetoclax. Dr. Fletcher highlights azole antifungal agents as a prime example, requiring significant venetoclax dose reductions to avoid adverse effects. Pharmacists are instrumental in ensuring accurate dosing, educating patients on medication adjustments, and maintaining clear communication with the team. This collaboration extends to determining dose durations and ramp-up schedules, ensuring that patients and providers are aligned on treatment plans.

Pharmacist Courtney Horn, PharmD, from Maryland Oncology Hematology, underscores the importance of comprehensive medication reconciliation (med rec). She explains that pharmacists often catch discrepancies in medication lists and identify significant interactions. By ensuring allopurinol prescriptions are incorporated into the EMR and maintaining ongoing communication with providers, pharmacists significantly mitigate risks of TLS. Shimanek adds that at RMCC, proactive planning for TLS management and admission workflows is another key area where pharmacists contribute. By coordinating with providers and prioritizing critical orders, pharmacists streamline transitions of care, especially for patients moving between inpatient and outpatient settings.



VENETOCLAX DISPENSING AND COORDINATION OF CARE

DISPENSING

When it is time to dispense venetoclax for the patient, the pharmacist or pharmacy technician will obtain the patient's insurance information, identify where the prescription can be filled, and initiate a search for potential patient assistance programs, if needed. Ho shares that, at Maryland Hematology Oncology, venetoclax use in AML requires careful attention to a different ramp-up schedule compared to other indications. It is essential to confirm the diagnosis, have clinical notes prepared, and ensure the treatment is used in combination with azacitidine to facilitate insurance approvals and confirm correct dosing. Authorizations for venetoclax in AML are generally straightforward with proper documentation. The team also assists patients in securing copay cards and applying for grants to help cover treatment costs. If grants are unavailable, they explore the manufacturer's patient assistance program (PAP) to make certain patients can access therapy.

At Rocky Mountain Cancer Center, Maricar Ocampo, CPhT, a pharmacy technician and patient financial counselor, provides centralized support for all clinics in Colorado. She plays a pivotal role in helping patients secure grants and assistance programs. Ocampo emphasizes the importance of having access to the EMR, lab results, office visit details, and clinical check-ins, noting that pharmacy technicians are integral to tasks such as prior authorizations, assistance coordination, refill calls, and medication adherence. She highlights that medically integrated pharmacies are the best option for streamlined care. Speed of funding is crucial for AML patients, especially with increasing barriers due to Medicare changes. Staying organized is key, and Ocampo uses a Smartsheet to track grants and maintain efficiency. When prior authorizations require appeals, the clinic works quickly to navigate these challenges, facilitating timely access to treatment for patients.

COORDINATION OF VENETOCLAX TREATMENT INITIATION

Effective coordination is essential when initiating venetoclax treatment, particularly for AML patients who may require inpatient care for ramp-up dosing. Pharmacists, nurse navigators, and pharmacy technicians play a crucial role in this process. Once the medication is acquired, they inform patients about whether they need to bring their home medication to the hospital for use during treatment. Additionally, pharmacists and nurse navigators work to synchronize the initiation of venetoclax with accompanying HMAs.

At many centers, proactive communication and collaboration streamline this process. Shimanek highlights that when inpatient treatment is planned, pharmacists often receive chart messages from the care team to prioritize orders. In Colorado, pharmacists have access to hospital notes, either through integrated systems or separate platforms, to review the patient's medications and labs, ensuring seamless coordination. For hospitals where venetoclax is not on formulary, the RMCC MIP arranges for medication delivery, either directly to the hospital floor or via a family member.

Ho emphasizes the importance of clear communication with patients and their caregivers to confirm treatment settings. For outpatients, the MOH team makes certain patients can pick up their medication conveniently, minimizing delays. This comprehensive approach ensures that venetoclax treatment starts promptly and with minimal disruption, supporting better outcomes for AML patients.

REMISSION ASSESSMENT AND ON-GOING PATIENT MANAGEMENT

EFFECTIVE management of AML patients receiving venetoclax-based therapy requires a structured approach that balances treatment, remission monitoring, and long-term maintenance. Dr. Narang underscores the importance of frequent early monitoring, particularly during the first cycle, with patients being seen at least twice in the first week and once weekly thereafter to prevent potential complications. Visits are alternated between physicians and advanced practice providers (APPs), with a prefer-

Remission assessment and on-going patient management - continued

ence for scheduling before weekends to avoid issues that may arise during that time.

Dr. Fletcher frames the treatment journey into distinct phases: what he describes as an initial induction phase during the first cycle, followed by a maintenance phase aimed at sustaining remission and improving quality of life. He emphasizes his goal is transfusion independence and he uses dose adjustments as a tool for sustainability on therapy. Proactive dose adjustments may increase medication tolerability, help reduce pill burden, decrease number of lab checks, and decrease prophylactic medications. To support patients long-term and help keep them in remission as long as possible, he adopts dose reductions and incorporates growth factor support to enhance neutrophil recovery. Additionally, Dr. Fletcher provides each patient with a personalized treatment plan during their initial visit, outlining the schedule, medications, and preventive care measures, ensuring a clear understanding of the process and fostering collaboration in their care.

BONE MARROW BIOPSY

A bone marrow biopsy to evaluate remission of disease is a crucial component of AML treatment with venetoclax and azacitidine. It is recommended to perform this assessment between days 21 and 28 of the first cycle, with remission defined as less than 5% leukemia blasts with accompanying cytopenias.[4] Both Dr. Fletcher and Dr. Narang emphasize the importance of this evaluation in their clinical practices.

Dr. Fletcher integrates this biopsy into the treatment discussion from the initial consultation, laying out a clear plan that includes the biopsy at the end of the first month. This practice helps manage cytopenias effectively by identifying response early and allows for drug holds to facilitate count recovery, when needed. He highlights that over 50% of patients respond within the first cycle, with nearly all responding within two months.

Conducting timely biopsies not only assesses disease response but also minimizes prolonged cytopenias, reducing transfusion burdens and improving patients' quality of life.

Dr. Narang echoes this sentiment, stressing that bone marrow biopsies are essential for evaluating treatment efficacy and guiding dose adjustments. When the biopsy indicates remission, his practice adjusts venetoclax dosing to cycles such as three weeks on and one week off, or two weeks on and two weeks off, based on the patient's white blood count and transfusion requirements. He views the biopsy as a non-negotiable part of the treatment protocol and believes that greater education is needed within the oncology community to reinforce its significance in optimizing outcomes.

In cases of resistant disease, repeat bone marrow biopsies should be performed during subsequent cycles as clinically indicated to monitor progress and guide ongoing treatment decisions. This proactive approach to assessment and dose management is key to improving long-term patient outcomes while balancing treatment-related toxicities.

CYTOPENIAS

Once remission is confirmed through a bone marrow biopsy, adjustments to the venetoclax treatment regimen are essential to optimize patient outcomes and minimize adverse effects. Clinical trials have demonstrated that venetoclax may be interrupted for up to 14 days or until the absolute neutrophil count (ANC) is ≥500/µL and platelet count is ≥50 x 10^3/µL to allow for count recovery.[5] In clinical practice, dose and duration adjustments are often made once remission is achieved to prevent hematologic toxicities, such as cytopenias, and to support long-term treatment tolerability. Table 1 is found in the PQI and contains venetoclax dosage modification for hematologic adverse reactions.[4]

Dr. Fletcher discusses the importance of dose reductions, noting that "less is more" in AML treatment as long-term sustainability relies heavily on patient quality of life. With growing experience and supporting data, he has adopted a more aggressive approach to dose reductions while incorporating growth factor support. He says this support, often provided mid-cycle, helps enhance neutrophil recovery, reduce the duration of neutropenia, and minimize the need for prophylactic medications. He highlights that these adjustments allow patients to feel better and maintain their daily activities, and "do more of what they want to do."

Dr. Narang also adopts a proactive approach, employing growth factor support like G-CSF (granulocyte colony-stimulating factor) and ensuring regular blood transfusions are available for AML patients. His clinic maintains dedicated time slots for transfusions each week, which are adjusted based on patients' needs and hemoglobin levels. This practice ensures that patients receive timely care while avoiding unnecessary interventions. Every patient who starts venetoclax therapy will be

Remission assessment and on-going patient management - continued

seen by a practitioner at least once a week, with visits alternating between a physician and advanced practice provider.

These strategies, grounded in both evidence and practice, ensure that hematologic adverse events are managed effectively while prioritizing patient well-being and quality of life throughout treatment.

Table 1. Venetoclax dosage modification for hematologic adverse reactions[4]

Adverse Reaction	Occurrence	Dosage Modification
Grade 4 neutropenia with or without fever or infection; or Grade 4 thrombocytopenia	Occurrence prior to achieving remission	In most cases, do not interrupt venetoclax due to cytopenias prior to achieving remission.
	First occurrence after achieving remission and lasting at least 7 days	Delay subsequent cycle of venetoclax and monitor blood counts. Upon resolution to Grade 1 or 2, resume venetoclax at the same dose in combination with HMA.
	Subsequent occurrences in cycles after achieving remission and lasting 7 days or longer	Delay subsequent cycle of venetoclax and monitor blood counts. Upon resolution to Grade 1 or 2, resume venetoclax at the same dose in combination with HMA, and reduce venetoclax duration by 7 days during each of the subsequent cycles, such as 21 days instead of 28 days.

PATIENT-CENTERED ACTIVITIES: EDUCATIONAL TOOLS AND FOLLOW-UP

PROVIDING patient-centered care is a critical component of successful AML treatment with venetoclax. One of the first steps in this process is ensuring that patients are informed about their prescription status and the availability of medications for pick-up. This may involve directly engaging the patient or a family member to coordinate with the pharmacy. Effective communication between the care team and the patient is essential, as emphasized previously by Ho, who highlights the importance of caregiver involvement to ensure a seamless process.

Horn elaborates on the value of an integrated care team within the provider's office. She explains that the inherent trust patients place in their doctor's office extends to the pharmacy team, fostering confidence in the care provided. By managing prior authorizations, financial assistance, and pharmacy coordination, the care team allows patients to receive their medications faster and with fewer obstacles. "Patients know they can call, ask for us by name, and we will answer their questions directly," she shares. This hands-on approach not only enhances the patient's experience but also ensures timely access to necessary medications and builds a solid foundation of trust and support throughout their treatment journey.

Several educational tools are helpful and available for patients with AML who are taking venetoclax. Pharmacists at all three clinics provide the NCODA-led Oral Chemotherapy Education Sheet to pa-

Patient-Centered Activities: Educational Tools and Follow-up- continued

tients. Shimanek notes that “OCE sheets have been monumental” for improving patient education. These sheets serve as a structured guide for both patients and care teams, ensuring clarity around medication schedules, side effect management, and treatment expectations.

Hecker emphasizes the value of supplemental tools such as calendars, which help patients track their treatment regimen. She highlights the importance of tailoring education to each patient’s unique circumstances and using clear, personalized communication. “Doing your homework” before engaging with the patient is crucial, as the patient often serves as the most accurate source of truth regarding their dosing and adherence. This preparation allows the care team to clarify any misunderstandings and avoid adding confusion.

Hecker also stresses the importance of listening to and learning from patients, adapting language or educational approaches as needed to ensure comprehension. Clear communication, continuous education, and keeping the clinic team informed are integral to maintaining a cohesive treatment plan. These practices foster patient trust and engagement while promoting adherence to venetoclax therapy.

As referenced in the PQI, Patients should be instructed on recognizing signs and symptoms of infection, such as fever, chills, sore throat, burning during urination, and unusual tiredness, and provided with clear guidance on who to contact should these symptoms arise. In addition to informing patients about the need for the follow-up bone marrow biopsy, patients should also be made aware that lab monitoring, such as CBCs, plays a role in treatment decisions. For patients requiring hospitalization for treatment initiation, it is important to review the steps for preparing for their hospital admission with both the patient and their caregiver. This discussion helps alleviate concerns and allows a smoother transition to inpatient care.

At Maryland Oncology Hematology, APPs conduct chemotherapy education sessions, with pharmacists supplementing this teaching through focused patient counseling. Pharmacists play a pivotal role in ensuring that patients understand the nuances of their venetoclax-based treatment, using tools like OCE sheets to explain complex topics such as dosing schedules and medication handling.

As Horn explains, counseling extends beyond just venetoclax. Pharmacists emphasize hydration, the importance of taking allopurinol to prevent TLS, and the rationale behind the entire treatment plan, including supportive medications. They also educate patients on avoiding grapefruit and managing side effects like gastrointestinal symptoms, fatigue, and diarrhea, ensuring patients have medications like loperamide on hand, if needed.

Shimanek underscores the importance of vigilance regarding infection risks, advising patients to report even minor symptoms such as fever (over 100.4°F), chills, or unusual fatigue. Patients are encouraged to be proactive and advocate for themselves, reporting any signs of bruising, bleeding, or other abnormalities, even if they seem minor.

Pharmacists also stress adherence to scheduled lab visits and close communication with the care team before making any changes to medication or treatment cycles. Educating patients about proper diet, sleep patterns, and staying active helps manage fatigue and improve overall quality of life during treatment.

Hecker highlights the role of oral pharmacy RNs at RMCC, who conduct follow-up phone calls at 7-day and 21-day intervals and then quarterly. These check-ins complement the pharmacists' work by addressing adherence, tolerance, side effect management, and psychosocial concerns. Patients may share information with one team member that they might not share with another, emphasizing the importance of collaboration within the care team. Hecker also uses the "teach-back" method, asking patients to explain how they are taking their medications following pharmacist instruction to confirm understanding and adherence.

As mentioned above, TLS is a concern in patients receiving venetoclax, particularly during treatment initiation and dose ramp-up, and is highlighted in the PQI Patient-Centered Activities. Proper risk assessment and preventative strategies are essential to ensure patient safety. The Venetoclax (Venclexta®) for the Treatment of Acute Myeloid Leukemia PQI and the TLS Risk Assessment Tool are valuable resources for detailed guidance on TLS risk stratification, ramp-up dosing schedules, dose adjustments for drug interactions, and patient counseling.

Dr. Narang emphasizes several key factors to consider when assessing TLS risk, including elevated LDH levels, impaired kidney function, and the need for oral or IV hydration. High-risk patients require close monitoring and may benefit from IV hydration and close observation in an inpatient setting during the initial ramp-up phase. Proactive measures, such as confirming that patients have adequate hydration and access to necessary prophylactic medications, reduce the risk of complications and improve patient outcomes.

IMPLEMENTING THE PQI IN CLINICAL PRACTICE

THE Venetoclax (Venclexta®) for the Treatment of Acute Myeloid Leukemia PQI serves as a practical and essential guide for healthcare teams, helping to standardize care while addressing patient-specific needs. Shimanek and Horn share insights into how the PQI is utilized in their practice to enhance patient care. Shimanek highlights that the PQI helps streamline processes, particularly in ensuring that pharmacists and the care team are aligned on critical tasks like assessing TLS risk, managing side effects, and coordinating medication access. Horn explains that the PQI serves as a framework for counseling and supporting patients throughout their treatment journey. She uses it to guide conversations about dosing, hydration, and supportive medications. Additionally, the PQI helps her make certain patients understand why each medication is necessary and how it fits into the broader treatment plan. She notes that the PQI improves efficiency by building standard practices, such as hydration protocols and TLS management, into the EMR, making it easier to provide seamless care.

Dr. Fletcher shares a best practice and underscores the importance of detailed documentation in facilitating continuity of care among colleagues. He ensures that all his notes for AML patients are structured consistently, with explicit details about treatment plans, supportive care protocols, and prophylactic measures. His notes include:

Treatment specifics, including venetoclax dosing, duration, and accompanying medications.

A supportive care section outlining transfusion goals, lab monitoring schedules, and transfusion thresholds (e.g., hemoglobin or platelet levels).

An infectious disease (ID) section specifying the patient's prophylactic regimen, including antivirals, antibiotics, and antifungals.

Dr. Fletcher explains, "If one of my colleagues is covering for me overnight and a patient issue arises, they can review my notes and immediately see the entire care plan—from the treatment schedule to supportive care and ID measures. This clarity allows for consistent care, even when I'm not directly available." By prioritizing precise, accessible documentation, Dr. Fletcher enables his colleagues to provide smooth, informed care at all times.

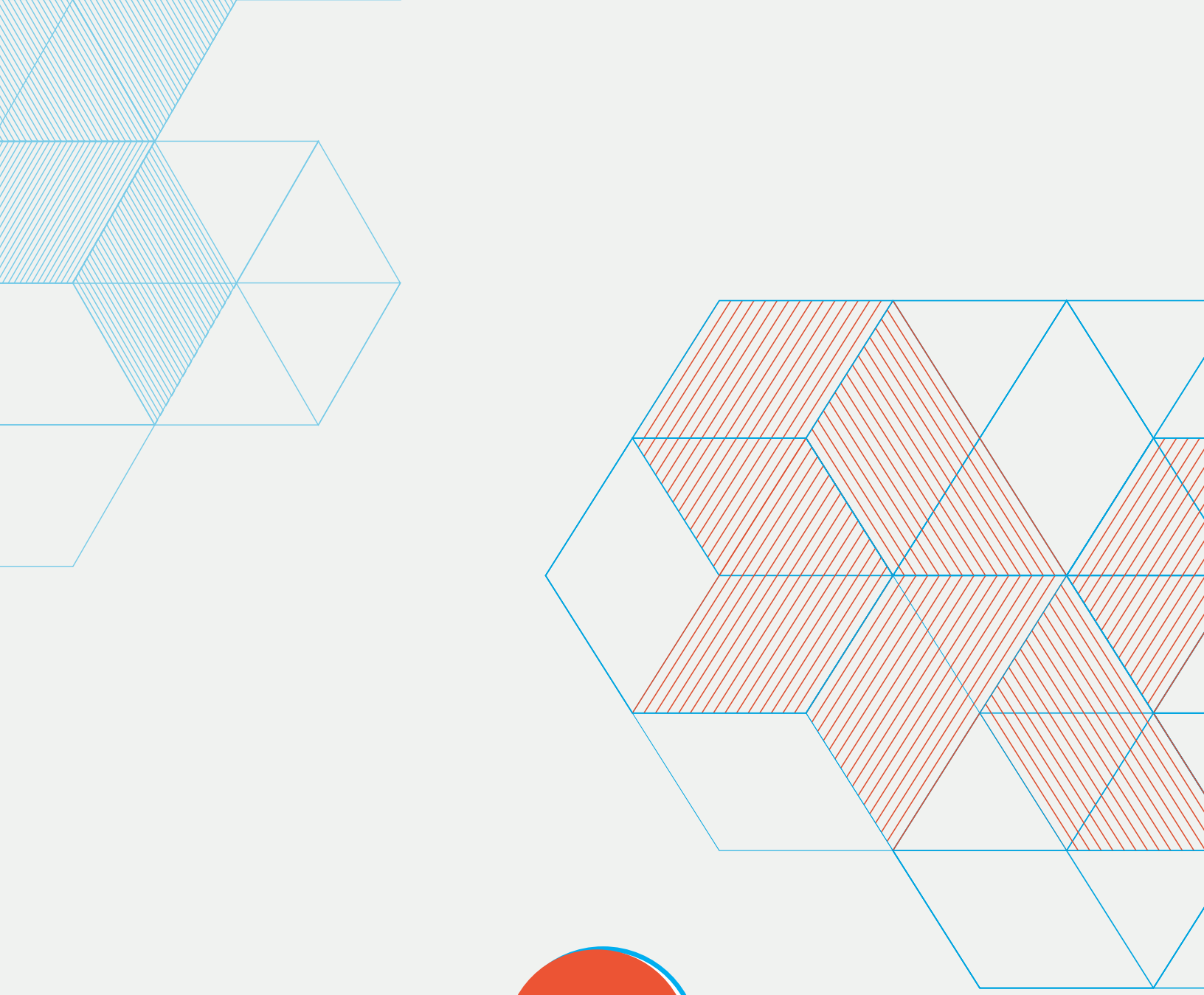
SUMMARY

THE PQI's structured approach to AML care empowers healthcare teams to deliver high-quality, patient-centered care while ensuring robust collaboration among providers. By implementing best practices such as detailed documentation and comprehensive communication, clinical teams can navigate complex treatment scenarios with confidence. This fosters not only improved outcomes for patients but also a cohesive and efficient clinical environment.

Positive Quality Intervention in Action

REFERENCES:

1. American Cancer Society. 2024, https://www.cancer.org/cancer/types/acute-myeloid-leukemia/about/key-statistics.html. Accessed 27 November 2024.
2. Choi J, Shukla M, Abdul-Hay M. Acute Myeloid Leukemia Treatment in the Elderly: A Comprehensive Review of The Present and Future. *Acta Haematol* 2023;146:431-57.
3. National Comprehensive Cancer Network Guidelines. Acute Myeloid Leukemia version 3.2024. https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed 26 November 2024.
4. Venclexta® (venetoclax) [prescribing information]. North Chicago, IL: AbbVie Inc.; July 2024.
5. DiNardo CD, Jonas BA, Pullarkat V, et al. Azacitidine and Venetoclax in Previously Untreated Acute Myeloid Leukemia. *N Engl J Med* 2020;383(7):617-29.
6. 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 2022*;135(24):2137-45.
7. Wei AH, Panayiotidis P, Montesinos P, et al. Long-term follow-up of VIALE-C in patients with untreated AML ineligible for intensive chemotherapy. *Blood 2022*;140(25):2754-2756.
8. Aldoss I, Dadwal S, Zhang J, et al. Invasive fungal infections in acute myeloid leukemia treated with venetoclax and hypomethylating agents. *Blood Adv 2019*;3:4043-4049.
9. Mei M, Aldoss I, Marcucci G, Pullarkat V. Hypomethylating agents in combination with venetoclax for acute myeloid leukemia: Update on clinical trial data and practical considerations for use. *Am J Hematol* 2019;94:358-62.
10. Jonas BA, Pollyea DA. How we use venetoclax with hypomethylating agents for the treatment of newly diagnosed patients with acute myeloid leukemia. *Leukemia 2019*;33:2795-2804.



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