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CHRONIC MYELOID LEUKEMIAS (MJ MAURO AND G SAGLIO, SECTION EDITORS)

A Multi-disciplinary Approach to Managing Chronic Myelogenous Leukemia Patients on Oral Anticancer Therapy at a Large Academic Medical Center

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Abstract

Purpose of Review Since the discovery of imatinib, an oral breakpoint cluster region—Abelson murine leukemia tyrosine kinase inhibitor, chronic myelogenous leukemia transformed from a hematologic malignancy primarily treated with intravenous chemotherapy to a disease almost solely managed with oral agents. While certainly there are benefits to taking a medication at home, this change in treatment modality also came with unique challenges, including patient adherence, medication acquisition and cost, and toxicity management.

Recent Findings Pharmacists are uniquely equipped to assist with educating patients, safe prescribing, and access to medications. Several studies have described the benefits of an integrated oral anticancer medication management program in the ambulatory setting, including improvements in patient adherence, side effect management, patient comprehension, and drug-interaction detection. Pharmacists are also specially trained to assist with medication dose adjustments, relative lab monitoring, and co-pay assistance.

Summary Here, we describe the multidisciplinary workflows established to manage oral therapies in chronic myelogenous leukemia patients in a malignant hematology clinic at a large academic medical center. By using the unique talents of the clinic pharmacist, clinic nurse, and specialty retail pharmacy group, patients can be triaged to help ensure the correct skill set is used to optimally care for patients. An acuity-based monitoring structure can improve the ability to reach and safely monitor a large volume of patients.

Keywords CML · Oral chemotherapy · TKI · Monitoring

Introduction

Since the discovery of imatinib, an oral breakpoint cluster region—Abelson murine leukemia (BCR-ABL) tyrosine kinase inhibitor (TKI), chronic myelogenous leukemia (CML) transformed from a hematologic malignancy primarily treated with intravenous chemotherapy to a disease almost solely managed with oral agents. Patients taking imatinib, a first-generation BCR-ABL TKI, had a major cytogenetic response of 87.1% compared to 34.7% in those receiving interferon plus cytarabine [1]. These results ultimately changed the landscape for the treatment of CML. After the discovery of imatinib came three second-generation oral TKIs (dasatinib, nilotinib, and bosutinib), and a third-generation oral TKI (ponatinib), providing a broader arsenal for oncologists to effectively treat CML, while allowing patients to take their medication in the comfort of their own home. While certainly there are benefits to taking a medication at home, this change in treatment modality also came with some unique challenges.

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Oral Anticancer Therapy Challenges

One challenge has been ensuring patients are adherent to their oral TKI therapy. The ability to self-manage their illness at home by taking a medication every day is appealing and comforting to most patients; however, this also places more onus on the patient to ensure that they are taking their medication every day. Non-adherence has been proven to adversely affect response rates in CML. Five-year event free survival (EFS) was found to be 76.7% in adherent patients versus 59.8% in non-adherent patients, with non-adherence defined as unwarranted interruption of treatment for more than 1 week [2]. Marin et al. found adherence was an independent predictor for obtaining major molecular response (MMR) in patients taking imatinib. Patients greater than 90% adherent to their imatinib treatment had a 6-year probability of obtaining MMR of 94.5 vs 28.4% of patients ≤ 90% adherent [3]. Uninterrupted treatment is critical to CML disease response, and yet it has been reported that up to 1/3 of patients are non-adherent with their regimen [4].

In addition to managing adherence, the conversion to oral therapy has created other challenges for the oncology clinician. Prescription co-pays may be unaffordable, despite patients having prescription insurance. Patients may also have a high deductible plan, again making access to their medication difficult [5]. The process for obtaining medication assistance and funding for these patients can be tedious and time consuming with additional paperwork and documentation required. Additionally, all of the oral agents used to treat CML have an abundance of drug interactions, requiring a trained critical eye for review. With the advent of oral TKI therapy came new, unique side effect profiles. Education to patients and their families is exceedingly important to ensure they can effectively manage these at home and know when to call their provider. When cost and side effects to oral therapy are not addressed or managed appropriately, they become additional barriers to adherence, ultimately leading to reduced efficacy of oral anticancer therapy [5].

Oral Anticancer Monitoring Program Background

These challenges have led many institutions to develop pharmacist-led oral anticancer agent monitoring programs. Pharmacists, as part of a multidisciplinary team, are uniquely equipped to assist with educating patients, safe prescribing, and access to medications. Several studies have shown that a pharmacist-managed oral anticancer monitoring program improves adherence, side effect management, patient comprehension, and drug-interaction detection while assisting with TKI dose adjustments, relative lab monitoring, and co-pay assistance [6, 7••]. Lam et al. found an imatinib adherence rate of 88.6% in a pharmacist-managed program compared to 65.8% in the usual care arm [6]. The oncology nurse can also play a vital role in an oral anticancer program team. A multidisciplinary approach with the clinic pharmacist and nurse working in tandem with the internal specialty pharmacy team only augments this approach further. Morgan et al. found patients receiving their oral anticancer agent from the institution's specialty pharmacy had a high medication possession ration (MPR) of 0.92, with MPR calculated as the days supplied divided by the total number of days observed [8••]. At Froedtert and the Medical College of Wisconsin, we have a pharmacist-led oral anticancer monitoring program where clinic pharmacists work closely with clinic nurses and the internal specialty pharmacy team to provide high-level follow-up for all patients receiving oral treatments. While our program encompasses all oncology disease states, herein, we will focus on how our interdisciplinary group manages the CML population.

Drug Acquisition

When it is determined that a patient will begin on an oral anticancer agent, a physician or advanced practice provider (APP) enters a medication-specific treatment plan into the patient's electronic medical record (EMR) to begin the insurance approval and acquisition process (see Fig. 1 for an overview of the acquisition process). Located within the treatment plan are several orders, including a referral to the clinic pharmacist, a test prescription, an electronic patient consent, and any supportive care prescriptions that may be necessary, such as antiemetics. The attending physician signs the above orders, plus the first prescription for the oral anticancer agent, which is located in Cycle 1 of the treatment plan.

The clinic pharmacist receives an electronic notification of a new referral to the oral anticancer program whenever a new treatment plan is placed and signed. This prompts the pharmacist to review the patient's chart for medication accuracy and appropriateness. The pharmacist screens for potential drug-drug interactions as well as drug-specific renal and/or hepatic dosing adjustments that may be recommended. If the pharmacist recommends changes to dosing based on their screening, they discuss it with the attending physician, who then updates the patient's treatment plan if they agree with the modifications. Once the correct drug and dose is verified, the pharmacist releases the test prescription from the treatment plan to Froedtert's Medication Prior Authorization (MPA) team. The MPA team is comprised

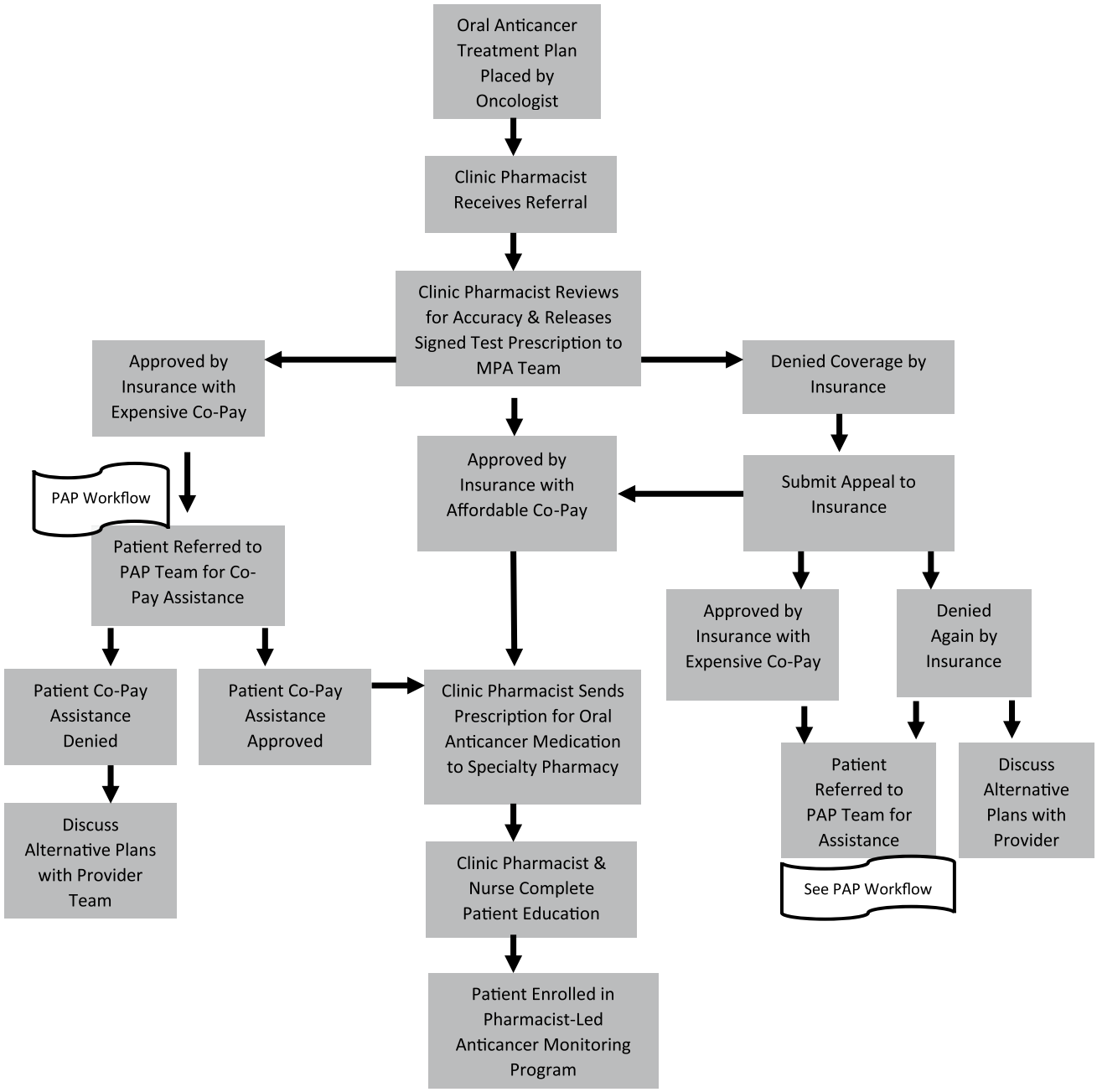

Fig. 1 MPA, Medication Prior Authorization; PAP, Patient Assistance Program. When the oncologist decides to start a patient on a new oral anticancer therapy, a treatment plan is placed and signed within the electronic medical record. A referral is sent to the clinic pharmacist which initiates the insurance approval process and subsequent acquisition of the medication for the patient. Our MPA team submits a test prescription to the patient's insurance company and completes any required prior authorizations and determines coverage for the medication. Sometimes, the provider is required to complete an appeal with insurance if the medication is denied coverage. Other times, the patient's co-payment may be expensive and they require financial assistance or their insurance denies an appeal, in which case our PAP team takes over to assist. There can be several steps in the process; however, our team's goal is to acquire the medication for the patient at an affordable cost and ensure appropriate education, monitoring, and follow-up moving forward

of over 50 pharmacy technicians who work on medication approval, prior authorization, and patient assistance throughout the Froedtert Health System. There are two technicians dedicated to the oncology service line at Froedtert Health, one who primarily works on oral medication prior authorizations, and the other works on financial assistance utilizing available patient assistance programs (PAP). The MPA team technicians are located within Froedtert Health's specialty pharmacy, which is certified by the Quality Oncology Practice Initiative.

Upon receipt of the test prescription, the MPA team begins the process by submitting the medication to the patient's insurance for approval. The test prescription contains all necessary elements of a prescription including drug name, dosage form and strength, dose, quantity, number of refills, and special instructions, but will not actively display on the patient's home medication list. Once the claim is submitted to insurance, the MPA technician documents updates in the "referrals" section of the EMR so that the treatment team can follow the submission progress.

If the oral anticancer medication is denied by the patient's insurance, the MPA team technician messages the team noting the denial and if an option is available to complete an appeal. If an appeal is pursued, the clinic team works with the attending physician to compose an appeal letter and gather supporting literature. These documents are then sent to the MPA technician who submits this information to the patient's insurance. Updates on the appeal process are documented by the MPA team within the EMR.

If a medication appeal is unsuccessful or if the medication is approved by the patient's insurance but has a high co-pay, the MPA technician sends an electronic message notifying the team and asks if they can contact the patient to pursue medication assistance. If the decision is made to pursue assistance, the patient will be referred to the PAP technician to assist with this process. The PAP technician tries to obtain financial assistance for the patient via several routes, including prescription drug grants, manufacturer co-pay cards, or manufacturer-provided medication programs. The PAP technician works closely with the patient, clinic pharmacist and nurse, and prescribing physician to obtain necessary signatures and patient information to complete assistance paperwork. If the patient is not eligible for assistance or is denied assistance, the PAP technician notifies the clinic pharmacist and nurse, who work with the attending physician and APP to determine next steps for the patient.

Once an oral anticancer medication is approved and is affordable for the patient, the MPA or PAP technician notifies the clinic pharmacist and nurse and documents the approval in the EMR, including dates of approval, copay information, insurance information, and dispensing pharmacy (if dictated by insurance). The patient is then scheduled for medication teaching and the clinic pharmacist sends the oral anticancer prescription and any applicable supportive care prescriptions to the dispensing pharmacy. Whenever possible, prescriptions are filled at a Froedtert internal pharmacy. This allows an easier path to determine adherence and refill records, as the clinic oral anticancer team works closely with the internal retail pharmacy team. Finally, the patient is scheduled for a collaborative teaching visit with both the clinic pharmacist and nurse.

Oral Anticancer Therapy Patient Education

The clinic pharmacist and nurse complete a comprehensive medication teaching with the patient and their support system when applicable. At this visit, any pertinent baseline laboratory and/or testing (i.e., electrocardiograms) will be completed. Written and verbal information is provided to the patient, including the patient's diagnosis, goal of treatment, schedule of medication administration, plan for missed doses, storage information, drug-drug and drug-food interactions, safe handling information, short- and long-term common adverse effects, rare but serious adverse effects, and symptoms that would require contacting their healthcare provider. Additionally, adherence is a major focus in this education session with patients and their families. Depending on the patient's treatment goals, a deep molecular response (BCR-ABL international scale $\leq 0.01\%$) for at least 2 years is important if the patient is interested in discontinuing their TKI treatment and moving into a treatment free remission (TFR). Several trials have demonstrated the safety and feasibility of treatment discontinuation in patients with CML who have achieved a sustained deep molecular response. Approximately 50% of patients who are eligible to attempt TFR are able to successfully discontinue their TKI. For example, the STIM trial found that imatinib could be safely discontinued with close follow-up in patients that had been on treatment for at least 2 years and with undetectable disease. At 12 months of follow-up, patients had a 41% probability of maintaining a complete molecular remission and all patients who relapsed responded when imatinib was reintroduced [9]. In a more recent publication, the LAST trial found that 60.8% of patients remained in TFR after TKI discontinuation [10]. It is important for patients to understand the importance of taking their medication every day and how this may impact their ability to reach the treatment milestones required for TKI discontinuation and TFR. At the teaching visit, the clinic pharmacist will introduce the oral anticancer monitoring program to the patient as an additional way for our team to monitor and support patients on CML treatment at our institution.

Monitoring and Refill Management

Once teaching has been completed, the clinic pharmacist adds the patient to a confidential list of patients on the oral anticancer monitoring program within the EMR. The clinic pharmacist will follow up with the patient via telephone call on a weekly basis for the first month of therapy, then monthly thereafter and will also coordinate the patient's

prescription refill during these follow up calls. If a refill is due, the clinic pharmacist releases the provider-signed prescription to the appropriate filling pharmacy. Refills are not added to the oral anticancer agent prescription until the patient has completed at least 3 months of therapy and on a stable dose for 2 months.

When the patient is due to be contacted for their routine follow-up or medication refill, the pharmacist calls the patient and documents a progress note in the EMR. The clinic pharmacist reviews the medication in detail, updates the home medication list, screens for new drug interactions, assesses most recent lab work, and inquires about missed doses. The patient is also asked about adverse effects or toxicities they may be experiencing and is triaged to the appropriate provider team if necessary. Further recommendations may be made by the pharmacist for follow-up labs, clinic visits, or additional supportive care prescriptions or over the counter (OTC) medications if needed.

Clinic Nursing Role

Oncology nurses play a vital role in the oral anticancer program team. Having the nurses involved in teaching visits has been a positive experience at our institution as they add valuable perspective and often assist with ensuring proper follow-up lab and provider appointments are scheduled. At Froedtert & the Medical College of Wisconsin, our oncology nurses work regularly with one attending and APP team, allowing them to see the same patients repeatedly and develop close and trusting relationships. This in turn improves the nurse's ability to identify treatment concerns early and address these with the provider. Our clinic nurses also answer live telephone triage in addition to patient messages sent via EMR. It is not uncommon for patients to call the triage line with side effects or toxicities to their treatment. Since our nurses are routinely involved in oral anticancer education, they are better equipped to recognize drug-related side effects and toxicities and work with the clinic pharmacists and providers to address these promptly. During telephone triage calls, the nurses can also help address symptoms, reinforce patient education, and discuss side effect management. They often collaborate with the pharmacist if the patient reports starting a new prescription or OTC medication to rule out any potential drug-drug interactions. For patients who are non-adherent or are having side effects that require stricter monitoring, the clinic nurse may schedule a nurse visit in between provider visits to allow for closer follow-up.

In addition to their role in patient education and management of side effects, the oncology nurse follows the BCR-ABL1 levels of CML patients, specifically those who are attempting a TFR, and calls them with their results. During these calls, the nurse provides additional education and reassurance to patients if needed. If TFR patients lose major molecular response (MMR), the nurse works with the provider team and clinic pharmacist to resume TKI therapy as quickly as possible.

Acuity-Based Monitoring Structure

Froedtert & the Medical College of Wisconsin is a busy academic medical center with high volumes of patients seen within the cancer center and on oral anticancer therapy. At the time of this review, a total of 424 patients on an oral anticancer agent are being followed by the clinic pharmacists in the malignant hematology clinic. One hundred six of these patients (25%) have a diagnosis of CML. Due to finite resources and the growing numbers of patients on oral anticancer medications, it was important to find a way to maintain the quality of our oral anticancer program despite increasing patient numbers. One way we accomplished this was by developing an acuity-based monitoring structure, which allows the clinic to better use the unique talents of each multi-disciplinary team member to improve our ability to monitor and reach each patient. This meant triaging patients, based on acuity, into two groups. One group includes those patients that require rigorous monitoring, and the second group includes those patients who have proven to be stable and require less frequent monitoring. This ultimately led to our sign-off procedure. See Fig. 2 for details on our number of patients and which patients have been signed off on by the clinic pharmacist.

In order for the pharmacist to sign-off from routinely following a patient, certain criteria must be met (Table 1). Not all anticancer medications are eligible for sign-off at our institution; however, all of our CML medications qualify. If the criteria are met, the clinic pharmacist notifies the patient that they will no longer be contacted on a routine basis and documents a progress note indicating that they are signing off. The next prescription refill for the oral anticancer medication will be sent with one year of refills. Although the clinic pharmacist no longer contacts the patient on a monthly basis, they continue to complete a clinical review of the patient each time the patient is seen in clinic. This includes a review of the patient's lab results and for drug-drug interactions, as well as their adherence and tolerability as reported to the nurse, APP, or attending physician during their visit. If the patient is determined to no longer meet sign-off criteria, the clinic pharmacist resumes monthly telephone calls with the patient. Or if a patient in TFR loses MMR and needs to resume treatment, the clinic pharmacist will assist with regaining access to their medication, sending

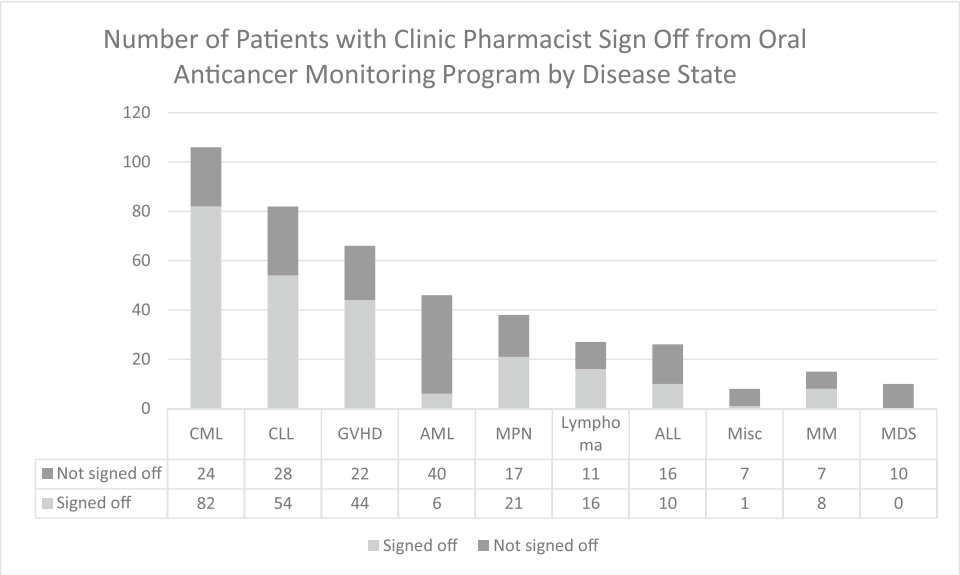

Fig. 2 CML, chronic myelogenous leukemia; CLL, chronic lymphocytic leukemia; GVHD, graft versus host disease; AML, acute myeloid leukemia; MPN, myeloproliferative neoplasm; ALL, acute lymphoblastic leukemia; MM, multiple myeloma; MDS, myelodysplastic syndrome. At Froedtert and the Medical College of Wisconsin, pharmacists in the malignant hematology clinic can sign off from following patients on the oral anticancer program when they have shown they are stable on therapy and adherent to their medication (see Table 1 for sign off criteria). Patients with chronic malignancies, such as CML and CLL, have a higher number of patients eligible for sign off. The 8 patients in the miscellaneous category include patients receiving oral anticancer medications for systemic mastocytosis, Erdheim-Chester disease, hairy cell leukemia, and acute promyelocytic leukemia

Table 1 At Froedtert & the Medical College of Wisconsin, an acuity-based monitoring structure was developed to allow pharmacists the ability to sign off and transition monitoring to the specialty pharmacy when stable. Stable patients are defined as meeting the below criteria. Certain high-acuity anticancer medications are not eligible for sign off; however, all the CML TKIs are eligible

Criteria for oral anticancer program sign off
• Patient has completed 3 months of the medication AND meets all of the following
• No medication dose change required for past 2 months
• No medication holds or delays required for past 2 months
• No pertinent lab abnormality for past 2 months
• No adherence issues for the past 2 months
• No significant medication related toxicity for the past 2 months
• Patients medication list does not contain significant medication interactions requiring close monitoring
• Patient clinically has shown they are able to manage the medication without rigorous monitoring and phone calls from the clinic pharmacist

the prescription to the appropriate pharmacy, and will reenroll the patient in the Oral Anticancer Chemotherapy Monitoring Program with monthly follow-up calls. As mentioned previously, we attempt to fill oral anticancer agents with our internal specialty pharmacy team. If the clinic pharmacist signs off, our specialty retail pharmacy team assumes responsibility for monitoring the patient on a routine basis. They work collaboratively to alert the oncology clinic team when there are adherence or toxicity concerns with a patient. Using our retail specialty pharmacists as extenders has been a helpful approach to keep these patients under close surveillance despite no longer receiving a monthly call from the oncology clinic.

Discussion

Our team's clinical review and follow-up is a continuous process for as long as the patient remains on their oral anticancer medication. It is important for the patient to continue to be followed and monitored throughout their treatment. This may include more rigorous phone follow-up and lab monitoring for high acuity patients, and less follow-up for others based on the patient's needs and whether signing off is deemed appropriate. Regardless of the patient's unique follow-up plan, the clinic pharmacist continues completing a clinical review at a minimum of each clinic touch point. At the time of this review, 82

out of the 106 patients with CML are managed primarily by retail specialty pharmacists, clinic nurses, and clinic providers with the clinic pharmacist completing periodic clinical reviews. The clinic pharmacists more rigorously monitor and manage the remaining 24 patients with CML. In addition to ongoing clinical and adherence assessments, our PAP technicians track patients who need grant funding or manufacturer assistance and contact them to renew funding and ensure uninterrupted access to medications. Additionally, if the patient or retail pharmacy alerts us that their insurance is changing, the MPA team will reinitiate the authorization process with the new insurance to ensure the medication is approved as quickly as possible.

Because our malignant hematology clinic follows a substantial volume of patients, we have been evolving our program over the years to adapt and use the resources we have to allow for the best care for our patients. The number of patients on oral anticancer medications continues to rise; however, the number of pharmacy resources is not necessarily increasing at the same rate. While CML medication management is a large part of our program, we also monitor patients on oral anticancer medications for other disease states, as well as patients who are receiving intravenous anticancer treatment or other supportive therapies. By approaching our oral anticancer monitoring program as a multidisciplinary team, utilizing oncology clinic pharmacists, oncology clinic nurses, internal retail specialty pharmacists, and pharmacy technicians, we have been able to triage patients to help ensure the correct skill set is used to optimally care for patients. The clinic pharmacist may manage patients with higher acuity, while more stable patients are signed out to our retail specialty pharmacy colleagues. Clinic nurses assist with anticancer agent education, insurance paperwork, phone triage, BCR-ABL1 level monitoring, and ensuring appropriate follow-ups are scheduled. Lastly, our pharmacy technicians ensure continuous access to oral anticancer medications by working through insurance issues, prior authorizations, and assistance.

Inherent challenges still exist with managing a large volume of patients. Patients may still not fill their oral anticancer prescription refill, not answer their phone or return voice messages, or stop coming to appointments. Despite our best efforts, patients may still have an unintended break in treatment. Patients may have a change in insurance or insurance lapse that ultimately leads to a gap in treatment while our team attempts to get their medication re-authorized. Another potential treatment disruption is at the start of the New Year when large volumes of patient assistance are renewed: patient assistance programs are often inundated with renewal requests, which can lead to treatment interruptions. Despite these challenges, we believe our program provides high-quality care and follow-up to this increasing group of patients taking oral anticancer treatment.

Conclusions

Oral anticancer agents provide effective and convenient treatment options for patients with chronic myelogenous leukemia. There are some inherent challenges with these therapies, including medication access, patient adherence to therapy, and extensive monitoring for safety and efficacy. Based on our institution's experience, a multidisciplinary, pharmacist-led oral anticancer agent monitoring program can help ensure patients receive access to medications, appropriate education, and structured follow-up.

Compliance with Ethical Standards

Conflict of Interest Angela Canadeo, Mary Fournogerakis, and Felicia Zook declare no potential conflicts of interest.

Human and Animal Rights and Informed Consent This article contains no studies with human or animal subjects performed by any of the authors.

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