

Steps to Success:

Integrating Oral Oncolytics into Chronic Lymphocytic Leukemia (CLL) Practice

Introduction

In the last decade, oral oncolytics have transformed the treatment landscape of Chronic Lymphocytic Leukemia (CLL). At the time of this publication, six oral agents have been approved by the U.S. Food and Drug Administration (FDA) for the treatment of CLL: acalabrutinib, ibrutinib, duvelisib, idelalisib, zanubrutinib, and venetoclax. These oral agents have not only enhanced outcomes compared to traditional intravenous chemoimmunotherapy but have also provided the opportunity for more convenient medication administration.¹ However, with the increased use of oral therapies, the cancer care team now faces challenges such as medication adherence, polypharmacy, financial toxicity, and interruptions in continuity of care.^{2,4}

As the use of oral oncolytics grows, cancer programs must prepare themselves for the successful implementation of oral therapy programs. Effective integration of oral oncolytics into community practice depends on multidisciplinary collaboration, accurate and efficient medication dispensing, patient education and adherence, and thorough data capture.⁴ A multidisciplinary team, including physicians, advanced practice providers (APPs), nurses, pharmacy staff, financial navigators, and social workers are essential to providing patients with optimal clinical, financial, and psychosocial support throughout their treatment journey.

Various factors impact timely medication dispensing. Most notably, prior authorization, access to specialty medications and insurance processing. Establishing insurance coverage is often the rate-limiting step to filling oral oncolytic prescriptions, particularly when prescriptions must be filled at an outside specialty pharmacy based on insurance requirements. Having processes in place to navigate the potential financial barriers is an important operational component of oral oncolytic dispensing.

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Medication adherence is strongly linked to the patient's comprehension of their disease and treatment. Effective patient education is vital to establishing adherence and compliance.⁵ Utilizing a multidisciplinary care team to deliver education can be a powerful approach to helping patients understand different aspects of treatment. While prescribers are often the first to educate patients and their caregivers about CLL, other care team members, such as nurses and pharmacists, can help counsel patients about the importance of treatment, how to take medications, treatment duration, common side effects, and potential drug interactions. In addition, a multidisciplinary approach is important in supporting shared decision-making between the healthcare team and the patient to select the optimal treatment plan.

Lastly, data capture and outcomes reporting are necessary to assess the success of an oral oncolytic program. Concrete outcomes data is needed to gauge the impact of specific interventions and process changes, as well as to identify areas of opportunity. Cancer programs should continuously consider how they can measure outcomes when implementing oral oncolytic programs into their practices.

With oral oncolytics as frontline treatment for CLL, providers must understand the complexities of these medications—from the logistics of dispensing to the challeng-

es of adherence—to effectively incorporate them into practice. To optimize the integration of oral agents into community practice, the Association of Community Cancer Centers (ACCC) has published the following Effective Practice Guide. It aims to help cancer centers navigate through the challenges of oral oncolytic regimens.

Survey Results

In early 2022, ACCC conducted a survey across its provider network to evaluate current practice patterns in integrating oral oncolytics into CLL practices. Survey participants included 49 practices. One-third of respondents represented academic and/or National Cancer Institute cancer programs, while one quarter each came from private practice and community cancer programs, and 16 percent represented hospital/hospital systems.

Among the 130 respondents, 58 percent were medical oncologists, and the others were nurses (15%), other physicians (10%), pharmacists (8%), financial/patient navigators (7%), advanced practice providers (6%), social workers (3%), and administrators (3%).

The landscape survey also assessed the percent of CLL patients treated per year within responder practices. Greater than 50 percent of practices treat at least 50 CLL patients per year.

Nearly half of all respondents reported that their program does not have an established workflow for integrating oral oncolytics into CLL practice. For the 40 percent of

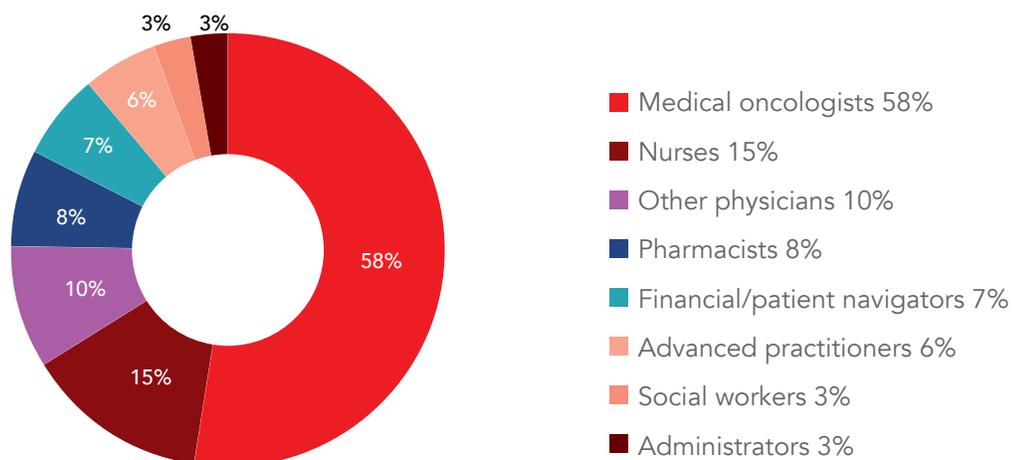
programs that do have established workflows, the most referenced workflows were multidisciplinary team coordination, coordination with specialty pharmacy, assessment of coverage and financial assistance programs, patient education, and processes for monitoring adherence and adverse events.

In terms of patient education, the survey found that 81 percent of cancer programs use materials from provider organizations (i.e., National Comprehensive Cancer Network, ACCC, NCCN), 42 percent use resources from patient advocacy organizations, 38 percent use pharmaceutical manufacturer patient education resources, and 38 percent use in-house created or adapted materials.

The use of these resources highlights the importance of tailoring patient education to specific needs and challenges faced by the patients. By continuously evaluating and improving patient education resources, providers can better equip patients with the knowledge and tools needed to effectively manage their care. It is equally important to ensure that providers are well informed about the latest treatment options and best practices. Education for multidisciplinary care team members about integration of oral oncolytics occurs primarily through continuing education programs (34%), written documents/guidelines (33%), and live in-person or virtual trainings (26%).

When it comes to determining the type of treatment for a patient with CLL, respondents noted that patient performance status, age of patient, out-of-pocket costs, and

Figure 1. Survey Participants Breakdown by Role



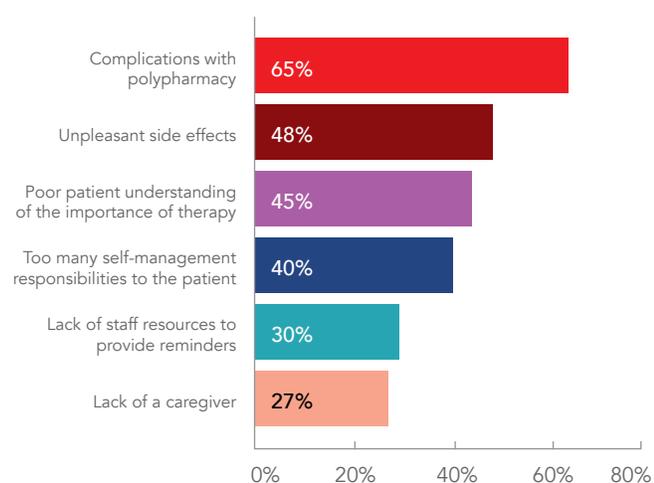
comorbidities are the major factors that impact choice of therapy. The primary barriers to choosing oral medications over IV treatments for patients with CLL, were cost of medication, patient adherence, patient cognitive factors, care coordination and operational challenges (i.e., external pharmacy drug supply, delays in obtaining medication).

Cancer programs can adopt several strategies to overcome the barriers to using oral oncolytics effectively. These strategies include patient and caregiver education, financial advocacy/navigation, referrals to social workers and financial advocates, and utilization of nurse navigators and/or pharmacy staff to communicate with specialty pharmacies. In addition, oral oncolytics adherence programs, CLL treatment-related pathways/practice protocols, and comprehensive geriatric assessments can also help improve patient outcomes. Lastly, cancer programs can facilitate referrals to patient advocacy organizations and provide healthcare providers with education about health literacy and adherence strategies, as well as transition services to enhance the quality of care delivered to patients.

Regarding adherence to oral oncolytics, survey respondents reported that the top three challenges to adherence were complications of polypharmacy (65%), unpleasant side effects (48%), and poor patient understanding of the importance of therapy (45%).

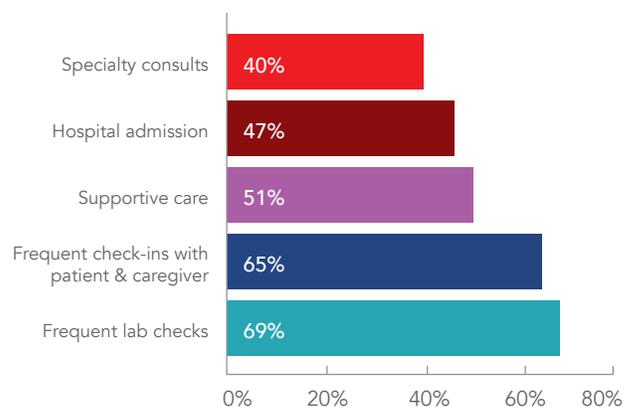
In-person toxicity and adherence assessments (58%), use of calendars and diary sheets (55%), and frequent commu-

Figure 2. Top Challenges to Medication Adherence



nication with patients (51%) were the main strategies used to enforce adherence to oral oncolytics.

Figure 3. Managing Toxicities of Oral Oncolytics



To manage toxicities of oral oncolytics, programs institute frequent lab checks (69%), frequent check-ins with the patient and caregiver (65%), supportive/palliative care services as needed (51%), hospital admission when indicated (47%), and consultation of other specialties (40%).

Financial toxicity is a significant challenge faced by cancer patients, which impacts access to necessary treatment and overall well-being. However, cancer programs can adopt several strategies to mitigate the financial burden experienced by patients. The survey data showed the primary strategy for managing financial toxicity is the identification and enrollment of patients into manufacturers' free drug or copay assistance programs (68%). In addition, patient education about insurance coverage and the cost of cancer care (60%), screening for risk of financial distress (58%), insurance coverage optimization (57%), incorporation of financial considerations into shared decision making (42%), and referral to external organization (22%) are effective strategies to manage financial toxicity. These results suggest that a multifaceted approach to manage financial toxicity can help alleviate the burden experienced by patients. -

Case Studies

Penn Medicine Lancaster General Health

LOCATION: Lancaster, Pennsylvania

CENTER TYPE: Community Cancer Program

CLL PATIENTS TREATED: Approximately 100 CLL patients/year

PHARMACY TYPE: Internal Specialty Pharmacy Providers/Medically Integrated Dispensing



The Ann B. Barshinger Cancer Institute of Penn Medicine Lancaster General Health (LGH) is a comprehensive community cancer program servicing Lancaster County, Pennsylvania, that treats more than 100 patients with CLL per year. Lancaster General Health has their own specialty pharmacy through which CLL oral oncolytics are processed and dispensed. Oral oncolytic prescriptions are ordered by physicians through the Epic EMR system after which they are routed to the system's specialty pharmacy.

The specialty pharmacy team then works on processing the prescription and submitting the insurance authorization. Depending on the medication or the patients' insurance, the oral oncolytic may need to be filled at a specific site (i.e., other specialty pharmacy, or pharmacy benefits manager (PBM) specialty pharmacy, etc.), which the LGH specialty pharmacy team helps to determine.

Lancaster General Health has a medically integrated pharmacy that helps to streamline communication between the dispensing pharmacy and the clinic staff and to reduce delays from the medication being prescribed to the time it is available for the patient. When the health system pharmacy receives a prescription for an oral oncolytic, it alerts clinic prior authorization nurse, clinic triage nurse, and clinical oncology pharmacist via the electronic medical record (EPIC) to initiate the process of oral oncolytic dispensing.

One difference at Lancaster General Health is a prior authorizations nurse who is solely dedicated to insurance authorization. This nurse tracks the oral oncolytic prescription to ensure that it's being processed through the insurance. If there is an insurance denial or high copay, the specialty pharmacy will alert the prior authorization nurse. For denials, the nurse will work on the appeal and for high copays, the nurse will send a referral to McKesson to seek financial assistance.

The prior authorization nurse serves as a liaison between the specialty pharmacy, McKesson and the patient and follows the prescription until it is safely in the patients' hands. Recently, the program noted that nearly every McKesson referral was going directly to pharmaceutical companies for a free drug. Due to this finding, a specialty pharmacy team member has been obtaining grant money for patients in need instead of automatically applying for a free drug, greatly reducing medication turnaround time since grant funding is much more quickly obtained than a free drug.

One difference at Lancaster General Health is a prior authorizations nurse who is solely dedicated to insurance authorization.

While the oral prescription is being processed through the specialty pharmacy, several other efforts are being coordinated simultaneously, depending on when the medication is expected to arrive. After the initial prescribing, the nurse navigator and clinic triage nurses will consult with the physician regarding relevant labs, electrocardiogram, and other necessary monitoring and relay this information to the schedulers. The nursing team works with the scheduling team to schedule necessary appointments ahead of time and is key to ensuring that important labs and monitoring are not neglected in the time that it takes the patient to receive the medication.

At the same time, the clinic oral oncolytic pharmacists will review the prescription for appropriateness, document the regimen in the chart, and schedule the patient for an oral chemotherapy education session. This in-person oral chemotherapy education session informs the patient on monitoring parameters, drug interactions, supportive care medications, potential start date, etc. For patient education at Lancaster

General Health, patients are given information packets from Penn Medicine's Oncolink website as well as clinic contact information and calling parameters.

Oral chemotherapy workflows are developed by clinic oncology pharmacists. Scheduling of treatment education, monitoring, and lab visits are coordinated based on an estimate of when the medication will arrive, thus it is imperative that team members communicate thoroughly and effectively. The cancer care team at Lancaster General Health primarily communicates via EPIC EMR system in-basket messages and chart notes. When the specialty pharmacy receives a prescription, they document this in a telephone encounter, which gets routed to the pharmacy authorization team and the prior authorization nurse. From submission of the authorization, to filling of the prescription, the specialty pharmacy team and prior authorization nurse documents every step of the process. The only instance when the communication is outside of the Epic EMR is if the prior authorization nurse sends a referral to McKesson for financial assistance, at which point the communication is done through email.

In the best-case scenario, the patient can receive their medication within 24 – 48 hours of the prescription being written if insurance authorization is obtained the same day. Delays occur depending on the patient's insurance. Additional delays are experienced when the medication needs to be filled from a source outside of the health system. Lancaster General Health has found that the prior authorization nurse is essential in ensuring the prescription is moving along at each step. When a prescription is filled by an external pharmacy, a triage nurse follows up with the pharmacy after the first prescription. This is to confirm that the prescription is filled and delivered to the patient to ensure coordination of patient care.

Having a staff member solely dedicated to tracking these prescriptions has greatly enhanced the efficiency of their oral oncolytic process overall.

Once a patient receives the oral oncolytic, the cancer care team follows up with them once a week for four weeks, then

every other week for two weeks, and then a month from the last bi-weekly session. Patients who are having difficulties with their oral oncolytic are continuously followed at weekly intervals. If patients are experiencing potential side effects, the nurses will conduct a full clinical assessment, give recommendations, and escalate to providers as needed. The cancer center has a physician assistant who is available during the day to see patients for urgent side effect evaluation, and a physician who is on-call every night.

To maintain adherence, the specialty pharmacy tracks when patients are due for their next refill and the nurses conduct follow-up calls as much as possible to ensure that patients are taking their oral oncolytic. These efforts are documented in the chart and routed to the provider only if the patient is having an issue.

One barrier noted by Lancaster General Health is the amount of outreach that patients are receiving from cancer care team members. For instance, for CLL regimens that include both oral and IV agents, the patients are receiving two separate education sessions from different providers, which is helpful in reiterating the regimen, but also complicates things as more drugs and more people are involved. From the specialty pharmacy to schedulers to different nurses, the patient may be getting phone calls from many unfamiliar people, which could prevent them from returning important phone calls. In addition, low health literacy can further complicate these dynamics. Thus, an area of improvement is to explain to patients—at an appropriate health literacy level—what to expect throughout the process in terms of logistics and communication.

Another area of opportunity at Lancaster General Health is in data capture for their oral oncolytic program. When the prior authorization nurse role was initially implemented at their center, data was being tracked for the first few years to document how the role was affecting turnaround time, medication adherence, and other metrics for oral chemotherapies. More recently, however, there have been gaps in data capture and opportunities to enhance metric tracking to better understand how the oral oncolytic program is impacting their patients.

Key Takeaways:

- Automated process for benefits investigations and financial assistance assessment reduces time to fill for oral oncolytics in CLL
- Utilization of translation services to provide patient education materials in patients' native language increases patient comprehension and closes the education gap
- Pharmacist led patient case management program for oral oncolytics provides in-depth tailored education and outreach

American Oncology Network

LOCATION: Fort Myers, Florida

CENTER TYPE: Integrated Health Network

CLL PATIENTS TREATED: Approximately 100 CLL patients/year

PHARMACY TYPE: Internal Specialty Pharmacy Providers/Medically Integrated Dispensing



American Oncology Network (AON) is a network of health-care providers within community oncology settings who partner together to optimize community-based oncology care. Currently, AON's platform consists of 107 physicians and 89 advanced practitioners across 18 states in over 70 clinics. AON covers all areas of hematology and oncology in addition to some non-oncology services. They treat over 100 patients with CLL per year. By servicing many rural areas, AON expands access to high-quality cancer care around the country, ensuring that all patients receive optimal management.

Since AON is a network of community-based practices rather than a singular community center, its business model is different from that of traditional practice sites. At AON, many patient services are centralized to streamline care, including specialty pharmacy, pathology and diagnostics services. When AON assimilates a practice into its network, it dissolves any existing specialty pharmacy licenses associated with the practice, using its clinical and management expertise to assist the community site in centralizing services through AON's own specialty pharmacy. AON's specialty pharmacy provides oral oncolytics to approximately 70 clinics and ships the medications to patients.

While decentralized specialty pharmacies may be more convenient in some regards, the advantage of a centralized pharmacy is that it can be more cost-effective for smaller practices by reducing their overhead. Having a centralized pharmacy model also means that new practices joining AON without

their own specialty pharmacies will not need to set up anything—they can simply use the already established specialty pharmacy. Additionally, AON's centralized specialty pharmacy is a medically integrated dispensing pharmacy that allows streamlining of care coordination and communication.

When a provider within AON is ready to prescribe an oral oncolytic, they will send the prescription to the AON pharmacy via their electronic medical system (most commonly OncoEMR). Upon receipt of the prescription, multiple steps occur to process the oral oncolytic in the following order: a clinical pharmacist reviews the prescription for appropriateness; benefit investigation is conducted for active coverage; prior authorization is submitted; patient financial assistance is consulted as needed; the patient is contacted to schedule delivery; the prescription is filled and shipped; pharmacists provide counseling; and clinic nurses review the EMR prior to subsequent refills to evaluate appropriateness for continuation of treatment and to reduce waste. At AON, there is an internal centralized prior authorization team that takes care of filing prior authorizations, managing denials, and submitting appeals. Once a prescription is approved, a team of technicians works with the patient and prescriber to secure financial assistance. This includes copay cards, grants, assistance funds, or potentially free drug from the manufacturer if the patient meets criteria. AON prioritizes taking a proactive approach on ongoing annual renewal of applications for medication grants and patient assistance programs to secure financial assistance for the patient and reduce the administra-

tive burden for network clinics.

Approximately three-quarters of prescriptions are processed through the AON pharmacy, and the other quarter is transferred to other specialty pharmacies based on the patient's insurance requirements. For prescriptions that cannot be filled at AON, the AON technicians ascertain which preferred pharmacy is in the network and arrange for the prescription to be sent out. Even if the prescription cannot be filled at the AON pharmacy, the AON prior authorization team will complete a benefits investigation and financial assistance work-up for the patient to ensure that there are minimal delays to the patient obtaining the medication. In fact, the AON team has automated its benefits investigation and financial assistance process, through a partnership with a company called RxLighting, to significantly reduce the time to fill for oral oncolytics. Furthermore, to ensure that nothing falls through the cracks, the technicians then follow up with the outside pharmacy daily until the medication is shipped to the patient.

The typical turnaround time from when the prescription is initially written, to when the patient receives the medication is around 72 hours. Some medications can even be delivered the same day if there are no insurance issues. At AON, there is a quality management committee consisting of senior leadership staff that are responsible for ensuring that oral oncolytic prescriptions are being processed in a timely fashion. Prior to the patient taking their first dose of a medication, a clinical pharmacist will call them to provide counseling over the phone.

AON's centralized specialty pharmacy is a medically integrated dispensing pharmacy that allows streamlining of care coordination and communication.

Depending on the medication, patients will be monitored monthly or more frequently (weekly or biweekly) after first starting the medication in the form of nursing assessments lab checks, or phone calls to the patient. At AON, all patients who receive oral oncolytics are enrolled in Pharmacist-led care management program that provides structured patient outreach calls and education. AON also maintains a list of oral oncolytics that have more complex regimens or adverse event profiles to provide tailored in-depth education and

outreach to patients on these therapies. Additionally, AON utilizes in-house translational services to translate patient education materials into multiple languages, thereby improving the quality of patient education by bridging the language barrier gap and improving health literacy.

When a patient calls in with questions or concerns, the care management team triages the issues and helps to determine what type of support the patient needs (i.e., do they need to be seen in the clinic? Should they be admitted to the hospital? etc.). The medical team members most commonly communicate via the EMR; pharmacy staff will post interventions and notes in the EMR. AON also provides a dedicated email address that patients can use to reach providers for questions, concerns, or status updates with a quick turnaround time. In addition, patients can also contact AON providers 24-hours, seven days a week, on their toll-free number or leave feedback on survey calls.

In addition, AON utilizes various patient education resources to help educate patients. They include NCODA Oral Chemotherapy Education (OCE) sheets, Chemocare resources, as well as manufacturer-provided patient starter kits.

Overall, AON reports strong adherence to oral oncolytics among their patients as the medications are primarily filled within their system, so they can monitor how patients are taking their medications and follow up about refills. A potential area of improvement identified by AON is their use of technology; AON leadership has noted that they would like to leverage technology to better engage and empower patients to be more proactive in their healthcare.

Key Takeaways:

- In-person patient education sessions at the initiation of oral oncolytic allow for a thorough assessment of patient health-related social needs
- Comprehensive patient education resources that include disease education, medication education and cancer-related terminology increase patient health literacy
- Developing integrated medication and appointment calendar together with a patient during 1st education session greatly increases patient understanding of treatment plan

Pontchartrain Medical Center

LOCATION: Covington, Louisiana

CENTER TYPE: Community Cancer Center

CLL PATIENTS TREATED: Approximately 10 CLL patients/year

PHARMACY TYPE: Internal Physician Dispense/MID



The Pontchartrain Cancer Center (PCC) is a private community practice located in Hammond, Louisiana, that services a rural population with an average of one to 10 patients with CLL per year. At PCC, the oral oncolytic process starts with the provider prescribing the oral medication to the in-house pharmacy. Due to Louisiana state laws, the in-house pharmacy at PCC is a physician-dispensing pharmacy that does not utilize pharmacy technicians. After the order is placed, a separate treatment plan visit is scheduled for patient education and consent.

Like other programs, prescriptions that are filled inhouse are often filled within 24 to 48 hours if there are no prior authorization issues. At PCC, nurses complete the prior authorizations for oral oncolytics. If a prescription cannot be filled in-house due to insurance requirements, then the script is sent to another specialty pharmacy, with which a PCC nurse conducts daily follow-up calls to ensure the prescription is being processed in a timely manner. The average turnaround time for outside prescriptions is five to seven days, and all the oral oncolytic prescriptions are tracked in a log to ensure that patients are obtaining their medications within a week or less. Any significant delays are escalated to upper management at PCC. All documentation for the oral oncolytic process is completed in PCC's OncoEMR system or on spreadsheets.

At the treatment plan visit, the goal is to be able to deliver the oral oncolytic directly to the patient. Providers at PCC find that having the medication on hand greatly enhances the effectiveness of the patient education. One unique aspect of patient education at PCC is that the center has cultivated a robust "binder" of information for patients and caregivers ranging from typical drug information to practical tidbits, including suggested home remedies, calling precautions, emergency room parameters, and a glossary of oncology-specific medical terminology. The nurses also build calendars into the patient handouts to highlight therapy start dates, lab draws, refill reminders, and more.

The patient calendar includes a comprehensive patient treat-

ment plan with follow-up clinic visits and lab monitoring (built in the same visit), which improves patient understanding of the treatment plan and the overall process. Of note, PCC has a separate protocol for venetoclax prescriptions in which the ramp-up schedule is built into the patient calendar. Patients are encouraged to bring the calendar and education binder to all their clinic appointments as well as to other healthcare providers (i.e., primary care physicians and specialty providers) to ensure better communication across healthcare teams taking care of oncology patients.

Once a patient starts on a medication, a nurse will follow up with the patient within several days of initiation, as well as weekly or monthly calls to ensure compliance. After an intervention (i.e., dose reduction), patients are followed up within 24 hours. Even with monthly compliance calls, the patients are also scheduled to come to the clinic once a month for evaluation. As with prescription turnaround time, compliance is also tracked, and reasons for non-compliance are examined by upper management. Telemedicine is also utilized by the providers throughout the month to discuss side effects, insurance coverage, and more comprehensive aspects of care, such as advanced care planning.

PCC prides itself on being a close-knit community practice that knows its patients intimately and provides personalized care to patients and families. For example, the nurses provide hand-labeled pill boxes to patients to simplify medication administration, if needed. Because they have such a close relationship with their patients, the nurses and providers at PCC can evaluate the patient's health literacy, psychosocial barriers, and caregiver support before starting a patient on therapy. Additionally, the practice will consult home health agencies for medication management as needed.

Despite their thorough oral oncolytic process, PCC providers face various challenges in ensuring that oral therapies are processed and administered successfully. One of the major obstacles noted is the influence that health insurers have over

the dispensing of prescriptions. Based on insurance demands, many patients may be required to have their specialty prescriptions filled at outside pharmacies. A common theme of outside specialty pharmacies is that they may dispense a 90-day supply of medication, which, in the setting of a new oral oncolytic, can lead to unnecessary drug waste and spending if patients have tolerability issues and need dose modifications or medication changes. A better practice, according to PCC leadership, may be to implement shorter fills of medications upfront to assess tolerability and adherence before prescribing a full supply. Care coordination challenges may occur when a prescription is filled at the outside specialty pharmacy, especially if a patient is receiving education from an outside SPP in addition to an in-office dispensing pharmacy. For instance, if the prescriber has recently reduced the dose of the medication, but that script has not been fully processed yet, it is possible that the outside specialty pharmacy may call the patient to educate on the original dose, which would be confusing for the patient.

Furthermore, there is often a lack of communication between specialty pharmacy coverage and infusion coverage, which presents a problem when patients need to start on combination intravenous (IV)/oral regimens. In general, PCC prefers to start both IV and oral medications at the same time (when indicated and clinically appropriate) to minimize confusion and improve adherence, but if there are delays in coverage for the oral portion, they will start the IV medication first. If initial debulking with an IV agent is necessary in CLL, then the practice will stagger the start of the IV and oral oncolytics.

Ultimately, while insurance payers are necessary, the differences in prior authorizations and dispensing requirements add another layer of complexity to an already-complex system, and payers exert a significant amount of influence on the ability to fill a prescription. In a small community practice such as PCC, this influence can often be felt more strongly than in a larger practice setting that may have a greater voice with their insurance partners. Lastly, staffing shortage and turnover pose another significant barrier to patient care, as highlighted by the experience of PCC. With a heavy reliance on phone calls to support patients, the burden of outreach often falls entirely on nursing staff due to a lack of pharmacy technicians. Furthermore, patients may be hesitant to pick up calls from unrecognized numbers, making it challenging to ensure timely communication. These challenges are becoming increasingly difficult to overcome, making it more important than ever for

PCC to maintain its patient-centric approach to care. While staffing challenges persist, PCC remains committed to providing high-quality, personalized care to all its patients.

Key Takeaways:

- In-person patient education sessions at the initiation of oral oncolytic allow for a thorough assessment of patient health-related social needs
- Comprehensive patient education resources that include disease education, medication education and cancer-related terminology increase patient health literacy
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Conclusion

Oral oncolytics for the treatment of CLL require close collaboration of multidisciplinary care team members, specialty pharmacies, and patients and caregivers. In addition to multidisciplinary collaboration, factors such as timely medication dispensing, financial assistance, patient education and adherence, and comprehensive data capture are also critical to a successful oral oncolytic program. To effectively integrate oral agents into community practices, ACCC hopes to help cancer centers navigate through the complexities of oral oncolytic programs with this effective practice guide.

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Program Tools

To help cancer centers implement oral oncolytic programs into CLL treatment, ACCC has designed a *patient journey infographic* that highlights different aspects of the oral oncolytic process, from the point of treatment decision-making to long-term monitoring. The goal of the tool is to outline the general workflow and considerations for oral oncolytics that can be adapted for any practice setting.

Oral Oncolytic Clinical Workflow for Treatment of Patients with Chronic Lymphocytic Leukemia

Decision Point: Treatment

Discuss with patients:

- Goals of therapy in CLL and patient treatment goals
- Treatment options in CLL:
- Efficacy and adverse events of available therapies
- How treatments are taken (e.g., oral, IV)
- Duration of therapy (e.g., continuously, defined duration)
- Use shared-decision making to select treatment based on the clinical, social needs assessment and patients' goals

Clinical Considerations

Before Treatment Selection

Assess and Evaluate patients':

- Criteria for treatment initiation in CLL
- Cytogenetic Profile (e.g., del (17p), TP53 mutation)
- Functional status, functional and biological age
- Medical history and comorbidities
- Medication history for Drug-Drug Interactions
- Dietary preferences for Drug-Food Interactions

New Oral CLL Rx Received

Health-Related Social Needs Assessment

Before Treatment Selection

Assess and Evaluate patients':

Lifestyle and Economic Situation:

- Do they live alone or with a family member/partner?
- Do they work or retired? What is their financial situation?
- What is their daily activity level?

Social Situation:

- What kind of help and support do they need with daily activities and management of their condition?
- Do they have a dedicated caregiver?
- Would they like help connecting to resources for additional social support?
- Language proficiency and health literacy level
- What is their education level?
What is their English language proficiency?
What is their health literacy level?
- What is the preferred language for communication for the patient and caregiver?

Transportation Situation:

- Do they drive or have a caregiver with reliable transportation?
- Do they have trouble getting transportation to medical or laboratory appointments?
- How far do they live from the clinic?
- Are there healthcare facilities for laboratory monitoring close to the patient's home?
- Provide recommendations for support services, including navigation and/or advocacy organization resources

Dispensing Logistics

Complete the following:

- Assess if Rx will be filled in-house or at external SPP
- Build workflow for notifications to team on Rx status and care coordination
- If Rx will be filled externally establish follow call schedule with an external SPP:
 - Confirm Rx status: PA completed, processed, and filled
 - Date Rx shipped to patient and anticipated delivery
- Build workflow for patient communication on Rx status:
 - Educate patient and caregiver on what to expect (e.g., follow-up phone calls, who will call, anticipated Rx delivery date, PA and BI status)

Scheduling and Care Coordination

- Ensure oral chemotherapy consent is completed and signed
- Schedule initial patient educational sessions for oral oncolytic and IV therapy (if needed):
- If possible, coordinate oral and IV educational sessions
- Schedule necessary lab monitoring and tests:
- Develop EMR integrated clinic protocol for lab monitoring tests for a consistent workflow

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Prior Authorization and Benefits Investigation

Conduct Prior Authorization (PA) and Benefits Investigation (BI):

- Assign which team member(s) will be responsible for PA and BI
- Coordinate with clinic nurses to ensure complete information for faster PA processing to avoid rejections

- Evaluate the need for financial support (copay assistance, foundation funding, manufacturer free drug program) based on patient cost
- Educate patient and caregiver on the outcomes of PA and BI using patient-friendly language
- Educate patient on available financial support options*

**consider available ACCC Financial Advocacy Network Resources*

Treatment Initiation

During the Initial Patient Education Session:

- Review patient-specific goals of treatment
- Provide medication-specific education:
 - What AEs to expect and how to manage AEs if they occur (including OTC remedies)
 - Safe medication handling and disposal of unused medication
- Discuss the overall treatment plan and review the patient calendar:
 - How it works, How to take it (dose and frequency), and Duration of therapy
 - Follow-up appointments (clinic and laboratory)
- Discuss plan and strategies for patient medication adherence and persistency
- Educate on emergency management (where/whom to call, contact list)
- Provide patient educational materials and calendar to take home:
 - Develop a comprehensive educational binder that includes:
 - Disease and drug information, glossary of cancer medical terms, patient calendar
 - Utilize translation services to provide educational materials in patients' preferred language
 - If oral oncolytic medication is not available for 1st oral education session:
 - Utilize manufacturer-provided education kits
 - Educate about the logistics of obtaining the medication (i.e., expected timeline, reasons for potential delay)
 - Give instructions on what to do when a patient receives medication (i.e., call the clinic before starting)

Follow-up

Patient Counseling Questions

- How are you feeling overall?
Do you experience any trouble taking your medication?
- Have you experienced any adverse events since you started taking this medication?
- How many doses have you missed and why?
- When do you usually have trouble remembering to take your medication?
- Have you started any new medications or stopped taking any of your current medications?
- Have there been any changes at home or in your living, social or financial situation since we last spoke?

Follow-up Outreach

Ensure the following for each patient:

- Schedule follow-up clinic and laboratory appointments
- Establish workflow for follow-up monitoring of adherence and persistency:
 - First call 24 hrs post-treatment initiation
 - Weekly calls X 2
 - Bi-weekly calls X 2
 - Monthly calls thereafter
 - Adjust call frequency as needed based on individual patient needs
- During each follow-up:
 - Assess how patient is doing on medication
 - Presence of AEs, AE severity (grading), and management
 - If AE management is not achieved, establish triage to clinical pharmacist/provider for dose/regimen modifications, or other interventions
 - Re-assess patient medical and medication history
- Additionally, during monthly follow-up:
 - Evaluate patient adherence and persistency on medication:
 - Need for additional adherence persistency strategies
 - Need for home health to assist with medication management
 - Re-assess patient social needs and financial situation

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A publication from the ACCC education program, "Integrating Oral Oncolytics into Chronic Lymphocytic Leukemia Practice."
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