Integrating Oral Oncolytics into Chronic Lymphocytic Leukemia Practice
Case Studies Highlight Barriers and Successes

Introduction
In recent years, treatment for patients with chronic lymphocytic leukemia (CLL) has undergone a dramatic transformation, shifting from intravenous chemotherapy to oral chemotherapy. Oral oncolytic treatment for CLL offers many benefits, including convenience, better outcomes, and improved effectiveness. However, oral treatments also come with drawbacks to consider, including side effects, patient adherence, and financial toxicity.

Effective integration of oral oncolytics into community practice requires:

- Multidisciplinary collaboration
- Accurate and efficient medication dispensing
- Patient education and adherence
- Thorough data capture.

A multidisciplinary team that includes 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.

Delays in medication administration impact patient outcomes. Factors that attribute to delays include 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. Additionally, having processes in place to navigate the potential financial barriers for patients is an important operational component of oral oncolytic dispensing.

Patient medication adherence greatly impacts treatment success. Medication adherence is strongly linked to health literacy (i.e., the patient's comprehension of their disease and treatment). Effective patient education is vital to establishing adherence and compliance. 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.

Lastly, data capture and outcomes reporting are important to assess the success of oral oncolytic programs. 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 practice.

Current Practice
ACCC has developed an educational initiative Integrating Oral Oncolytics into Chronic Lymphocytic Leukemia Practice. The goal of this work is to raise awareness about programs that have effectively integrated oral oncolytics into the cancer care continuum, inclusive of tools and resources, as well as process improvement strategies that have been used to successfully integrate oral oncolytics.

In early 2022, ACCC conducted a survey across its
provider network to evaluate current practice patterns in integrating oral oncolytics into the care and treatment of patients with CLL. The survey received 130 responses. Results showed approximately 23 percent of programs treat between 26 to 50 patients with CLL per year, and 22 percent treat more than 100 patients per year. Nearly half of all respondents reported their program does not have an established workflow for integrating oral oncolytics into the care and treatment of patients with CLL.

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
- Processes for monitoring adherence and adverse events.

Through the Integrating Oral Oncolytics into CLL Practice initiative, three case studies were examined to highlight barriers and interventions to support effective treatment of CLL with oral oncolytics.

Penn Medicine Lancaster General Health

The Ann B. Barshinger Cancer Institute of Penn Medicine Lancaster General Health is a comprehensive community cancer program servicing Lancaster County, Pa., which treats more than 100 patients with CLL per year.

Lancaster General Health has its own specialty pharmacy through which CLL oral oncolytics are processed and dispensed. Oral oncolytic prescriptions are ordered by physicians through Epic (the electronic health record), then routed to the specialty pharmacy. Once the medication is processed through insurance, it is dispensed and delivered to the patient.

While the oral prescription is being processed through the specialty pharmacy, several efforts are happening behind the scenes. After the initial prescribing, the nurse navigator and clinic triage nurses consult with the physician regarding relevant labs, electrocardiogram, and other necessary monitoring, relaying this information to the appointment scheduler team. Simultaneously, oral oncolytic pharmacists review the prescription for appropriateness, document the regimen in the chart, and schedule the patient for an oral chemotherapy education session.

Lancaster General Hospital’s medically integrated pharmacy helps to streamline communication between the dispensing pharmacy and the clinic staff, while also reducing delays between medication prescription and dispensing to patients.

Cooperation among the cancer care team is based on an estimate of when the medication will arrive to the patient. The care team at Lancaster General Hospital primarily communicates via EPIC in-basket messages and chart notes. In the best-case scenario—and if insurance authorization is obtained the same day—patients receive their medication within 24 to 48 hours of the prescription being written.

American Oncology Network

American Oncology Network (AON) is a network of healthcare providers within community oncology settings who partner together to optimize community-based oncology care. Currently, AON’s platform consists of 107 physicians and 89 APPs across 18 states in more than 70 clinics. AON covers all areas of hematology and oncology in addition to some non-oncology services. The network treats more than 100 patients with CLL per year.

As a network of community-based practices, many patient services are centralized to streamline care, including specialty pharmacy and pathology and
diagnostics services. AON’s specialty pharmacy manages oral oncolytics prescriptions from approximately 70 clinics and ships the medications directly to patients. When AON providers are ready to prescribe an oral oncolytic, they send the prescription to the AON pharmacy via their electronic health record (most commonly OncoEMR).

Upon receipt of the prescription, multiple steps occur to process the oral oncolytic in the following order:

1. A clinical pharmacist reviews the prescription for appropriateness
2. Benefit investigation is conducted for active coverage
3. Prior authorization is submitted (if necessary)
4. Patient financial assistance is consulted, as needed
5. The patient is contacted to schedule delivery
6. The prescription is filled and shipped
7. Pharmacists provide patient counseling for oral oncolytics
8. Nurses review the EHR prior to subsequent refills to evaluate appropriateness for continuation of treatment and to reduce waste.

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. All patients who receive oral oncolytics are enrolled in a care management program that provides structured patient outreach calls and education. In addition, AON provides patient educational materials translated to multiple languages to reduce health literacy barriers.

Pontchartrain Cancer Center

The Pontchartrain Cancer Center is a private community practice located in Hammond, La., that services a rural population with an average of 1 to 10 patients with CLL per year.

At Pontchartrain Cancer Center, the oral oncolytic process starts with the provider prescribing the oral medication to the in-house pharmacy. After the order is placed, a separate treatment plan visit is scheduled for patient education and consent. Prescriptions filled in-house are done within 24 to 48 hours if there are no prior authorization issues. The average turnaround time for outside prescriptions is five to seven days.

All oral oncolytic prescriptions—internal and external—are tracked in a log to ensure that patients are obtaining their medications within a week or less. Providers at Pontchartrain Cancer Center find that having the medication available at the time of the initial oral oncolytic educational session on hand greatly enhances the effectiveness of patient education.

AON prioritizes a proactive approach on ongoing annual renewal of applications for medication grants and patient assistance programs to secure financial assistance for patients and reduce the administrative burden for network clinics.

One unique aspect of patient education at Pontchartrain Cancer Center is that the center has cultivated a robust “binder” of information for patients and caregivers ranging from typical drug information to practical tidbits, including patient medication and appointment calendars, suggested home remedies for adverse event management, contact information on who and when to call, and a glossary of medical terminology for cancer 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, patients are also scheduled to come to the clinic once a month for evaluation. As with prescription turnaround time, compliance is tracked, and reasons for non-compliance are reviewed by upper management.

Resources
To help cancer programs and practice implement oral oncolytic programs into the care and treatment of CLL patients, ACCC designed a patient journey infographic and an Effective Practice Guide that highlights various aspects of the oral oncolytic process, from the point of treatment decision-making to long-term monitoring. The goal of these tools is to outline the general workflow and considerations for oral oncolytics that can be adapted for any practice setting. ACCC aims to support cancer programs and practices as they navigate through the complexities of oral oncolytic treatment.

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

Clinical Considerations: Before Treatment Selection
Assess and evaluate patients’:
- Treatment initiation criteria
- Cytogenetic profile
- Medical history (e.g., comorbidities)
- Tumor burden
- Medication history (e.g., drug-drug interactions)

Scheduling and Care Coordination
Ensure the following:
- Oral chemotherapy consent is completed and signed
- Initial patient education session(s) for oral and/or IV therapy is scheduled
- Lab monitoring and tests scheduled

Dispensing Logistics
Complete the following:
- Assess if Rx to be filled in-house or in external specialty pharmacy
- Coordinate with infusion center (if needed)
- Build workflow notifications on Rx status and care coordination
- Educate patient and caregiver(s) on what to expect

Prior Authorization and Benefits Investigation
Conduct benefits investigation and assess patient cost exposure:
- Submit for prior authorization
- Evaluate any opportunities for copay assistance, foundation funding, free drug coverage, based on patient cost

Treatment Initiation
During the initial patient education session:
- Review patient-specific CLL treatment goals
- Provide medication-specific education
- Discuss medication adherence strategies
- Discuss safe handling and disposal of unused medicine
Provide educational materials and calendar for patient to take home.

Follow-up Outreach
Ensure the following for each patient:
- Schedule follow-up clinic and lab appointments
- Establish workflows for follow up monitoring
- Assess how patient is tolerating medication (e.g., side effects)
- Assess patient medication adherence and persistency
- Re-assess health-related social needs

Follow-up Questions for Patients
- How are you feeling?
- Have you had any trouble taking your medication?
- How many doses have you missed and why?
- Have you experienced any side effects from the medication?
- Have you started or stopped any new medication?
- Have there been changes to your living situation?

Health-Related Social Needs Assessment: Before Treatment Selection
Assess and evaluate patients’:
- Living situation
- Economic stability
- Social situation
- Transportation access
- Provide recommendations for support services, including navigation and/or advocacy organization resources.

Decision Point

A publication from the ACCC education program, “Integrating Oral Oncolytics into Chronic Lymphocytic Leukemia Practice.” Learn more at accc-cancer.org/integrating-oo-cll

The Association of Community Cancer Centers (ACCC) is the leading education and advocacy organization for the cancer care community. For more information, visit accc-cancer.org.

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