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