The Emerging Role of Oral Oncolytics

BY ALI MCBRIDE, PHARMD, MS, BCOP

The idea of a magic bullet—a single targeted drug that kills cells while minimizing the amount of toxicity to other areas of the body—was first hypothesized by Paul Erlich, an American biologist, on the eve of the 20th century. Since that time, new molecular targets have been discovered that regulate tumor cell growth and proliferation patterns. Drug candidates against these proteins have prompted a growth in research aimed at developing molecular drugs from the benchtop to the bedside. More than 3,500 novel approaches have been evaluated clinically or pre-clinically in the last decade.[1] Currently, more than 10,000 clinical trials with novel and approved agents, alone or in combination, are ongoing, with over 12 percent having entered phase III status.[1] Oral oncolytic agents are being approved rapidly. Of the more than 800 new oncology therapies currently in the pipeline, 25 to 35 percent are oral agents.[1]

Oral oncolytic agents have several advantages over the parenteral route, including patient convenience, prolonged drug exposure, and non-invasive administration. These agents provide unique opportunities in patient care but also large challenges to our interdisciplinary teams. Developing an oral chemotherapy workflow that includes financial assistance, high-quality patient education, side effect self-management support, and monitoring and follow-up is critical. This complex workflow involves many members of the cancer care team, including pharmacists, pharmacy technicians, financial navigators, physicians, advance practitioners, and nurses. Workflow tasks include biomarker testing and next generation sequencing, medication drug interaction review, patient and caregiver education and re-education, financial assistance, side effect management and monitoring, drug refill management, and thoughtful decisions on the site of the dispensing pharmacy (i.e., in-office dispensing, specialty pharmacy, mail order).

Taking a closer look at next generation sequencing and molecular pathology, we know that the evaluation of mutation markers, such as FGFR or NTRK, has changed the current dynamic of treatment. Many oral chemotherapy agents now exist to address specific mutations or fusion protein targets, and targeted therapies are being used for many off-label indications. This requires education and a greater understanding of molecular testing—from your prescribing clinicians, to your nurse educators, to your financial navigators, to your pharmacy technicians who process prior authorizations.

Turning our attention to patient adherence and monitoring, several effective workflows have been published in the literature with varying structures and staff participation. These strategies all drive down into the same workflow, one that addresses pre-assessment risk for adherence prior to the start of chemotherapy, as well as appropriate monitoring strategies for dosing and refill evaluations. Defining a model that works to address medication interactions early on may reduce incorrect dosing and lower side effects. Refill workflows can be especially challenging if patients are using a mail order pharmacy. How can we ensure that these patients are correctly evaluated for drug dosing or drug interactions? How do we ensure that automatic refill processes take into account dose changes based on labs and other monitoring values? How do we monitor automatic refill processes to identify instances of drug waste?

As you can see, the issues are complex, and the solutions will require participation and buy-in from all cancer team members. But it is critical that we work together to develop and implement value-based (e.g., efficient and cost-effective) oral chemotherapy workflows that minimize patient risk and maximize patient outcomes. OI

Reference

1. Food and Drug Administration. Hematology/Oncology (Cancer) Approvals & Safety Notifications. Available online at: fda.gov/drugs/resources-information-approved-drugs/hematologyoncology-cancer-approvals-safety-notifications. Last accessed December 16, 2019.

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