

Integrating Oral Oncolytics into Pharmacy Practice

As of November 2018, the U.S. Food and Drug Administration has approved more than 50 oral anticancer medications, and approximately 35 percent of the oncology therapies in development are oral agents.¹ In a 2016 Association of Community Cancer Centers (ACCC) membership survey, almost half (43%) of respondents reported having adopted a formal oncolytic program or protocol to manage these agents.² In addition to reducing office visits, the benefits to patients of oral oncolytic therapies may include the convenience of self-administration and a potential reduction in medication complications.

Despite the continued growth in approvals and indications, many barriers limit patient access to oral anticancer medications. For instance, oral oncolytics are typically associated with higher out-of-pocket costs compared with infusional therapies and time to treatment initiation is often increased by logistical barriers such as insurance coverage and co-pays, prior authorization, limited distribution networks via select specialty pharmacies, and delays with mail-order and specialty pharmacy processing.³ Additionally, patient medication adherence to oral oncolytics can be more challenging to monitor compared with intravenously administered cancer therapy.

Pharmacists are leading the way in developing strategies to optimize the integration of oral anticancer therapies into practice. For instance, pharmacists have expanded their role in safety management via dosing and adverse event monitoring, increased their involvement in pharmacogenomics teams/services to help identify actionable gene mutations, and have adopted a broader role in supporting patient engagement and medication adherence. New dispensing models such as in-house (vs. external specialty pharmacy) have established process efficiencies that may reduce time to treatment initiation. Finally, pharmacists are lobbying for changes in oral parity legislation.

Resources for Navigating Access to Oral Oncolytics

For patients who are struggling with the cost of oral oncolytics, team-based approaches to financial support and advocacy are indispensable when helping patients to identify financial resources and reduce out-of-pocket costs.⁴ In many oncology pharmacies, pharmacy technicians play an increasingly key role on the financial navigation team and are able to consolidate existing resources and develop new resources to support patient access to oral oncolytics. Specially trained pharmacy staff work with nurse navigators, financial

advocates, and others to process prior authorizations and patient assistance requests and to identify potential financial resources, patient assistance foundations, and to establish the availability of manufacturer patient assistance programs or co-pay cards for patients with no or suboptimal commercial insurance access.

In order to optimize patient access to these resources, pharmacy and financial assistance staff can identify patients who might qualify for co-pay cards or patient assistance, gather the information necessary, enroll patients in manufacturer co-pay or assistance programs, and apply for foundation grant funds. At a policy level, pharmacist organizations such as the National Community Oncology Dispensing Association, Inc. are also working with patient assistance foundations to draw attention to the increase in funding that will likely be required to enable more patients to access new oral oncolytics as they enter the market.

In-House Specialty Pharmacy Dispensing Models

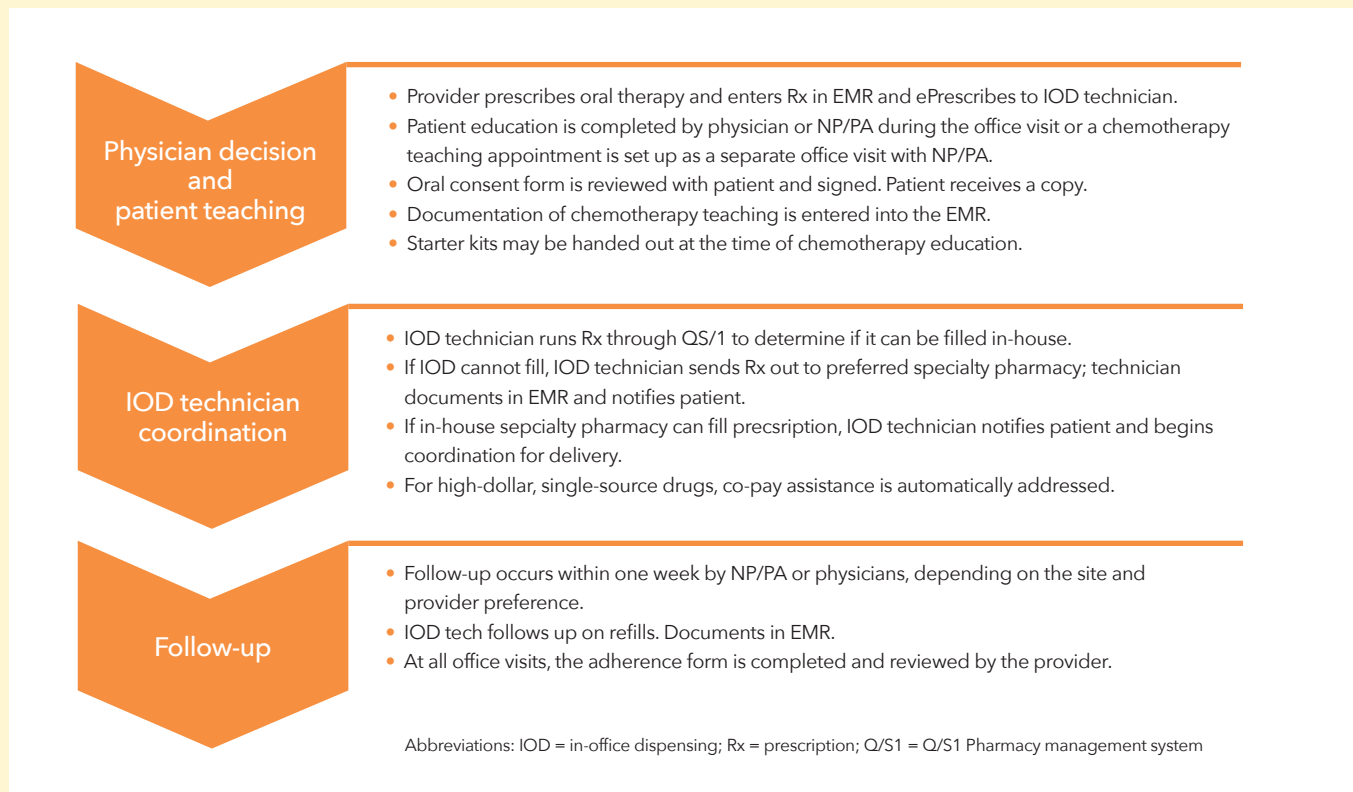
Although oral agents are typically dispensed via third party specialty pharmacies, many insurance plans now permit in-house specialty pharmacies as an alternative. This integrated specialty pharmacy model, typically located within large healthcare networks or practices, makes it possible for patients to collect their specialty anticancer medications directly from the oncology program. Pharmacists and specialized pharmacy technicians are key to the effectiveness of this medically integrated dispensing model. Not only do oncology pharmacists provide dispensing services and manage inventory of oral oncolytics, but they also have an expanding role in ensuring drug delivery, medication reconciliation, and prospective assessment of drug-drug interactions. Additionally, in collaboration with oncologists, oncology nurses, and advanced practice providers, oncology pharmacists provide ongoing patient education on drug administration, side effect recognition, safe handling and potential drug interactions, and monitoring for adverse events. Adverse events remain a primary barrier to medication adherence. In-office dispensing provides an opportunity for early identification of toxicities and supports timely intervention through dose adjustment and symptom management.

Establishing integrated pharmacy processes for oral anticancer therapies is undoubtedly challenging; however, this approach provides real-world implementation that potentially reduces patient out-of-pocket expenses and time to treatment initiation,

CASE STUDY: Arizona Oncology Process Workflow

Redesigned process workflows are emerging as a key resource for integrated pharmacies to ease the assimilation of oral anticancer drugs into patient care and better facilitate patient access to these therapies. For example, pharmacists at Arizona

Oncology, an Oncology Care Model (OCM) practice and US Oncology affiliate, have developed an in-office dispensing (IOD) process workflow to manage oral oncolytic prescribing, dispensing, and monitoring (see figure below).



Arizona Oncology has 12 medically integrated dispensing sites. During each on-site patient encounter, pharmacists review possible drug interactions with patients to minimize the risk of reduced efficacy or increased toxicity, and the treating provider completes adherence forms. Patients also have access to direct phone lines to in-office dispensing pharmacy technicians who return voicemails within 24 business hours. If the oral anticancer agent must be delivered directly to the patient's home, in-office dispensing sites can use FedEx to ship, track, and confirm the delivery of patient medications.

Arizona Oncology's IOD program combines physician prescribing with drug distribution, pharmacy benefit manager (PBM) contracting services, retail pharmacy system technology, and clinical electronic medical records (EMRs). Recognizing that establishing and maintaining patient relationships is an important factor in sustaining and growing an effective in-office dispensing

program, Arizona Oncology documents patient communications about dispensing in its EMR and uses tools in its workflow process such as oral chemotherapy consent forms, follow-up adherence forms, and treatment pathways that are informed by National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (e.g., Clear Value Plus).

Both the Oncology Care Model (OCM) and ASCO's Quality Oncology Practice Initiative (QOPI) have effective process flow tools that help physicians more effectively initiate treatment, identify financial assistance eligibility and options, deliver patient education, address potential adverse events, and support patient adherence. Other potential workflow tools include US Oncology's IKnowMed order sets, which automatically schedule patient education, laboratory tests, and follow-up as soon as treatment is planned.

improves patient adherence to medication and outcomes, and helps to identify gaps and potential opportunities for improvements across the pharmacy service line. A recently published study in the *Journal of Oncology Practice* describes the implementation of an integrated, closed-loop, pharmacist-led oral chemotherapy management program at the University of North Carolina, Chapel Hill Medical Center and Ralph H. Johnson Veterans Affairs Medical Center in Charleston, South Carolina. The program resulted in improved patient knowledge regarding oral anticancer therapy, improved adherence rates that exceeded nationally established thresholds, and superior molecular response outcomes for patients with chronic myeloid leukemia.⁵

The Quest for Oral Parity

Insurance coverage for oral anticancer therapies has not kept pace with medical innovation. Outdated insurance benefit designs continue to cover oral medications under the pharmacy benefit, which often means high out-of-pocket costs for patients. Conversely, intravenous (IV) chemotherapy is covered under most plans' medical benefit, resulting in minimal co-pays or no out-of-pocket cost to patients. In addition, many approved oral oncolytics do not have IV or injectable alternatives, and they may be the only option for some patients. As oral oncolytics become more common options for cancer treatment, patients will be challenged to pay higher out-of-pocket costs for their care.

Conclusion

All indications are that oral oncolytics will play an increasingly prominent role in the treatment of different types of cancers moving forward. The benefits of orally administered anticancer therapies will increase patient demand and present new challenges to cancer programs seeking to respond to changing patient needs. By anticipating those needs and proactively offering solutions, pharmacists will continue to play a significant role in making these therapies available to as many patients as possible. To these ends, oncology pharmacy professionals will need ongoing education about best practices for administering oral oncolytics and educating patients. ■

Have parity laws increased access to oral oncolytics?

To date 43 states and the District of Columbia have adopted oral parity legislation that protects patients' access to the drugs they need by ensuring they pay no more for orally administered anticancer therapies than those administered by infusion. A 2017 analysis of health claims data revealed that some states that have enacted parity laws have seen reductions in estimated monthly out-of-pocket spending at the lower end of spending distribution (e.g., decreases by \$19.44 at the 25th percentile versus \$10.83 at the 75th percentile). But those states have also observed increased spending for prescriptions at the highest end of spending distribution (i.e., at the 90th and 95th percentiles). Investigators speculate that part of this increase could be due to variations in coverage (i.e., high-deductible plans) and medication costs.⁶

These variations have led some oncology pharmacists to recommend strengthening federal parity laws to reach plans regulated by the Employee Retirement Income Security Act (ERISA), which include most private sector health plans, and large, multi-state health plans. Pharmacist associations have worked alongside ACCC and other stakeholders to raise awareness about the importance of oral parity in insurance coverage by lobbying state and federal legislatures, developing educational materials, and coordinating letter campaigns. ACCC members have testified at Congressional briefings and advocated for federal oral parity legislation during annual Capitol Hill Day meetings with lawmakers.

This article is a follow-up to a conversation with pharmaceutical leaders hosted by ACCC in October 2018 during a pre-conference workshop at its 35th National Oncology Conference. There, Aimee Faso, PharmD, BCOP, CPP, clinical assistant professor at UNC Hospitals and adjunct faculty at UNC Eshelman School of Pharmacy; Linda Frisk, PharmD,

pharmacy director at Arizona Oncology Associates; and Michael J. Reff, RPh, MBA, founder and executive director of the National Community Oncology Dispensing Association (NCODA) addressed strategies oncology pharmacists can use to optimize access to oral oncology therapies.

References

1. Community Oncology Alliance. *Fact Sheet: Patient access to oral oncolytics*. <http://www.communityoncology.org/pdfs/fact-sheet-oral-oncolytics.pdf>. Accessed November 27, 2018.
2. Association of Community Cancer Centers. *Steps to Success: Implementing Oral Oncolytics*. https://www.accc-cancer.org/docs/projects/resources/pdf/implementing-oral-oncolytics-final.pdf?sfvrsn=274a112_0. Accessed March 4, 2019.
3. Niccolai J L, Roman DL, Julius JM, et al. Potential obstacles in the acquisition of oral anticancer medications. *J Oncol Pract*. 2017;13(1):e29- e36.
4. Doshi GK, Condon K, Schwartz JR, et al. Medically integrated pharmacy: A team-based approach to improve oral oncolytic therapy for cancer patients. *J Clin Oncol*. 2018;36:30_suppl, 140-140
5. Muluneh B, Schneider M, Faso A, et al. Improved adherence rates and clinical outcomes of an integrated, closed-loop, pharmacist-led oral chemotherapy management program. *J Oncol Pract*. 2018;14(6):e324.
6. Dusetzina SB, Huskamp HA, Winn AN, Basch E, Keating NL. Out-of-Pocket and Health Care Spending Changes for Patients Using Orally Administered Anticancer Therapy After Adoption of State Parity Laws. *JAMA Oncol*. 2018;4(6):e173598. doi:10.1001/jamaoncol.2017.3598.

The **Association of Community Cancer Centers (ACCC)** is the leading education and advocacy organization for the cancer care community. ACCC is a powerful network of 25,000 cancer care professionals from 2,100 hospitals and practices nationwide. ACCC is recognized as the premier provider of resources for the entire oncology care team. For more information, visit acc-cancer.org or call 301.984.9496. Follow us on Facebook, Twitter, and LinkedIn, and read our blog, ACCCBuzz.

The **ACCC Oncology Pharmacy Education Network** advocates on behalf of hematology-oncology pharmacists as vital members of the cancer care team, and is committed to developing educational resources and multidisciplinary connections that advance the field and elevate oncology pharmacy professionals to top-of-license practice.



Association of Community Cancer Centers