

CASE STUDY

In-Office Dispensing of Oral Oncolytics: A Continuity of Care and Cost Mitigation Model for Cancer Patients

Nancy J. Egerton, PharmD, BCOP

Newly approved oncology therapies in the United States continue to expand cancer treatment options for patients. In 2015, 18 cancer drugs were approved by the FDA, 9 of which were oral drugs.¹ The oncology pipeline currently has an estimated 836 drugs in clinical development, with 25% being oral agents.²

The emergence of targeted therapies for treating cancer has allowed for more precise treatment based on tumor mutations and patient genotypes. This past year, we also witnessed the emergence of immuno-oncology drugs being utilized for an increasing number of tumor types, such as melanoma, lung, and renal cell cancers. However, these breakthrough therapies come with escalating costs.

The “financial toxicity of cancer” is a term being used to describe the increased financial burden faced by patients with cancer due to multiple factors, including increased out-of-pocket (OOP) expenses for co-pays and deductibles for prescription drugs and medical care, lost income for patients while undergoing treatment, and indirect costs experienced by caregivers. Insurance companies, struggling to cover the rising expenses of cancer drugs, are shifting more of the cost burden to patients.

Over the past decade, oral cancer drugs have become more prevalent in the treatment armamentarium. Many patients now receive combination chemotherapy consisting of intravenous and oral drugs within the same regimen or as single therapies administered sequentially through multiple lines of therapy.

Cost and Coverage

Traditional infusion chemotherapy is covered under a patient’s medical coverage, and for Medicare patients, under Part B benefits; however, there are a few oral cancer drugs that are also covered under Medicare Part B. Oral cancer drugs are billed through a patient’s prescription benefits, and for Medicare patients, under Part D. Under the Affordable Care Act, the Medicare Part D benefit now includes coverage in the cov-

ABSTRACT

The high cost of cancer therapies continues to lead to questions of affordability for the healthcare system and to patients. Ensuring patient access to oral cancer drugs presents a unique set of challenges due to the significant cost of these novel agents, healthcare/payer policies, and established distribution practices. The National Community Oncology Dispensing Association, Inc (NCODA) is a grassroots, nonprofit organization established by pharmacists who are directly involved at the community practice level in assisting patients with the acquisition of their oral cancer drugs. Community oncology practices that embrace the NCODA Quality Standards are able to provide exceptional patient care by providing direct access to oral cancer drugs through the in-practice dispensary. Patient continuity of care is ensured by allowing practice staff to manage all aspects of drug therapy—from initial dispense to completion of therapy—and in-practice dispensing allows for improved patient convenience, safety, and compliance. Practice staff in the dispensary area work directly with patients to address the insurance coverage limitations and financial toxicity of procuring these drugs.

Medicare patients are not eligible to take advantage of patient assistance and/or co-pay programs that have been established by pharmaceutical companies. Foundations such as the Patient Access Network Foundation have been established to provide assistance to Medicare patients. This case report focuses on a new dispensary in a moderately sized oncology community practice that prescribes to the NCODA Quality Standards and outlines the processes developed to assist Medicare patients in accessing their oral cancer medications.

Am J Manag Care. 2016;22(4 Suppl):S99-S103

erage gap (“donut hole”). Before 2011, there was no coverage between the initial coverage limit to the OOP threshold and commencement of catastrophic coverage (Table 1⁴). The “donut hole” will be completely phased out by 2020 using a combination of Part D benefits and discounts for generic and brand-name drugs. However, despite the emergence of Part D benefits and the shrinking donut hole, due to the extremely high cost of oral cancer drugs, patients continue to have challenges with medication access because of OOP expenses. The cost for new oral cancer drugs is in the range of \$10,000 per month (Table 2⁵).

The federal anti-kickback statute precludes pharmaceutical companies from allowing Medicare beneficiaries to use co-pay coupons to help cover the cost of Part D drugs. The law specifies that coupons cannot be used for the purchase and/or payment of drugs paid for by any federal healthcare program, including Medicare Part D.⁶ It is acknowledged that allowing patients to use coupons would save OOP expenses for patients significantly; however, coupons could potentially induce patients to use more expensive brand-name drugs, subsequently increasing costs to the Medicare system and taxpayers.

Payers are managing oral cancer drugs by shifting management to their pharmacy benefit managers (PBMs), and PBMs then further control costs by limiting dispensing through specific specialty/mail order pharmacies. PBMs also place oral cancer drugs into cost-sharing tiers with variable co-pay expectations for patients. Overall, more of the cost burden of cancer care is being shifted to patients. Simply coping with the physical and emotional burden of a cancer diagnosis can be overwhelming for patients, even before the financial ramifications are taken into consideration. There are numerous reports of patients and families going into debt or declaring bankruptcy in order to cover the costs of their cancer medications, as well as examples of patients cutting back on drug doses and groceries, and utilizing less heat in their homes.⁷ All of the aforementioned are desperate measures patients may take to maintain medication access. The quality of cancer care suffers as a result, in addition to poor compliance and adherence to life-saving treatment plans.

As cancer therapeutics becomes more complex and costly, with more options for patients, healthcare providers are being challenged to take on a larger role in assisting patients to maintain access to treatments. Discussion about the cost of chemotherapy is now a standard part of pretreatment planning and has to be communicated from the physician when treatment alternatives are discussed with patients. Some community oncology practices employ staff specifically trained as financial counselors to meet with patients

prior to the start of their treatment. Patients meet with financial counselors and are apprised of their insurance benefits and limitations, allowing for a better understanding of their insurance coverage for their treatment plans and out-of-pocket expenses before their therapy begins.

Oral cancer therapies present a unique set of clinical management challenges for healthcare providers. Patients take these medications at home unsupervised, and therefore, patient education becomes more critical to ensure patients are taking their medications appropriately; timely follow-up contact with patients also needs to occur on a regular basis to monitor compliance and to mitigate potential toxicities. Clinical staff need to regularly assess if affordability is negatively impacting access to appropriate care.

In-Office Dispensing vs Specialty/Mail Order Pharmacies

As more oral drugs have become part of standard therapy for many cancers, there has been a recent trend within community oncology practices to establish in-office dispensing (IOD) services or retail pharmacies. Individual state regulations determine whether full retail pharmacies may be offered from within an oncologist’s practice; many states allow physician dispensing as an alternative to retail pharmacies.⁸ Both models allow for oncologists to dispense medications directly to their patients, which allows for close management of a patient’s cancer therapy.

Prior to this trend of IOD in community practices, the majority of oral cancer drugs, considered specialty drugs by PBMs, were obtained strictly through specialty/mail order pharmacies. These pharmacies manage many classes of specialty drugs, including those for hepatitis C, multiple sclerosis, rheumatoid arthritis, Crohn’s disease, and oncology. Additionally, specialty/mail order pharmacies strive to provide certain services for cancer patients and overall disease management, offering services such as dose accuracy assurance, education/telephonic outreach, waste management, adherence oversight, cost savings, and outcomes measures. However, oral cancer drugs being dispensed to patients from a remote specialty/mail order pharmacy has the potential to cause many problems from both the provider and patient perspective. Significant delays in time to therapy start often occur. It is fairly typical for a patient to wait at least 1 to 2 weeks to receive their oral cancer prescription from a specialty/mail order pharmacy.

Also, prescriptions generated at the practice are typically e-prescribed or faxed to specialty/mail order pharmacies, so once that prescription leaves the practice, the provider loses control over the entire prescription event, including the processing and dispensing of the drug to the patient.

Table 1. CMS Part D Standard Benefit Plan⁴

	2015	2016
Deductible	\$320	\$360
Initial coverage limit (donut hole begins)	\$2960	\$3310
Out-of-pocket threshold	\$4700	\$4850

Unfortunate instances of prescriptions getting lost in this transition occur with some degree of frequency. Clinical staff members at the practice spend a significant amount of time on the phone trying to follow-up with specialty/mail order pharmacies on the status of the prescription, where it stands in the queue for dispensing, and when the medication is actually being dispensed to the patient. There is a significant amount of time, as well as resources, dedicated to this administrative burden, and the overall management of the patient's cancer therapy becomes quite fragmented.

Having dispensing services available at the practice setting offers a better care model for patients. However, challenges remain when deciding to start IOD services within a community practice. There is a paucity of information on how to go about establishing IOD services, which creates a strong need for establishing quality standards and guidelines to ensure best practices for this unique model of patient care.

NCODA

The National Community Oncology Dispensing Association (NCODA) was established in 2014 by a group of community-based oncology pharmacists to promote the practice of dispensing cancer medications directly to patients at the site of care: the oncologist's office. NCODA practices adhere to quality standards that establish best practices related to the dispensing and management of oral cancer therapies. NCODA also works directly with other practices to implement and improve practice IOD operations which ultimately result in improved quality of patient care. The NCODA Quality Standards⁹ include:

1. Patient-Centered Quality Standard: standard that ensures dispensing services are centered on patient safety and education to maximize patient outcomes.
2. Positive Quality Interventions Quality Standard: positive quality interventions are performed by clinical staff to coordinate patient care and safety.
3. Foundational Elements Quality Standard: fundamental standards and systems are identified for achieving the highest level of quality patient care.
4. Health Information Technology Quality Standard: extrapolation of quality data from health information technology provides improved quality of care.

It is NCODA's belief that IOD is uniquely positioned to provide improved and more cost-effective care compared with traditional specialty/mail order pharmacies. NCODA promotes the concept of the oncologist and the clinical and administrative staff at the clinic working together with the patient as a team, to offer a unique, high-touch, patient-centered model for managing oral chemotherapy.

Practices with IOD are able to coordinate all aspects of patient medication management using the electronic medical record, pharmacy dispensing program, and inventory and practice management systems. There is direct coordination and communication about patient care at all times with those managing the IOD and the physician. Further benefits of IOD include face-to-face patient education for all patients initiating an oral cancer medication, with personalized chemotherapy classes scheduled prior to the patient picking up their prescription from the dispensary. In addition to the oncologist, practice clinical staff, including both oncology-certified pharmacists and nurses, are directly involved with dispensing medications, patient education, and monitoring for side effects.

IOD allows the practitioner to optimize all aspects of cancer drug therapy management. Time to therapy is significantly decreased with IOD services, with patients being able to acquire their cancer medication the same day or within 2 to 3 days of prescription orders. Patient factors and clinical scenarios are known to on-site staff, which allows for a "nimble" approach to medication management. Significant cost savings are achieved by the elimination of unnecessary refills and close overall management of the patient's medication tolerance and side effects. One quality standard that NCODA practices adhere to is to schedule medication toxicity checks with a physician or advanced care practitioner within 2 weeks of the first fill of an oral cancer medication, to allow for early side-effect management and related dose adjustments. Refills for cancer medications are not processed without direct communication between the oncologist and the IOD pharmacist.

Patient convenience is also a critical element of the IOD model, allowing patients to obtain all their cancer

Table 2. AWP/Cycle for Select Oral Oncolytics⁵

Oral Oncolytic	Cancer Type	Cost (AWP)
Tagrisso (osimertinib)	Lung cancer	\$14,300
Imbruvica (ibrutinib)	Chronic leukemia	\$11,500
Tarceva (erlotinib)	Lung cancer	\$7,500
Farydak (panobinostat)	Multiple myeloma	\$8,200
Ibrance (palbociclib)	Breast cancer	\$11,800

AWP indicates average wholesale price.

medications—whether intravenous or oral—at a single location, thus allowing the overall care of the patient to be less fragmented. In addition to the onsite clinical staff support, practices have dedicated administrative support teams to complete immediate insurance benefit investigations, determine prescription coverage, and to provide comprehensive financial assistance services when needed.

Patient assistance staff members who are housed in the IOD department at the practice, are uniquely positioned to advocate for patients and their families. They help patients by navigating the complex network of assistance programs, and help them complete the forms and applications required to apply for assistance. For Medicare patients, financial support can be obtained through patient foundations, such as the Patient Access Network Foundation (PAN), the Chronic Disease Fund, and the Leukemia & Lymphoma Society. Patient foundations provide critical funding resources, which allow patients to access these vital cancer drugs. The patient assistance staff streamlines the application process to the various foundations using specific forms and online tools. Typically, notification of a foundation award is achieved rather quickly, but tracking of the foundation awards is also critical to ensure patients have continuous access to financial support as their cancer treatments progress. Timely re-applications are also important to prevent unintended treatment interruptions.

IOD Practice

A moderately sized community oncology practice began IOD services in January 2015 after it had become apparent to physician practice leadership that oral cancer drugs were increasingly becoming a more critical part of cancer treatment regimens. It was also felt that IOD and management of oral therapies would lead to less fragmented care plans, offer patients a convenient service, and improve patient outcomes.

Renovations to an area of the clinic were done in order to provide a full service dispensary, including a patient counseling area. All of the necessary computer hardware and dispensing software was acquired and linked into the practice management system and electronic medical record. Staff were hired that were to be specifically dedicated to the IOD department, and included a full-time pharmacist, technician, and administrative assistant, as well as 2 individuals trained and dedicated to obtaining prior authorizations (PAs) and patient financial assistance for oral cancer drugs.

At the practice, the patient financial assistance staff has been a key component in the success of the IOD program, providing timely and efficient assistance to patients at any point in the prescription process. When a prescrip-

tion is received at the dispensary for an oral cancer drug, a PA request is completed on the same day. Unless there are extenuating circumstances, the PA is usually obtained that same day from the insurance company. The staff then identifies any patient out-of-pocket expenses, deductibles, or co-pays. All patients eligible for assistance are enrolled in the appropriate program based on whether they have a commercial or a Medicare prescription plan; uninsured patients also have assistance options explored for them.

The “life of an IOD prescription” is as follows: a) a treatment decision is determined by the oncologist; b) a prescription for an oral cancer medication is generated by the practice physician or advanced care practitioner in the electronic health record; c) the prescription is e-prescribed directly to the IOD pharmacy system; d) the patient’s insurance information/prescription benefit is available in the practice pharmacy system, coverage is determined immediately, and PA status is identified; e) through the IOD pharmacy system, the prescription is adjudicated and patient OOP expenses/co-pays are identified; f) the practice staff helps to enroll any eligible patient in patient assistance programs that are available for commercially insured patients (pharmaceutical companies’ co-pay cards and drug-specific programs are utilized to mitigate patient OOP expenses) and for Medicare patients (foundation funding and resources are obtained).

The practice has worked very closely with PAN to obtain assistance for Medicare patients. The process with PAN has been streamlined and is very efficient from the practice perspective: 1) patient assistance staff goes to PAN website and clicks “apply now”; 2) disease is selected; 3) insurance type is selected (Medicare); 4) drug is selected; 5) staff selects option “applying for someone else”; 6) staff identifies “self” as person completing information on behalf of patient; 7) staff enters patient information, income level, number of household members, and insurance information after obtaining this from the patient; 8) staff enters prescriber information; 9) staff contacts the patient via phone and asks for permission to accept terms of PAN agreement; 10) staff clicks “accept”; 11) within a few seconds, there is notification of patient award including available balance, enrollment date, and end date; 12) patient-specific PAN ID# card is generated, which includes Rx Group#/Bin#, which is sent to the IOD pharmacist to use as a co-pay card while processing the prescription.

The provision of comprehensive financial assistance services are a quality standard for NCODA IOD practices. From January to November 2015, the practice’s IOD patient financial assistance staff has obtained over \$400,000 in awards granted to Medicare patients through various foundations (Table 3). For patients who are Medicare beneficiaries, with-

■ **Table 3.** 2015 Practice Foundation Support Medicare Patients, by Disease

Disease	Foundation Support Amount
Lung cancer	\$52,500
Breast cancer	\$64,100
Prostate cancer	\$143,100
CLL	\$60,000
NHL	\$46,500
Melanoma	\$7,500
Myeloma	\$10,000
Renal	\$15,000
Colon	\$32,500
Total	\$431,200

CLL indicates chronic lymphocytic leukemia; NHL, non-Hodgkin lymphoma.
Source: New York Oncology Hematology practice internal tracking data.

out the dedicated practice staff researching and obtaining assistance from foundations such as PAN, many would not have access to the oral drug therapies so critical to their care.

Conclusions

Cancer therapies have become more complex and more expensive, requiring the oncologist and their staff to take on a larger role to ensure patient access to treatments. IOD services, both clinical and administrative, offer an additional level of support at the oncology practice for improved continuity of care and better overall management of a patient's cancer therapy. As additional oral cancer drugs are brought to market and approved by the FDA, there will be an increased number of opportunities to prove that IOD services allow for better patient outcomes. Studies done at NCODA member practices will demonstrate improved patient convenience and satisfaction, better medication adherence patterns and toxicity management, as well as significant cost savings to patients and the healthcare system.

Author Affiliation: National Community Oncology Dispensing Association, East Syracuse, NY; New York Oncology Hematology, Albany, NY.

Source of Funding: None.

Author Disclosures: Dr Egerton's employer is the location of an in-office dispensary.

Authorship Information: Concept and design; acquisition of data; drafting of the manuscript; critical revision of the manuscript for important intellectual content.

Address correspondence to: Nancy J. Egerton, PharmD, BCOP, Vice President, National Community Oncology Dispensing Association, and Manager of Pharmacy Services, New York Oncology Hematology, Albany, NY. E-mail: nancy.egerton@usoncology.com.

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