

Oral Therapies and Safety Issues for Oncology Practices

Patient support is key to delivering safe oral chemotherapy

by Rolando DeCardenas and John S. Helfrich, RPh

Of the approximately 750 new therapies currently being tested for oncology, 30 to 35 percent are in oral form. All signs indicate that this number will only increase as researchers and pharmaceutical companies develop new anti-cancer therapies. Thus, special attention must be given to the safety issues that arise from this trend.

Clearly, for patients, oral formulations offer many advantages; the most obvious one is convenience. Taking medications at home instead of traveling to a hospital or clinic several times each week makes receiving anti-cancer treatments easier. The process is less time-consuming, less physically draining, and generally gives patients more control over their care and their lives.

Another significant benefit of oral chemotherapies is the potential for reduced side effects. Typically, oral therapeutics are formulated with a lower dosage that is taken for a longer period of time. If side effects occur, they may appear more slowly, allowing physicians more time to adjust the treatment plan, or prescribe medications that can help relieve side effects before they become unbearable. Of course, this benefit is only possible if the physician is aware that the patient is experiencing side effects.

While oral oncology drugs provide new options in the way cancer is treated, they also create many challenges for physicians—specifically in ensuring the safe delivery of this form of treatment. For example, *how does the prescribing physician know whether or not the prescription was filled and if the patient is taking the drugs as prescribed? Or, how can oncologists effectively monitor patients for side effects, especially in between appointments?*

Causes of Non-Adherence

While taking medications at home provides patients the control they desire, optimal patient outcomes depend on strict adherence to prescription instructions. For many reasons, however, patients do not adhere to their treatment regimens. Successful oral oncology programs: 1) develop a plan to identify causes or reasons why patients do not adhere to their treatment regimens and 2) provide the right patient support to help avoid potential problems. Six common reasons for non-adherence are:

1. **Patients do not completely understand the prescribed treatment.** Following a cancer diagnosis, patients often



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feel overwhelmed and frightened, resulting in a less than ideal situation for comprehending detailed and often complex instructions for the recommended treatment.

2. **Some patients may have periods during their treatment when they do not “feel sick” anymore, or perhaps they never felt ill.** Patients who feel fine are often less motivated to continue treatment. Continual education and reminders from a healthcare provider can help these patients understand the need for completing treatment.
3. **Patients experience unpleasant side effects.** Some patients choose to quit taking their chemotherapy rather than deal with side effects. Because patients on oral chemotherapy are not reporting to the infusion room for treatments several times each week where oncology nurses are continually asking how they feel and what they are experiencing, physicians have a more difficult time monitoring for side effects or other adverse reactions that can be addressed through changes in dosage or other medications.
4. **Patients simply forget to take medications.** For patients whose treatment includes taking multiple pills several

times a day or who already take multiple prescribed medications and are now adding additional instructions, remembering to take medications can be difficult.

5. **Pharmacy-related challenges.** Some patients have a difficult time getting to the pharmacy to fill prescriptions. Other patients may take their prescriptions to a pharmacy that does not have the medication in stock. Patients may also find as they fill the prescription that the co-pay is very expensive.
6. **Cost-related challenges.** Oral chemotherapy is expensive and presents special challenges for Medicare Part D patients. These patients are affected by the coverage gap between the initial coverage limit and the catastrophic coverage threshold within the defined standard benefit under the Medicare Part D prescription drug program. Within this “doughnut hole,” beneficiaries pay

100 percent of the cost of prescription drugs before catastrophic coverage kicks in. For some patients, this significant out-of-pocket expense can lead to not refilling prescriptions or cutting dosages to try to stretch medications. While many oncology practices offer financial counseling to patients and offer to help them seek financial assistance for in-office treatments, oral chemotherapy prescriptions are typically filled outside the office where practice staff may not be aware of a patient’s inability to afford the treatment.

Expanding the Bandwidth of Your Oncology Practice

Today the average size of oncology practices in the United States is about 2.4 oncologists. Many of these private practice physicians are still adjusting to reimbursement decreases from both Medicare and private payers, stemming from the

Specialty Pharmacy in Action: Two Case Studies

Patient A

A recent Care Advantage patient, a 31-year-old female with chronic myelogenous leukemia (CML), began taking Gleevec® (imatinib mesylate). The patient began experiencing several side effects, including nausea and severe joint and muscle pain, especially in her hips. She was prescribed the common pain medication, Darvocet, which caused her to feel drowsy. Her pain and drowsiness negatively impacted her daily routine, causing her to become depressed and anxious about continuing treatment. With a history of suffering from anxiety attacks, the patient was prescribed Ativan to treat her anxiety disorder.

As a wife and active mother of two young children, the patient wanted to continue treatment, but felt isolated and overwhelmed by the side effects of her therapy and the medications she was using to treat those side effects. Through the oral oncology specialty pharmacy, the patient received the extra support she needed to continue treatment. Oncology-trained nurses were able to invest extra time listening as she explained the severity of her pain. These nurses received multiple phone calls from the patient to answer questions, including finding information not covered in the drug manufacturer literature about whether exposure to the sun would cause adverse effects. The patient care team also worked with the patient to identify relaxation and visualization techniques to help her better cope with the pain.

The patient care team’s moral support and expert side-effect management helped to reduce the patient’s

apprehensions. The end result: the patient did not miss a dose of Gleevec, and after six months of treatment she remains in remission.

Patient B

While many patients battling cancer require clinical and emotional support, a significant portion of patients also require financial assistance. This scenario was true with a 72-year-old patient with renal cell carcinoma that had metastasized to his lungs. The patient’s physician prescribed Nexavar® (sorafenib) tablets.

While the convenience of taking an oral treatment offered many benefits to the patient and his wife, Nexavar is an expensive drug. As a Medicare Part D participant, the patient was quickly pushed into the coverage gap known as the “doughnut hole.” During support calls from the pharmacy, nurses recognized that the patient, who lives on a fixed income of Social Security, needed financial support.

The pharmacy team regularly works with a wide variety of assistance organizations, and understands the requirements each program has for patients applying for grants. The team was able to assist the patient in securing grants in 2006, 2007, and 2009. In 2008, when rules for one of the financial assistance organizations changed and the patient did not qualify for assistance, the team worked with another organization that provides financial support to Medicare Part D beneficiaries. Combining the assistance received through both foundations, Care Advantage has helped the patient secure \$25,000 in financial assistance for medication costs over four years.

Oral Oncology Specialty Pharmacies Help Oncologists Enhance Clinical Outcomes

- Oncology-specific clinical expertise gives physicians confidence in the care their patients receive
- Direct patient follow-up saves physicians and staff valuable time
- Improved therapy adherence and patient education enhances clinical outcomes
- Facilitation of access to financial assistance programs saves practice staff time
- Follow-up communication regarding patient status ensures coordinated cancer care.

Medicare Modernization Act (MMA) of 2003. The result is leaner times and more pressure to operate practices with as few clinical and non-clinical staff as possible.

So while oral oncology drugs offer many benefits, they also raise quite a conundrum for practices to provide patients on oral chemotherapy the added support they require, especially without the opportunity to see patients regularly in the infusion room. Larger oncology programs may be able to dedicate an advanced practice nurse to oversee an in-house program for following up with and monitoring patients on oral chemotherapy. Smaller practices, however, may not have the staffing resources available to provide these services. An oncology nurse at the practice has the expertise, but he or she most likely does not have the time to provide the level of service required while still preparing admixtures, managing the infusion room, and providing care to patients receiving treatments.

A viable solution is for oncologists to look to an oral oncology specialty pharmacy for broader and deeper support. This type of pharmacy addresses adherence challenges by bringing clinical oncology expertise to the delivery and management of oral therapeutics. This support helps optimize patient care, while also reducing the practice workload.

For example, OncologyRx Care Advantage™, is an oral oncology pharmacy developed by US Oncology. The program provides support services specifically designed to address adherence challenges to oral chemotherapy, including:

- Allowing patients to receive prescriptions via mail at home or at their physician's office. To ensure safety, the Care Advantage pharmacy purchases all drugs directly from the US Oncology distribution center, which buys directly from the manufacturers and uses electronic pedigree (E-Pedigree™) data management to track drugs from the maker to the pharmacy.
- Ensuring that on the initial prescription order, an oncology-certified nurse on the CARxES (Chemotherapy Adherence & Prescription Education Support) team reinforces the education already provided by the oncologist and his or her staff. Along with dosing instructions, the nurse provides information about possible side effects and reminds the patient to watch for symptoms.
- Providing pharmacy tools, such as calendars, diaries, dosing cards, and instruction sheets to help patients track their treatment regimens.
- Ensuring that patients receive weekly follow-up phone

calls from oncology-certified nurses. These calls are designed to gain information about how the patient is feeling, ask about any changes he or she is experiencing, and review prescription details to ensure patients are adhering to doses, timing, and

other instructions.

- Monitoring prescription refills. As treatment progresses, staff at the oral oncology specialty pharmacy monitors prescription refills. If a patient does not refill at the expected time, the nurse calls the patient to determine if he or she is not taking the prescription at the correct dosage, not taking it at all, or if financial considerations exist.
- Ongoing communication between pharmacy staff and the prescribing physician about patient progress and/or changes.
- Managing many of the complex reimbursement issues associated with oral oncology treatments. This management includes handling insurance coverage verification and helping patients seek co-pay assistance to ensure access to treatment therapy.
- Providing 24-hour access to pharmacists. Patients can call any time to ask questions and discuss concerns and adverse events.

Patients taking oral chemotherapy need all types of support, and a specialty pharmacy staffed with oncology certified nurses and pharmacists is uniquely qualified to meet these needs. For an example of how a specialty pharmacy can meet the unique needs of patients on oral chemotherapy, see the case studies on page 41.

Outside the Box

For most oncologists, changes in the field of cancer care have been a driving force for looking outside the box to improve the delivery of care. Trends ranging from the form of chemotherapy to the way services are reimbursed require oncologists to become more creative in the way they run their practices. The bottom line, however, is that oncologists want better patient outcomes, and now is the time to determine how to address the many challenges this oral form of treatment presents. The use of a specialty pharmacy can be a key to unlocking a successful future in oral therapeutics. 📞

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