# Oral Oncology Products

## BARRIERS TO SUCCESSFUL ADOPTION

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*Pharmaceutical manufacturers* are focusing their attention on developing oral forms of chemotherapy. The endeavor to offer drugs that can be delivered more easily has yielded both new oral agents and oral forms of drugs traditionally administered by IV.

The magnitude of the movement toward oral agents is best demonstrated by the fact that between 20 and 25 percent of the 400 new antineoplastic agents under development are expected to be in oral form.

Although oral forms of supportive care agents, including the anti-emetics, have been prescribed for several years, oncologists are just beginning to use many oral chemotherapy products. Today, oral drugs represent only a small share of the cancer treatment market, but that will soon change. Three types of products are coming online, including:

- New oral forms of products currently available only in infusions or injections, and newer chemotherapy agents
- New classes of drugs such as oral cytostatic products, which will be used alone and in combination with chemotherapy products to control certain types of cancer and reduce the toxic effects of other drugs
- Supportive care agents, including anti-emetics.[1]

The implications of these new treatment options are important as the huge number of "baby boomers," 77 million Americans born between 1946 and 1964, moves into late-middle and old age and the number of patients with age-related cancers is likely to increase. Products that can hold cancer in check for long periods of time with a reasonable quality of life will mean that individuals with cancer may be taking cancer treatment drugs and supportive care agents for five, 10, or even 20 years—far longer than today.[1]

Oral agents are easy to use and offer the promise of less frequent visits to the physician's office. This promise is not trivial, especially as we have come to realize that many forms of cancer may be managed with these drugs. Still, oral oncology therapies are encountering a number of obstacles, including concerns about patient compliance and reimbursement. Will patients take all the medicine they should and take them on schedule? Will patients tell their doctors in a timely manner about the side effects they are having? Will insurance companies pay for oral medications so patients can afford them? As yet, these questions remain unanswered, and consequently the use of oral cancer agents has been limited.

Several distinct groups of stakeholders, including medical oncologists, nurses and other staff in oncology practices, pharmacists, and patients and their families, will play an active role in the introduction of oral agents to the marketplace. In one of our previous studies, all these stakeholders rated efficacy and safety, economics, and patient quality of life as important concerns.[1]

To gain more insight into these issues and into the barriers that oral oncology products may face in clinical practice, ELM Services, Inc., an oncology consulting company in Rockville, Md., recently completed a study for the Association of Community Cancer Centers on the use of one oral form of chemotherapy in office-based practices.

ELM Services conducted interviews with oncologists and oncology nurses in 12 oncology private practices. The goal was to solicit the impressions of clinical staff regarding the differences between oral and standard forms of chemotherapy. The practices were geographically diverse and ranged in size from three to nine medical oncologists. Data collection took place in the spring and summer of 2001.

### *Results*

Figure 1 shows the attitudes of nurses and physicians from the participating practices toward oral and IV agents along six dimensions: patient compliance, ability to satisfactorily maintain optimum dose, the availability of the drug, treatment-associated toxicity, ease of administration, and likelihood of obtaining insurance approval. Attitudes were measured on a 5-point scale, with lower scores representing preference for IV agents and higher scores for oral agents. The figure standardizes the median scores across all respondents so that 0 is a neutral score and any positive number favors oral agents, while negative numbers favor IV drugs.

The oncologists and nurses surveyed indicated little difference between oral and IV agents in terms of compliance, dose maintenance, and toxicity. However, both nurses and physicians viewed oral drugs as being more easily administered, and nurses found it more difficult to obtain insurance approval for oral drugs. Nurses would typically be more aware of insurance issues than their physician counterparts because they are responsible, or work with the staff members responsible, for filing and following through on claims.

While scores on the availability of products were relatively neutral, many respondents commented on delays

in obtaining oral agents because local pharmacies sometimes had a policy of not stocking them.

## Barriers to Expanded Use

Perhaps the most interesting aspects of the study were the answers to the open-ended questions that asked respondents to describe their recent experiences prescribing oral chemotherapy. These responses highlighted a number of obstacles, which fall into one of three broad categories: financial, cultural, and practical.

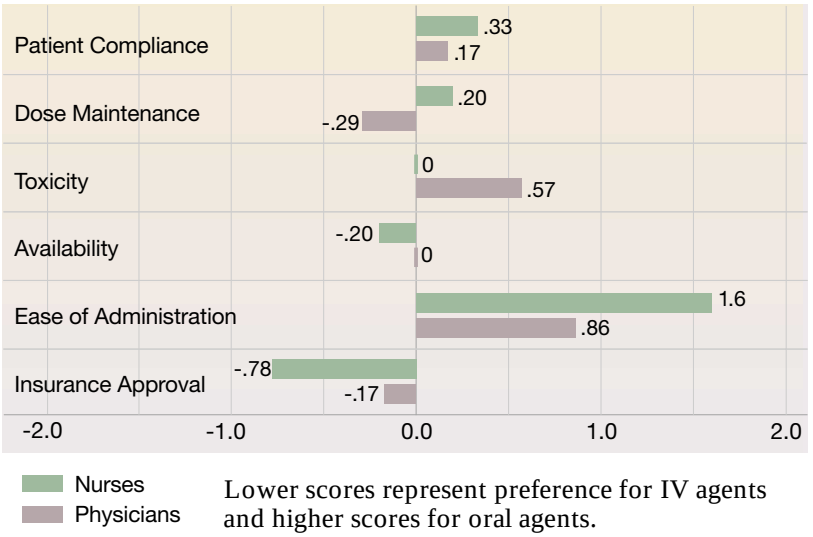
*Financial.* Office-based oncology practices derive most of their revenues from treating patients with chemotherapy. The practices are compensated both for delivering the drugs and for the drugs themselves. Reimbursement of any kind is often lacking with oral agents. There are no administration fees and, unless the practice also dispenses the drugs, there is no involvement in their purchase. The oncologist simply writes a prescription, and the patient goes to a pharmacy and obtains the product. Consequently, the practice will realize almost no revenue from those patients who are treated entirely with oral agents. While it is unlikely that any physician would base a treatment decision solely on financial considerations, it is also unrealistic to assume that financial considerations can be completely ignored, especially if IV drugs offer equivalent outcomes.

The one case in which oncology practices can realize revenue from patients treated with oral chemotherapy is when the practice also dispenses the product. Three of the 12 practices that participated in our study dispensed oral agents. As the availability of oral chemotherapeutic drugs increases, the number of dispensing practices is likely to increase as well.

*Practical.* A number of respondents indicated that their patients experienced delays in obtaining oral products because they were not in stock at local pharmacies. Given the fact that independent pharmacies have little experience dealing with antineoplastic agents and that the demand for oral forms of chemotherapy has yet to stabilize, these delays should come as no surprise. However, such delays make practitioners hesitant to rely on oral agents. Although a two- to three-day delay in the initiation of therapy for most solid tumors is unlikely to affect the clinical outcome, the psychological distress this delay can cause patients who are already quite anxious about their therapy is considered unacceptable.

*Cultural.* From the patient's perspective needles, weekly visits to the doctor, and constant monitoring are now expectations that accompany a diagnosis of cancer. Consequently, while oral agents are seen by many patients as preferable because they eliminate these onerous aspects of care, some patients object to them precisely because they are not 'business as usual." Some patients seem to believe that the efficacy of chemotherapy is directly related to its morbidity and that oral agents, because they are easier to take, cannot be as effective. In addition, while many patients are pleased to avoid weekly or daily visits to the doctor, a cohort of patients may actually be reassured by these visits and, therefore, be less attracted to a therapeutic modality that eliminates the need to visit the practice on a regular basis.

**Figure 1: Nurse and Physician Attitudes Comparing Oral and IV Agents**




Lower scores represent preference for IV agents and higher scores for oral agents.

## Discussion

Medical oncologists provide evaluation and management services, make referrals for diagnostic testing, radiation therapy, surgery, and other procedures as necessary, and offer any other support needed to reduce patient morbidity and extend patient survival. The core activity in medical oncology is, however, the provision of infusional chemotherapy. The entire structure of office-based practices revolves around this activity, and it is what distinguishes medical oncology from most other specialties. This reality and the fact that physicians receive no reimbursement for providing oral therapy to Medicare patients are the principal barriers to the availability of oral agents. The advent of oral agents ultimately means that medical oncology will need to change its identity. Acknowledging this reality is difficult at a time when assaults on the profession are being mounted by public and private payers who are anxious to reduce compensation for the treatment of cancer patients.

If oral agents ultimately deliver on their promise of combining equally efficacious therapy with better adverse event profiles and easier administration, they will gradually gain their appropriate share of the marketplace. However, for the reasons noted above, the entry of these drugs into everyday care is slower than one would expect and may not come easily.

## Reference

[1]Thomas F, Cahill AG, Mortenson LE, et al. Oral chemotherapy, cytostatic, and supportive care agents: new opportunities and challenges. *Oncol Issues*. 15(2):23-25, 2000.

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