Oncology Issues

ISSN: 1046-3356 (Print) 2573-1777 (Online) Journal homepage: https://www.tandfonline.com/loi/uacc20

Oral Chemotherapy, Cytostatic, and Supportive Care Agents

New Opportunities and Challenges

Fred W. Thomas, Anthony G. Cahill, Lee E. Mortenson & Mason Schoenfeldt

To cite this article: Fred W. Thomas, Anthony G. Cahill, Lee E. Mortenson & Mason Schoenfeldt (2000) Oral Chemotherapy, Cytostatic, and Supportive Care Agents, Oncology Issues, 15:2, 23-25, DOI: 10.1080/10463356.2000.11905117

To link to this article: https://doi.org/10.1080/10463356.2000.11905117

Oral Chemotherapy, Cytostatic, and Supportive Care Agents

New Opportunities and Challenges

by Fred W. Thomas, R.Ph., Anthony G. Cahill, Ph.D., Lee E. Mortenson, D.P.A., and Mason Schoenfeldt

Many of the more than 350 new anti-cancer drugs now in development hold tremendous potential for changing the way the medical community treats cancer. Several products in development are designed to effectively hold cancer in-check and stop it from spreading. Others are designed to improve the safety profile of chemotherapy products. Many of these new products may transform some forms of cancer into a "chronic, manageable disease" similar to HIV, chronic leukemia, and diabetes.

Although oral forms of supportive care agents, including the anti-emetics, have been prescribed for several years, oral chemotherapy products (such as *Xeloda*) are just beginning to find usage among oncologists. Today, oral drugs represent only a small share of the cancer treatment market. That will soon change. Three types of products are coming on-stream in the next several years, 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 toxicity effects of other drugs.
- Supportive care agents, including anti-emetics.

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. The number of patients with age-related cancers such as prostate and colorectal is likely to increase. Products that can hold cancer in check for long periods of time with a reasonable quality of life mean that individuals with cancer may be taking cancer treatment drugs and supportive care agents on a continual basis for five, 10, or even 20 years—far longer than at present.

Several distinct groups of stakeholders, including medical oncologists and related staff of oncology practices, pharmacists, and patients and their families, will play an active role in the complex issue of oral products as they are introduced in the marketplace.

According to a new study by ELM Services, Inc., all these stakeholders rate efficacy and safety, economics, and quality of life for patients as important concerns. As might be expected, oncologists, oncology nurses, and practice administrators identify efficacy as a primary issue associated with a decision to use oral compounds. Reimbursement—for oncology practices, pharmacists, and most importantly, for patients—is also rated as a key consideration.

ELM conducted interviews with oncologists, oncology nurses, practice administrators, patient advocacy groups, and public policy leaders. The goal was to study the issues surrounding oral drugs, as well as to analyze current reimbursement policy concerning oral drugs. The results of this research were published in the report, *Oral Chemotherapy and Supportive Care Agents—Navigating through the Policy and Business Issues.*[1]

EFFICACY AND SAFETY: NOT THE ONLY CRITERIA

According to survey results, 96 percent of responding medical oncologists have used oral chemotherapy products, including *Xeloda*, *Cytoxan*, and *VePesid*. Sixty-three percent of the surveyed medical oncologists are familiar with the drug, *Orzel*, and 92 percent of those oncologists expect to use the product once it is approved. Eighty-five percent of the surveyed medical oncologists indicate that they are *very likely* to use the new oral cytostatic products.

Efficacy and safety are primary

Fred W. Thomas, R.Ph., is vice president, Pharmaceutical Research and Analysis, for ELM Services, Inc. Anthony G. Cahill, Ph.D., is a private consultant in health care and public policy issues. Lee E. Mortenson is president of ELM Services, Inc. and ACCC Executive Director. Mason Schoenfeldt is a research associate with ELM.

considerations in the choice by an oncologist and patient to use any treatment regimen. According to the survey, 90 percent of responding medical oncologists state that efficacy data will be the most important factor in their decision to use new oral products.

In an ideal world, the choice would naturally be to use the product that "works best" and has the least number of side effects. However, in the complex world of health care politics and economics, the choice is not always so straightforward and clear. In the case of oral drugs for the treatment of cancer, the economic aspects, including who will pay for these new oral agents, are even more far-reaching.

According to the Social Security Act (Section 2049, as amended), Medicare will reimburse for oral products only "...when they have the same active ingredients as a non-self-administerable anti-cancer chemotherapeutic drug or biological that is covered when furnished incident to a physician's service...." This policy was amended to include prodrugs, but the fact remains that the newer oral drugs face barriers to reimbursement.

The Health Care Financing Administration, which administers Medicare, seems unlikely to focus on reimbursement of oral products until Congress has first addressed the issue. In turn, key congressional staff have clearly indicated that any action by Congress to include a prescription drug benefit in Medicare will not include oral chemotherapy products because of the high cost.

Oncology practices have a major stake in how (and if) new oral products are reimbursed. Oncologists using an oral drug instead of a drug currently administered in the office through an infusion or injection face a loss of income from administration fees as well as from any margin the practice makes from the drug itself.

As one oncologist noted: "I would use [an] oral [drug] if I don't risk a financial loss for my practice." Similarly, pharmacists are unwilling to stock or dispense a drug for which they cannot be reimbursed. New and innovative programs to assist physicians to become dispensers of oral products are being introduced in several states.

Eighty-three percent of the surveyed medical oncologists are *very concerned* or *somewhat concerned* about reimbursement for the new oral cytostatic products. Although 98 percent of the surveyed medical oncologists have used oral versions of the 5HT-3 anti-emetic products, 75 percent said they would increase their use if these products are included in a Medicare prescription drug benefit.

While the economic aspects of oral chemotherapy are significant for oncology practices, a far more important group—patients—is often overlooked. Focusing too closely on reimbursement for oncology practices may miss the point. From the patients' perspective, a drug that is out-of-reach of their personal income and is not reimbursable under their public or private insurance plan is unlikely to be used by them, regardless of whether the drug is more convenient, or recommended by their physician.

WHO WILL MONITOR PATIENT COMPLIANCE?

If significant numbers of cancer regimens actually do revolve around oral drugs in the future, another relevant issue emerges: patient compliance. When asked about this in an oral-based regimen, one oncology nurse remarked: "Oral chemotherapy sounds easier, but it may not be! Who's going to worry about the patient taking the right number of pills in the right order or having sufficient anti-emetics? Who's going to monitor timing and compliance, and get the patient in for blood work if something begins to go wrong? These are the things we need to worry about...."

ORAL CHEMOTHERAPY, CYTOSTATIC, AND SUPPORTIVE CARE AGENTS

According to the ELM study, medical oncology respondents indicated:

- 96 percent have used oral chemotherapy products, including *Xeloda*, *Cytoxan*, and *VePesid*.
- 63 percent are familiar with the drug, *Orzel*, and 92 percent of those oncologists expect to use the product once it is approved.
- 85 percent are *very likely* to use the new oral cytostatic products with 90 percent stating that efficacy data will be the most important factor in their decision to use these products.
- 83 percent are *very concerned* or *somewhat concerned* about reimbursement for the new oral cytostatic products.
- 98 percent have used oral versions of the 5HT-3 anti-emetic products, with 75 percent stating they would increase their use if these products were included in a Medicare prescription drug benefit.

In fact, 65 percent of the surveyed medical oncologists said they are "somewhat concerned" or "very concerned" about patient compliance relative to oral chemotherapy products. Reasons for this concern include the fear that patients may forget to take their medication or be intimidated by complicated dosing, and that patients may deliberately skip doses.

THE CLASH OF SCIENCE AND POLITICS

Before oral agents will be accepted and widely used, several challenges and concerns still need to be addressed. These include a confusing set of federal and state government policies regarding use and reimbursement, resistance from oncologists who face a loss of income, and issues surrounding patient compliance and ability to obtain drugs and be adequately reimbursed. Efficacy and safety are critical, but reimbursement issues will drive the success or lack thereof of the new oral agents. These concerns will present a challenge to the oncology community because several products in development appear to offer therapeutic advantages.

Pharmaceutical companies will play an active role in working with providers to obtain reimbursement for oral drugs and manage patients taking oral cancer treatment therapy. Several programs, including Oral Reimbursement for Cancer Agents (ORCA), are in test phases to assist medical oncologists in obtaining reimbursement and in understanding state laws regarding the dispensing of oral drugs in their offices. Other programs are focusing on assisting the practice in making the drugs readily available for patients, and in managing compliance issues. Ninety-six percent of the surveyed medical oncologists said pharmaceutical manufacturers should provide or sponsor programs that assist the practice or patient in obtaining reimbursement, or provide assistance in managing patients on oral chemotherapy as new products are introduced. Financial relief was most frequently mentioned.

Regulatory or legislative changes will likely be required to provide a better mechanism for reimbursement of oral cancer treatment drugs.

Regulatory or legislative changes will likely be required to provide a better mechanism for reimbursement of oral cancer treatment drugs. While HCFA and Congress appear reluctant to act, the potential for advances in therapy and patient convenience with new oral drugs will push the policy makers to effect changes in public policy.

Patient advocacy groups, reflecting the views of patients and their families, are likely to become increasingly involved in the issue of oral cancer treatment agents in this age of exploding information availability. The extent to which patients perceive that they are active participants in their own treatment; feel some sense of control over their lives; and can approach a lifestyle and routine which is as close to their pre-cancer lives as can be managed, are important issues from the point-of-view of patients. If the newer oral agents do, in fact, offer increased efficacy, safety, and convenience, patients and patient advocacy groups will take an active role in the debate.

In a world of budgetary constraints, efforts to stabilize public and private health care costs, and unfavorable demographic trends, innovative oral cancer treatment regimens will face increasing scrutiny beyond the usual efficacy, safety, and reimbursement questions. Everyone who is a part of the equation, including patients, oncology practices, policy makers, private insurers, and pharmaceutical companies, will need to work together to master this "brave new world" of cancer treatment.

REFERENCES

[1]*Oral Chemotherapy and Supportive Care Agents—Navigating through the Policy and Business Issues*. Rockville, Md.: ELM Services, Inc.; 1999. For information, concerning the purchase of this study, contact lmortenson@elmservices.com.