ORAL CHEMOTHERAPY: Progress with Challenges

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Oral chemotherapy is fast coming of age. With increasing frequency, oral cytotoxins are displacing intravenous (IV)-based chemotherapy in the treatment of a number of cancers. Patients with multiple myeloma take thalidomide and dexamethasone. Those who suffer from anaplastic astrocytoma can ingest temozolomide in pill form. Patients with metastatic colorectal cancer self-administer oral capecitabine, and those with chronic myeloid leukemia rely on imatinib mesylate, which they take orally. Today, 20%–25% of the 400 new antineoplastic agents under development are expected to be oral agents, and oral drugs comprise 5% of the growing oncology drug market.

Oral Therapies Offer Benefits

The shift to oral agents is occurring for a number of reasons. Many patients tolerate oral chemotherapeutic agents better than chemotherapy administered by traditional IV-based therapy and they like the time saving and convenience that come with oral agents. Compared to standard intravenous therapy, oral anticancer drugs make receiving cancer treatment more convenient for patients by allowing flexibility in taking medication without disrupting work or other activities. In addition, oral anticancer drug therapy often results in less time spent in hospitals because of the absence of intravenous administration and related side effects. Several studies have shown that patients overwhelmingly prefer oral therapy to intravenous chemotherapy treatment. These differences in therapy work to improve quality of life for people with cancer and can translate into savings for the health care system. However, oral chemotherapy is not less toxic than IV chemotherapy, and patients may still experience side effects, such as neutropenia, diarrhea, or stomatitis.

Patients who self-adminster oral chemotherapy may also experience a newfound sense of freedom and control over their therapy, taking them out of the role of passive receivers of treatment. This may help improve the quality of life of patients with cancer while they are on a chemotherapy regimen.

Though oral agents offer a number of benefits, the growth in their use raises many related, practical cancer care issues that physicians and nurses need to address, such as how best to help patients, particularly the elderly, through a patient education and oral management program.

For example, patients may not comprehend complicated drug regimens. Elderly patients may be visually or hearing impaired, and may require more feedback from nurses about oral agents and their complexities. An oral medication like temozolomide may require a patient to take an initial dose for five consecutive days within a 28-day treatment cycle, and then come to a physician's office on the twenty-second and twenty-eighth days for blood work. Patients need to know when to report side effects and possibly postpone their oral treatment.

Compliance and accuracy, or lack thereof, may also present challenges. The more frequently a patient must take a medication during the day, the greater may be the chances of decreased compliance. Patients may forget to take medications and unintentionally skip treatment for their cancers. They may make errors in taking anticancer drugs that may be critically dangerous for them. They may also become embarrassed if they make mistakes and may be less than truthful with nurses and physicians when they do make them.

Lack of compliance may present a particularly harmful problem for patients with cancer who have no one at home to help them monitor their intake of oral agents. Many patients with cancer suffer from comorbidities requiring them to take other medications besides oral chemotherapy drugs. Patients who fail

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to explain the full complement of their medications to physicians or nurses run the risk of experiencing harmful drug interactions.

Credibility may also present a challenge. Patients with cancer may not believe that oral agents are as effective as those delivered intravenously.

Medicare Limits Patient Access

The scope and level of Medicare reimbursement pose a major challenge across the population of patients with cancer, because they directly affect the nation's seniors and because many private insurers utilize Medicare policy as a basis for their own coverage decisions. Under current law, Medicare covers chemotherapy as well as radiation treatment for cancer patients, but does not pay for oral anticancer drugs approved by the U.S. Food and Drug Administration (FDA) unless they are available in both oral and injectable form. Currently, Medicare Part B (outpatient) coverage involves only seven oral anticancer drugs. For example, Medicare does cover capecitabine and temozolomide, but does not cover oral hormonal agents used to treat breast cancer and prostate cancer.

In 1993, Medicare began reimbursing for oral agents that have an intravenous formulation, such as cytoxan, etoposide, and mephalan. In 1997, Medicare provided coverage for an oral antiemetic. When this medication is a part of a chemotherapy regimen, it completely replaces the IV dose for only one cycle at a time. For example, if a patient's chemotherapy cycle is once every three weeks, Medicare will only pay for one dose of the antiemetic in the three-week period. If a patient experiences nausea and needs an antiemetic a day or two after chemotherapy, Medicare will not pay for it. The patient has to buy it from a pharmacy.

There are also cost challenges to overcome with regard to oral agents. In an ideal world, cancer care providers would have the choice to use the product that works best and has the least number of side effects. This is not the case with oral chemotherapy.

If Medicare coverage for oral anticancer drugs does not change, many seniors may be unable to afford the new oral agents. Whatever recommendations their oncologists make, many Medicare beneficiaries are unlikely to use drugs that exceed the reach of their personal incomes and that are not reimbursable under Medicare or a private insurance plan. Living on fixed incomes and paying for drugs out-of-pocket that are consistently increasing in price often forces seniors with cancer to make dangerous, life-threatening choices between food and much needed prescription medicine.

To complicate matters even further, one-third of Medicare enrollees have no prescription coverage at all, and many others may participate in a health maintenance organization (HMO) senior plan that limits coverage to $1,000 per year.

Medicare costs for seniors have risen more rapidly than any other living expense. According to the National Institute for Health Management, consumer purchases of prescription drugs for 2001 rose by $22.5 billion over the previous year. Pharmacy sales are now at an all-time high of $154.5 billion, and spending on prescription drugs has been going up 17% a year since 1998. New prescriptions are the main reason, but prices also are increasing.

At the same time, many pharmaceutical companies have programs in place to make their medicines available to those who cannot afford to pay for them. According to the Pharmaceutical Researchers and Manufacturers of America (PhRMA), in 2001, more than 3.5 million patients received prescription medicines through these assistance programs, up from 1.1 million in 1997. Nearly 10 million prescriptions, with a wholesale value of about $1.5 billion, were filled, up from about two million prescriptions in 1997.

The Medicine Program was established by volunteers to alleviate the plight of patients who cannot afford to buy prescription medications. This program provides free prescription medicine for those who lack insurance coverage for outpatient prescription drugs, and for those who may not qualify for a government program such as Medicaid that provides health care insurance coverage—including prescription medications—for some low-income individuals. The program also provides medications for those whose income level creates a hardship in purchasing medications at retail prices.

According to the Medicine Program's 2000 report outlining the sponsor criteria for approval and enrollment, "individuals with family incomes ranging from below the national poverty level up to $60,000 annually can qualify." Those who qualify at the highest income levels are normally patients with AIDS, cancer, and transplants.

Patient assistance programs help, but greater access to medicines—such as a prescription drug benefit for Medicare beneficiaries—is still needed.

Congressional Action Needed

Despite recent breakthroughs in cancer treatment and the ever-evolving nature of cancer care, the present scope and level of Medicare coverage remain antiquated and unable to keep up with important developments in the cancer arena. Consequently, the lack of coverage of prescription drugs—coupled with the costs of these new drugs—has prompted concern by the Oncology Nursing Society (ONS) and others in the cancer advocacy community that patients and physicians are potentially being forced to compromise, or even forfeit, promising cancer care due to the lack of Medicare coverage for many of these life-saving therapies.

Therefore, many in the cancer community are advocating enactment of legislation in Congress to provide Medicare coverage of all FDA-approved oral anticancer therapies.

Senators Olympia Snowe (R-Maine) and John "Jay" Rockefeller IV (D-W. Va.), and Representative Deborah Pryce (R-Ohio) have introduced the "Access to Cancer Therapies Act" (S 913/HR 1624), which would expand Medicare Part B coverage to include all oral anticancer drugs approved by the FDA. The legislation seeks to provide our nation's seniors with access to the full range of the latest cancer-related prescription drugs at manageable costs to enhance the quality and standard of treatment for cancer.

Under the legislation, a small premium (or none at all) would be charged to low- and moderate-income seniors. The legislation would also cap Medicare beneficiary spending on prescription drugs at $3,000 as the maximum seniors would pay out-of-pocket. As of the beginning of September 2002, more than two-thirds of the members of the House of Representatives and more than half of the members of the Senate had signed on as cosponsors supporting the measure.

President Bush's proposed plan for a prescription drug benefit for seniors provides a Medicare drug discount card to save between 10% and 25%. This would not put imatinib mesylate within range of affordability for many patients with cancer. It is possible that if Congress fails to enact a comprehensive Medicare prescription drug benefit, policymakers may decide to enact the "Access to Cancer Therapies Act" as an incremental step to provide seniors access to oral anticancer drugs.

Reimbursement Policy Impacts Access to Quality Cancer Care

Significant issues also exist at the pharmacy level. For example, there may be an increased risk for errors in community retail pharmacies, at least until pharmacists can educate and familiarize themselves with a new array of complicated pharmaceuticals.

Many community pharmacies cannot afford to stock expensive drugs and run the risk of not being reimbursed. Discount mail-in plans may not be cost effective or practical when chemotherapy doses and drugs themselves can change often.

Educating patients with cancer takes time. Oncology nurses may spend one hour on chemotherapy education, but this important patient care service is not reimbursable by Medicare. Certified diabetic educators have made some inroads in getting patient education reimbursed. Medicare carriers throughout the country are, however, not consistent in recognizing the codes and in paying them when the charges relate to patient education.

Cancer is a complex, multifaceted, and chronic disease, and people with cancer require specialty nursing and clinical interventions at every step of the cancer experience. People with cancer are best served by multidisciplinary teams of health care professionals specializing in oncology care, including oncology nurses. Efforts are underway to educate members of Congress and their staff about the full range of services provided by oncology nurses in an attempt to ensure that the Medicare program pays adequately and appropriately for the comprehensive, quality cancer care provided by the multidisciplinary cancer care team.

Then, there is the challenge of reimbursement for outpatient cancer care that occurs in a variety of settings. Of the $238 billion Medicare spent in 2000, only $41 billion of that went to physician services. In January, a 5.4% cut in payment to doctors went into effect. This, in the face of hospital outpatient expenditures for Medicare patients that are up nearly 400% since 1985 and growing at a rate of 13% annually—twice the rate of inpatient expenditures. These figures are not particularly surprising in light of the shift from inpatient to outpatient services.

Medicare's reimbursement policies do not reflect the current reality that most cancer treatment occurs in the outpatient setting. This failure to shift payment policy from an inpatient-based system of care to one that serves ambulatory patients has resulted in underpayment of practice expenses associated with the administration of chemotherapy.

The current Medicare reimbursement system does not provide any reimbursement for a host of oncology nursing activities, and those payments that are made are often grossly inadequate. Without adequate support for the full range of services provided by oncology nurses, the viability of the nation's system of community-based cancer care will be threatened and outpatient settings will be unable to employ the oncology nurses necessary to provide quality care to patients.

Currently, the average wholesale price (AWP) payment methodology for drugs results in an overpayment for drugs that provides a cross-subsidization for other important oncology-related services for which the Medicare program currently provides no—or inadequate—reimbursement. ONS and other organizations in the cancer community support reforming the AWP system so that the government does not overpay for drugs, simultaneously with making much needed increases and improvements to the payment system for outpatient cancer chemotherapy administration (a.k.a. practice expenses).

At the time of this article, Congress is considering various ways to reform both components of the Medicare reimbursement system for outpatient cancer care—drug payment and oncology practice expenses.

Some people assert that if outpatient, community-based settings do not receive adequate Medicare payments, they will no longer be in a position to serve people with cancer. That would shift cancer patients back to hospital-based outpatient departments. However, the hospital-based outpatient area has already seen a 6.3% reduction in payments for drugs and medical devices instituted by the Centers for Medicare and Medicaid Services (CMS)—the federal agency with authority over the Medicare program (formerly known as the Health Care Financing Administration [HCFA]). Hospital outpatient departments (HOPDs) providing oncology services are already losing money and are not in a position to absorb more patients should other cancer care settings stop providing care and shift their patients to HOPDs.

For some time, the HMOs serving the Medicare population have been cutting back in their services for seniors, increasing the out-of-pocket costs for seniors, or ceasing coverage to Medicare beneficiaries altogether. For example, the Mayo Clinic recently announced that beginning in January 2003, its Florida facility will no longer accept Medicare assignment. This means Medicare patients can still be treated at the facility, but the patients will be responsible for paying the bills themselves and submitting the receipts to Medicare, which will likely reimburse the patients an amount that is less than what was paid.

The Mayo Clinic in Scottsdale, Ariz., has already implemented a policy of not accepting Medicare assignment, and at its main facility in Rochester, Minn., the Mayo Clinic only accepts Medicare as-

Available Resources

Various resources are available to assist health care providers in navigating reimbursement programs. Some of the information about pharmaceutical medication assistance programs can be obtained from the Internet, pharmacists, nurses, and social workers (Chisholm et al., 2000). Although literally dozens of medication assistance Web sites are available, the following are some of the more helpful ones:

- www.needymeds.com—Gives patients detailed information about each participating company's assistance program, including how the drug will be dispensed, refill information, and limitations of the program.
- www.cancersupportivecare.com/drug_assistance.html—Lists drug assistance programs from 29 companies, emphasizing oncology agents.
- www.themedicineprogram.com—Assists patients in program enrollment procedures, but requires them to pay $5 per medication as a processing fee.
- www.familyvillage.wisc.edu/hospital/meds.htm—Lists pharmaceutical assistance programs and provides links to needymeds.com and themedicineprogram.com sites.
- www.phrma.org—Contains the Web site of the Pharmaceutical Research and Manufacturers of America (PhRMA), and permits users to download the latest version of PhRMA's directory. The 2001–2002 Directory of Prescription Drug Patient Assistance Programs lists 57 pharmaceutical companies that provide medications to physicians whose patients could not otherwise afford them (PhRMA, 2001). The site only features the pharmaceutical companies that are members of PhRMA and offer some type of assistance program. Patients who do not have Internet access can obtain the directory by writing to PhRMA at 1100 Fifteenth Street NW, Washington, D.C., 20005, or calling 800.762.4636.
- www.rxassist.org—Compiles application criteria for more than 100 pharmaceutical companies and includes updated federal poverty guidelines often required for eligibility of potential applicants. Furthermore, this site provides online forms for patient enrollment. Many of the available Web sites on reimbursement have outdated information, and the fact that this site continually updates its information makes it very useful.

Patients and health care providers may also refer to the Physicians' Desk Reference (PDR, 2000), which lists the telephone numbers of pharmaceutical manufacturers. Another resource is the pharmacist's Red Book, which contains a guide to drug reimbursement, state AIDS assistance programs, and specific Medicaid reimbursement by state (Cardinale, 2001). When contacting different companies, inquire about all reimbursement programs. Although most pharmaceutical companies have programs designed to assist medically uninsured patients, not all programs cover every medication that the company manufactures. In particular, many companies are reluctant to reimburse for generic medications, although some exceptions exist.

Adapted from: Hallquist P, Mister S. Utilization of medication-assistance programs for medically uninsured patients: One public teaching hospital's experience. *Clin J Oncol Nurs* 5:6:249–250, 2001.

signment for Minnesota residents. Patients from out of state who go there for second opinions regarding their cancer will have to pay out-of-pocket, bill Medicare themselves, and accept whatever Medicare reimburses them. Medicare pays 80% of the "allowable" rate.

The closing down of Medicare HMOs has left more than two million enrollees without coverage. With the latest Medicare cut in physician reimbursement, physicians are beginning to refuse to accept Medicare beneficiaries as new patients.

In lieu of dropping their senior plans, some Medicare HMOs are raising costs for their enrollees. For example, in Arizona in 2001, one Medicare HMO asked patients to pay 20% of the cost of their chemotherapy. This is the same as the cost for patients covered under traditional, fee-for-service Medicare. Similarly, in Texas, a Medicare HMO asked members to pay $150 per drug, per treatment. This charge ballooned one cancer patient's $18-a-week copayment to $1,400 a week. Medicare HMOs consider these changes to be more member-friendly than raising monthly premiums or other copays for all members.

Health care providers and patient advocates, however, are concerned that such actions are an effort to de-select patients with cancer from participation in their plans. In addition, recently in California, an HMO that covers 80,000 lives—second only to Kaiser Permanente—filed for bankruptcy. The HMO cited Medicare's poor reimbursement for the lives it covers as the major reason for the bankruptcy.

Moreover, the current Medicaid nightmare only further weakens the viability of the nation's cancer care system. At least 39 states face financial problems, and many are cutting their Medicaid programs, benefits, and services to balance their budgets. In California, 6.5 million people (18.5% of the population) are on Medi-Cal (California's Medicaid program). This is a 7% increase over 2001. Medi-Cal reimbursement covers only 50%–60% of the cost of services. A recent analysis performed by one oncology practice showed that a number of drugs—topotecan hydrochloride, dexrazoxane, trastuzumab, and gemcitabine hydrochloride—are reimbursed far below the cost of purchase.

Nurses Can Make Their Voices Known

Without a doubt, oral chemotherapy will help many patients with cancer, but many challenges and issues exist that are associated with oral agents that beg for resolution. Our nation's policymakers need to hear from cancer care providers, including oncology nurses, about the impact that current Medicare policy and reimbursement have on the provision of quality cancer care to the nation's seniors.

Specifically, members of Congress need to have a better understanding of the adverse effect that lack of coverage for oral anticancer drugs, insufficient practice expense payments for chemotherapy administration, and cuts in payments to physicians and hospital outpatient departments have on the provision of the full range of oncology-related care to those Medicare beneficiaries in need.

People with cancer, oncology nurses, oncologists, and others involved in the cancer care community should work to communicate their concerns to their policymakers in an effort to affect the outcome of Medicare coverage discussions. Without hearing directly from those with the expertise and experience, our nation's policymakers will not have the full range of information or data they need to make informed decisions pertaining to Medicare reimbursement policy. HONI

For more information, please visit the Oncology Nursing Society Web site at www.ons.org, and click on "legislative action center."

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