Oncology Issues
The Journal of the Association of Community Cancer Centers

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PRESIDENT'S CORNER

REIMBURSEMENT POLICIES THREATEN CURRENT AND FUTURE CANCER TREATMENT

There are two major issues affecting the present status and, potentially, the future of cancer treatment: 1) the effect of cost containment on physicians' ability to continue to provide the best available cancer treatment for patients with neoplastic disease, and 2) the lack of government and third-party payer support for the development of, and medical costs associated with, clinical cancer research.

Oncologists are becoming increasingly concerned about their ability to continue to provide high-quality cancer care in an era of cost containment. Third-party payers are increasingly dictating what treatment regimens are eligible to be reimbursed and in what location those treatments must be given. Insurers' influence is being exerted through both the preadmission certification process and reimbursement mechanisms. For instance, a given treatment or operative procedure may be paid for on an outpatient basis, but will not be reimbursed in an inpatient setting, regardless of the age or physical status of the patient. Such determinations are being made by precertification clerks who have little insight into the clinical problems relative to a specific patient or to a diagnosis. In essence, health insurers are practicing medicine via their reimbursement policies.

As the cost of cancer treatment increases, many third-party payers are seeking to limit cancer care expenditures by not paying for "unproven cancer treatment." The definition of unproven treatment, in many instances, includes unlabeled, but medically accepted, indications for cancer therapy drugs approved by the Food and Drug Administration (FDA). FDA representatives are quick to point out that the Agency's function is to test the safety and efficacy of a new drug and to approve the labeling of a new drug. Any new or subsequent indication that is approved by the medical community, based on adequate scientific evidence, is considered standard medical treatment. In contrast to the FDA, the U.S. Pharmacopeia reviews new and effective indications for drugs based on the available body of scientific data. This makes the U.S. Pharmacopeia a much more logical resource for determining cancer treatment reimbursement policy.

The second major area of concern is the threat to future treatment advances because of the lack of support for continuing clinical research and protocol studies. To date, every major advance in the management of cancer has been based on careful research development of new treatment programs. These programs are then introduced and tested in clinical trials at university-based cancer centers and in the community hospital setting. State-of-the-art treatment has been funded by traditional mechanisms; additional research activity has been funded by research grants. At the present time, almost half of Phase III clinical trials are carried out in the community hospital setting, and the majority of these trials are funded through the Community Cancer Oncology Program (CCOP). There is a serious threat, however, that funding for this program will be reduced. Such a reduction

(Continued on page 23)

drug compendia treated as standard references for payment of new drugs and new indications."

Experimental therapy. "We must get across the point that while government is paying $3 billion for NIH research, another arm of the government (HCFA) is denying payment for clinical trial participation."

Congress Focuses on Patient Referrals

Rep. Fortney (Pete) Stark's (D-CA) "Ethics in Patient Referrals Act" has a "good shot of being passed," by Congress, according to Don Yesukaitis, Office of Federal services, Arthur Anderson & Company, Washington, DC. "Fraud and abuse in physician referrals is one of the hottest topics on Capitol Hill and across the country," Yesukaitis explained. In fact, the Inspector General of Health and Human Services is preparing a report on safe harbors in physician financing arrangements; that is, arrangements that will not be held in violation of Medicare's fraud and abuse laws. The proposed rules are due on May 1.

The revised bill that Rep. Stark introduced in February of this year is "much stricter," Yesukaitis said. "Stark is bullish on getting this bill passed, and he has the support of the Blue Cross/Blue Shield Association and the American Association of Retired Persons, as well as a number of physicians."

A key provision of the bill, according to Yesukaitis, is that a physician may not refer a Medicare patient to an entity in which that physician or a family member has an economic interest. If the bill is passed, "Stark probably would provide a transition period for existing arrangements, but has no intention to "grandfather' existing arrangements," Yesukaitis warned.

ACCC President Addresses House of Delegates

The ACCC is "dedicated to seeing that, in the present environment, we continue to provide state-of-the-art cancer care and community clinical research," said Irvin Fleming, M.D., ACCC President. To help ensure those goals, Fleming said that the Association will explore the development of patient advocacy efforts in reimbursement areas, including the possible development of a patient advocacy newsletter.

Kennedy To Reintroduce Health Bill

Sen. Edward Kennedy (D-MA) plans to reintroduce the minimum health benefits bill in April, according to Darrel Cox, Legislative Health Policy Analyst for the Committee on Labor and Human Resources of the U.S. Senate. The bill, which addresses the "growing number of uninsured," would ensure that employers provide physician and hospital services, prenatal care, diagnostic care, mental health services, and a catastrophic limit on out-of-pocket expenses," Cox explained.

Darrel Cox, Legislative Health Policy Analyst, *was the guest speaker at the ACCC Congressional Breakfast*

Two major changes in the bill that will be reintroduced are the inclusion of a public program with a 10-year phase in period that will provide access to health care for all Americans; and hardship pools that will decrease the cost of insurance for small employers (25 or fewer employees) by providing access to insurance coverage at lower rates.

Cox contended that the minimum benefits legislation will result in more "cost shifting than the reallocation of new funding." Analyses have shown that the inflationary impact of the legislation would be comparable to a 10 to 15 cent increase in the minimum wage.

Cox also said that the Committee on Labor and Human Resources of the U.S. Senate, which is chaired by Sen. Kennedy, "submitted a request for an additional one-half billion dollars for NIH funding of NCI-approved cancer centers." In addition, Cox said, construction grant legislation will be reintroduced within the next few months, requesting $150 million for additional space for research centers.

ACCC Breast Cancer Symposium

The Association's one-day breast cancer symposium, held in conjunction with the annual meeting, drew a number of expert researchers, physicians, and other members of the multidisciplinary cancer care team. The speakers at the symposium, which was chaired by William L. Donegan, M.D., chief of the department of surgery at Sinai Samaritan Medical Center, Milwaukee, WI, addressed topics that ranged from epidemiology and screening to surgery and systemic adjuvant therapy.

William L. Donegan, M.D., *Chief, Department of Surgery, Sinai Samaritan Medical Center, Milwaukee, WI, chaired the ACCC Breast cancer Symposium.*

Based on a preliminary review of the meeting participants' evaluation of the symposium, the Association's focus on a scientific, indepth examination of breast cancer was well received. ■

President's Corner

(Continued from page 3)

in support would have a serious impact on the ability to continue clinical trials in the community setting, as well as in university-based cancer centers. However, a more serious problem is that of third-party payers (Medicare, HMOs, and others) denying payment for the medical costs of patients enrolled on clinical trials. Widespread adoption of such a policy could bring clinical research to a halt and, thereby, have an enormous impact on the future care of cancer patients.

It is important that as we identify treatment constraints, we ensure that both patients and health care purchasers understand the limitations that insurers are placing on physicians' ability to provide state-of-the-art treatment. Those involved in cancer management realize the importance of continuing clinical trials in cancer centers, university centers, and the community if their ability to deliver state-of-the-art cancer care is to be sustained.

Irvin D. Fleming, M.D.
President