An Oncologist's Perspective

by Cary A. Presant, M.D., F.A.C.P.

The Medicare statutes and regulations promulgated by the Health Care Financing Administration (HCFA) for statutory implementation have been a benefit to cancer patients in the United States. On the positive side, the system generally ensures that patients receive the oncologic care that they need, including oncologic drugs and supportive care medications. Patients can receive their care in an ambulatory setting (either in physicians' offices or in hospital ambulatory cancer centers), and their care is reimbursed in considerable part by the government. Furthermore, new therapies are covered reasonably promptly, indicating that the statute and the regulations are, for the most part, working well. In addition, HCFA covers investigational therapies under a new set of rules that was formulated to implement the Executive Order directing coverage of investigational treatments.

While the accompanying article by John Whyte, M.D., provides an excellent overview of many of the aspects of Medicare drug policies, he has neglected to stress that off-label usage of drugs is universal and covered by statute and regulations. Off-label use refers to drugs that have been approved by the Food and Drug Administration (FDA) but used for indications beyond those approved in the labeled indications. Most of the FDA-approved medications are subsequently shown to be safe and effective in conditions that were not previously included in the labeled indications.

A major problem in HCFA's conduct of Medicare payment is its difficulty in interpreting what is "safe and effective." One would assume that the FDA has found that drugs are safe and effective by virtue of their approval. One would also assume that the FDA has demonstrated that the "benefits outweigh reasonably anticipated risks" and that there is "evidence of improved health outcomes (functional outcomes)," which is always stressed by the Oncologic Drug Advisory Committee and by FDA staff and scientists. Therefore, I believe that ethically and legally Medicare beneficiaries have the right to expect that if they have a disease for which a drug or device is indicated based on FDA approval, and their physician assesses that this drug or device is reasonable and necessary for the patient and his or her condition, such usage of the drug or device should *always* be covered by HCFA. In my interpretation, HCFA does *not* have the statutory authority to declare a safe and effective drug "not reasonable and necessary" for the approved condition once a patient's physician has ordered that drug for the patient. Nonetheless, Whyte stresses in his evaluation of Medicare drug policies that "FDA approval is a prerequisite not a guarantee of coverage" indicating that behind closed doors, HCFA should have the right to make such determinations independent of FDA. A better system would be for HCFA to always approve the use of a drug that is FDA approved, if the patient has the condition for which the drug was approved and if the physician certifies in the medical note that the use of the drug was reasonable and necessary for the patient.

A second problem with Medicare drug policies is that a patient and the patient's oncologist may not obtain pre-authorization from Medicare carriers for the use of a drug. This policy has resulted in Medicare beneficiaries having to sign "advanced beneficiary notices," which state that the patient will have to pay for the drug or procedure if Medicare does not approve the drugs after the claim is submitted. Such a practice is not to the benefit of the beneficiary, since the regulations do not protect the beneficiary who may have to pay a considerable amount of money. A more reasonable approach would be to have pre-authorization under certain circumstances, with rapid review by the carrier medical director or designee.

Another point to stress is that, in addition to local medical review policies, Medicare carriers can also establish their own guidelines *without* the review of the Carrier Advisory Committee. Such local carrier guidelines should be developed in conjunction with specialty societies, such as state oncology societies.

A third problem is the lack of consistency in guidelines and local medical review policies among different carriers. The result, it seems to me, is "unequal protection" for Medicare beneficiaries in different states. A better approach would be to assure patients that if any Medicare carrier has approved a usage for a drug or device, then every Medicare patient in the country should be expected to have such a drug or procedure paid for until a national coverage policy is developed and implemented.

I believe that the Medicare payment system generally works well. Whyte and his colleagues should be given credit for trying to continue to improve that process.

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