The reimbursement policies of Medicare, Medicaid, and private insurers can have a major impact on the ability of oncologists to deliver care to their patients. This article explores current issues of particular interest to oncologists.

Introduction

This article provides an overview of current issues in oncology reimbursement, with a special emphasis on Medicare/Medicaid policies. Topics included are coverage of off-label drug uses, possible changes to Medicare payment methods affecting hospitals and physicians, and the effect of reimbursement on the dissemination of new technologies.

Coverage Issues

A number of coverage issues recur in oncology. These coverage limitations can be the source of much difficulty for patients seeking treatment and for the physicians who provide it.

Off-label Uses of Drugs

The Food and Drug Administration (FDA) approves drugs based on the proposed labeling submitted by the manufacturer, and the indications for use included in the FDA-approved labeling are those that the manufacturer has demonstrated are safe and effective to the FDA's satisfaction. Once a drug has been approved by the FDA, however, physicians are legally permitted to prescribe the drug for any purpose without limitation to the indications set forth in the approved labeling. Consistently available reimbursement for "off-label" uses of cancer drugs has been a major problem in the past. Legislation and changing insurer practices have, however, significantly improved the situation.

Medicare-

For a number of years, Medicare's policy has been to allow its carriers to reimburse for off-label uses of approved drugs "taking into consideration the generally accepted medical practice in the community." [1] Under this long-standing policy, Medicare covered many cancer chemotherapy drugs, but coverage lacked uniformity across the country because it depended on local assessments of generally accepted medical practice.

To remedy this lack of uniformity, Congress enacted legislation effective in 1994 for drugs "used in an anticancer chemotherapeutic regimen." [2] Under this law, Medicare is required to cover any off-label use that is listed in any one of the three major drug-use compendia (the United States Pharmacopoeia-Drug Information, the American Hospital Formulary Service, or the American Medical Association's Drug Evaluations) or that is supported by articles in certain peer-reviewed journals. The list of approved journals includes the major cancer-related journals, as well as the important general medicine publications [3].

The Health Care Financing Administration (HCFA), which administers the Medicare program, has interpreted this law as applying only to drugs used as part of the chemotherapy regimen itself, and not to drugs used to treat the toxicities or side effects of the chemotherapy [3]. There is no official list of which drugs are contained in each category. There is a potential difference in Medicare coverage of an off-label use that is listed in a compendium and one that is merely supported by the literature. In the case of a compendium, Medicare is automatically required to cover the listed use. In the case of a literature-supported use, each carrier remains free to evaluate the literature and determine whether the published articles in fact support the use. Since there is a lag between the time that articles are published and the time that the compendia are revised to take them into account, it is likely that there will continue to be some lack of uniform coverage during that period.

Medicaid-

Medicaid's policy on coverage of off-label uses is more complicated. Generally, state Medicaid programs are required by federal law to cover all off-label uses that are listed in one of the three drug-use compendia identified above. A state may, however, establish a formulary and exclude
from the formulary any drug that does not have a "significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome," compared with other drugs that are included in the formulary [4]. Any excluded drug must nevertheless be available to patients on a case-by-case basis if authorized by the state prior to use.

Currently, Congress is considering major reforms to the Medicaid system, such as converting the program to block grants, under which the states will have great flexibility to design their own rules. This could result in greater diversity of state policies on coverage of off-label uses.

**Private Insurance**—In general, private insurers look to the major drug-use compendia and the peer-reviewed literature, and will pay for uses that are supported by those sources. In addition, a number of states have recently enacted legislation requiring insurance coverage of recognized off-label uses.

**Medicare Drug Coverage**
Many of the new injectable biologic drugs, such as the hematopoietic growth factors, can be self-administered subcutaneously but are also administered by health care professionals. This results in a potential issue of coverage under Medicare, which excludes coverage of drugs that "cannot" be self-administered. Medicare policy, however, is to cover drugs that are not "usually" self-administered [5]. Under this policy, Medicare is paying for growth factors except in those cases where the drugs are, in fact, self-administered.

Although Medicare does not have a drug benefit as such, there are three circumstances in which the program covers drugs. First, drugs, including oral drugs, are covered as part of the benefit for inpatient hospital or nursing facility services; therefore, drugs provided to inpatients are covered. (As discussed below, however, when there is a fixed payment for all services furnished to a hospital inpatient, there is no extra payment to cover drugs.)

Second, drugs that cannot be self-administered are covered by Medicare when they are furnished incident to a physician's professional service and included in the physician's bill. Chemotherapy and other injectable drugs furnished in the office are covered under this provision. For this coverage to apply, Medicare requires that the physician be present in the office suite and immediately available to provide assistance and direction, although a nurse or other assistant may actually administer the drug. In addition, if a nonphysician administers the drug, that person must be employed by the physician, rather than by the hospital or other entity [6].

Third, drugs are covered as part of the durable medical equipment benefit when they are administered through pumps that are reimbursed as durable medical equipment [7]. This coverage applies to both ambulatory infusion pumps and stationary equipment used in the patient's home, but it does not extend to disposable pumps, which are not considered to be durable medical equipment. In addition to these injectable drugs, Medicare covers a small number of oral drugs, including (beginning in 1994) several anticancer chemotherapy agents. Coverage of oral chemotherapy agents is limited to those drugs that have an injectable counterpart used for the same indication. Currently, four drugs qualify under this provision-cyclophosphamide, etoposide (VePesid), melphalan (Alkeran), and methotrexate.

**New Technologies**
A persistent issue, under both public and private health plans, relates to the coverage of new procedures and technologies. Since all health plans exclude coverage of items and services that are considered "experimental" or "investigational," any innovation faces an obstacle until it is regarded as standard practice. These provisions have proved troublesome to oncology because so many patients undergo nonstandard treatment.

Coverage in such situations can vary considerably among insurers. Some insurers will deny coverage of the patient care costs for any service designated as investigational, and may take the use of an informed consent form as evidence that the service was investigational.

Obstacles to coverage may be especially formidable in the case of expensive technologies. Even though cost is generally not explicitly a factor in determining whether a procedure is covered, a high-cost procedure will generally be carefully scrutinized with respect to its investigational status, whereas a new low-cost procedure may draw little attention.

A number of formal programs have been established to evaluate new technologies to determine whether they should be covered by insurance. Among private insurers, the most active may be the Blue Cross/Blue Shield Association's Technical Evaluation Program. This program, which provides nonbinding advisory opinions to local Blue Cross/Blue Shield plans, does not rely on community practice standards or consensus, but only on scientific evidence [8].

In the case of all insurers, the best route to obtaining a determination that a procedure is no longer experimental is usually the publication of articles in peer-reviewed journals supporting its safety and
effectiveness. Physicians who are developing new procedures should be mindful of the importance of literature to insurance coverage, and should seek to publish studies involving new procedures as quickly as possible.

**Clinical Trials**
The most disadvantageous situation for insurance coverage is a clinical trial, since the very existence of the trial is often viewed as conclusive evidence that the procedure being furnished is experimental. While it may be justifiable under the limiting language of insurance plans to deny coverage of the aspects of the trial that are truly experimental, when coverage is denied, it often extends to all aspects of the patient's care, including patient care costs that would have been incurred even if the patient had undergone standard therapy. Effective coverage of clinical trials will probably be available only when there is state or federal legislation requiring it.

**Fee-for-Service Payment Issues**
Third-party payers are increasingly attempting to impose cost controls on the fee-for-service sector. Many of these controls take the form of fee schedules or fixed-amount payment methodologies.

**Hospital Inpatient Services**
In 1983, Medicare began implementing a prospective payment system for inpatient hospital services in which the payment rates are fixed in advance and, except in rare cases, do not vary with the costs incurred in treating a particular patient. The amount of the payment is determined by the diagnosis-related group (DRG) into which each patient is classified. This system has been adopted by a number of Medicaid programs and some private payers, and may be used even more widely in the future.

The main effect of the DRG system on oncology relates to the dissemination of new technologies. Medicare does not assess the value of particular new technologies in determining whether to increase payment amounts. Instead, HCFA adjusts the DRG weights based on whatever costs hospitals incurred in the prior period under review. Thus, if hospitals are willing to incur increased costs to adopt a new technology, eventually the DRG weight will be increased to reflect those new costs, or a new DRG will be created solely for the new technology based on the higher costs incurred.

For example, bone marrow transplants were initially reimbursed at an amount that was only a fraction of their actual costs because they were classified into a DRG that consisted largely of much simpler procedures. Only after sufficient data had been accumulated on actual bone marrow transplants was a new DRG-at a much higher payment rate-established exclusively for such transplants.

A current issue is the appropriate DRG weight for blood-derived stem-cell transplants. Based on temporary codes that were previously in effect, Medicare payment for these procedures is much less than the payment for bone marrow transplants.

Fixed-price payment methods will undoubtedly continue to be a problem in the future, as cancer therapy appears to be moving in the direction of highly sophisticated and expensive procedures. Additional protections may have to be adopted to ensure that payment restrictions do not unduly interfere with the dissemination of new technologies.

**Hospital Outpatient Department Services**
The federal government is developing a fixed-price payment system for hospital outpatient department services for use by Medicare. Since Medicare wants to have reimbursement policies that create a "level playing field," and do not prefer a particular site of service, it is likely that a uniform system will eventually govern both physician offices and outpatient departments. Moreover, as in the case of the DRG system, it is likely that the system for Medicare outpatient services will eventually be adopted by other payers as well.

Historically, Medicare has reimbursed hospitals for the costs they incur in providing outpatient department services. The outpatient department remains the last major area in the Medicare program for which payment is not based on fee schedules or fixed payments. At the same time, growth of outpatient department services has been very rapid, as more procedures are transferred from inpatient status. Consequently, there has been substantial effort to develop a fixed-price system for outpatient services.

Current development efforts center on the use of "ambulatory patient groups" (APGs). In the case of patients undergoing procedures, APGs would not be based on diagnosis, but on a core procedure. The fixed payment for the APG would constitute payment for that core procedure, as well as for any associated laboratory and minor radiologic services, drugs, and supplies. In the case of medical...
visits, the APG would be based on the patient's diagnosis and on factors not yet identified. There could be multiple APGs applicable to a single outpatient department encounter. A fixed-price outpatient department payment system is likely to be implemented in stages. First, Medicare will probably establish fixed payment rates for radiology and diagnostic services, and outpatient surgery, since those are the categories of services that are now paid based partially on a fixed-price payment rate [10]. Development of APGs for other services will probably take several years. Thus, radiation oncology and outpatient surgery are likely to be the first oncologic services affected by the new payment structure, with chemotherapy payments not revised for some time. Fixed prices in the outpatient department will present the same potential obstacles to the use of new technologies as does the inpatient department discussed above.

**Payment for Physician Services**

Historically, private insurance has paid for physician services based on physician charges, subject to a limitation that payment does not exceed the physician's usual charge, or the customary and reasonable charge in the community. For many years, Medicare had a similar policy, in which payments were limited by the lower of the physician's customary charge and the local prevailing charge. In 1992, however, Medicare introduced a radically different payment methodology based on relative values. The system is being adopted by other payers and may eventually become universal. The Medicare fee schedule for physician services stems from a resource-based relative value scale (RBRVS). A "resource-based" system is intended to pay for physician services according to the resources used in providing each service (including the time and intensity of the physician's personal effort), but not to consider such factors as the value of the service to the patient or the physician's training and experience [11].

Despite its name, the Medicare RBRVS is, in reality, not yet fully resource based. The relative value for each physician service has three components-relative value units for physician work, office expenses, and malpractice insurance. The physician work component is currently resource based, but the other two components are not.

At the time that Congress enacted the requirement for Medicare to use the RBRVS, there was no methodology available for determining the overhead costs of each particular physician service. The law, instead, included a temporary methodology under which the relative values for the overhead and malpractice expense components are determined based on historical Medicare-allowed charges. Efforts to develop a replacement methodology that considers the actual resource costs incurred in furnishing each specific service are underway, pursuant to a requirement imposed by Congress that the practice expense components of the relative values be revised by 1998. The methodology to be used involves several steps:

1. Resources directly used in providing a service (eg, minutes of nursing time, supplies, equipment) will be estimated in detail for a small number of reference services. Oncologists and other physicians working with the HCFA contractor will develop this information.
2. The HCFA contractor will price the cost of these resources based on national cost information.
3. Using the reference services as a base, physician panels will estimate the resources used in related procedures.
4. Using data from a survey of physician practices, the contractor will estimate the indirect costs (eg, overhead) associated with each procedure.
5. The direct costs determined in steps 1 and 2 will be added to the indirect costs estimated in step 4 to determine the total resources used for each service [12].

HCFA contemplates that as many costs as possible will be treated as direct costs and determined in accordance with steps 1 and 2 above. There will be some indirect costs, however, and these will be allocated to particular services based on policies that have not yet been developed. Methodologies to allocate office overhead costs to particular services involve difficult issues that may greatly affect payment amounts. For example, in an oncology office that furnishes visits and chemotherapy, the overhead (RBRVS) associated with each procedure.

The Medicare RBRVS is likely to be used increasingly by other insurers, and its dissemination is already underway. Typically, other payers use the Medicare relative values, but with a different, higher conversion factor. Eventually, the RBRVS will probably become universally used in the fee-for-service sector, perhaps by government action, if not through the action of insurers. Government action could take the form of price and payment controls based on the fee schedule. A more market-oriented approach under discussion that is intended to facilitate patient comparison of charges might require physicians to use the RBRVS but allow each physician to set a personal
conversion factor.

**Chemotherapy Administration**

Most of the issues surrounding payment for chemotherapy administration involve the question of whether there should be separate payment for particular items or services, or whether payment for those items or services is already covered by the payment for another service. These issues exemplify the growing trend toward bundling items and services together, and making a single payment for the group regardless of the particular services furnished.

An example is the payment for chemotherapy administration by push (CPT 96408) and infusion (CPT 96410) on the same day. The CPT manual directs that the physician should report separate codes for each parenteral method of administration. Nevertheless, since insurers are not governed by the CPT, some will not pay separately for a push administration on the same day as they pay for an infusion. Medicare also had that policy during 1992, but subsequently decided to pay for both CPT 96408 and CPT 96410 on the same day. Medicare, however, will pay for only one push service per day, regardless of how many drugs are administered.

Another issue concerns separate payment for placement of the needle or for port access. While Medicare does not generally allow such a payment (considering it part of the chemotherapy administration service), some other insurers do make a separate payment.

Finally, there is the question of separate payments for supplies. Medicare's policy is that it generally considers the costs of supplies to be included in the payment for the related service, and the payment amounts for the services were computed on that basis. Separate payments for supplies are made only in unusual circumstances, where the lack of a separate payment for a relatively expensive supply (e.g., a surgical tray) could cause the procedure to be performed in the hospital outpatient department rather than the physician's office.

**Chemotherapy Management**

An issue of controversy over the last few years is the proper method of reporting and billing the physician’s management services related to chemotherapy. At present, Medicare takes the position that all physician evaluation and management services are included in the visit codes, and that the chemotherapy administration codes cover only the technical aspects of the procedure. As a result, if chemotherapy is administered to inpatients or in the hospital outpatient department (where the physician does not bill for the technical aspects of the chemotherapy administration), there is no Medicare payment for the physician's services, apart from the visit services.

Some private insurers do not follow Medicare's lead on this point. They view the chemotherapy administration codes as composed of both a technical and a professional component. Thus, in the hospital setting, a physician may bill a chemotherapy administration code with the modifier "-26" to indicate the professional component of chemotherapy administration, in addition to the visit code.

**Payment for Drugs Administered by Physicians**

Third-party payer policies tend to diverge in their approaches to reimbursing for physician-administered drugs. Private insurers frequently pay full charges for drugs without applying any kind of "usual, customary, and reasonable," or similar limitation. By contrast, Medicare's policy is, in essence, to reimburse physicians only for the cost of the drugs themselves, with overhead and administration costs considered covered by payments for office visits or for drug administration. Medicare pays the lowest of the physician's charge, the published average wholesale price (AWP), or, in some cases, the estimated acquisition cost [13]. The AWP is, in theory, the average price at which pharmacists and physicians can purchase a drug from a wholesaler. There are three commercial services that publish AWPs, which they determine based on, to varying extent, information from drug manufacturers and surveys of wholesalers.

The use of published AWPs as the benchmark for third-party reimbursement is a source of continuing controversy, because drugs are frequently available for purchase at prices less than AWP. In 1991, Medicare proposed to pay for drugs at 85% of AWP, although it eventually adopted the current rule of paying the AWP.

A few Medicare carriers adopted the practice of paying based on estimated acquisition cost rather than AWP. Other carriers may use a similar approach in the future. In 1994, HCFA initiated an effort to require all carriers to utilize surveys to determine acquisition cost, but the Office of Management and Budget, which must approve surveys and other paperwork requirements, has not yet approved the HCFA proposal.

A complicating factor in drug reimbursement methodologies is the variability in prices paid. This variation is both a function of the purchaser (largevolume purchasers frequently pay much less) and time (discounts come and go). The variability makes it difficult to administer fairly any system that is designed to pay for drugs on the basis of a cost pass-through or estimated acquisition cost.
Managed Care

The accelerating growth of managed care has many economic and policy implications for oncology and the rest of medicine. With respect to reimbursement, it seems likely that use of capitation and case-rate payment methods will increasingly replace the discounted fee-for-service methods that are common in managed care arrangements today. This change may give an advantage to large delivery systems, since large organizations may be in a better position to contract on such terms. Small groups of physicians may lack both the data necessary to accurately estimate the costs of treating patients and a patient population large enough to spread the risk involved.

In addition, Congress is considering changes in the Medicare system that would foster the growth of managed care in that program. Managed care organizations will probably be required to offer Medicare beneficiaries the same package of benefits that are currently available. Thus, the current favorable Medicare policies on coverage of off-label cancer drugs would continue. Presumably, however, the managed care organizations would have much greater flexibility in establishing payment methods. As a result, oncologists are likely to face increasingly tight payment restrictions in Medicare managed care arrangements, even if capitation or similar fixed payment structures are not adopted.

References:
2. Section 1881(t)(2) of the Social Security Act, United States Code, title 42, section 1395x(t)(2).
8. Testimony of Susan Gleeson, Executive Director, Medical and Quality Management, Blue Cross and Blue Shield Association, before the Committee on Finance, United States Senate, March 3, 1994.

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