8. Third-Party Payment Policies

8
Third-Party Payment Policies

INTRODUCTION

As one of several important economic and social forces influencing the adoption and use of medical technologies in recent years, third-party payment policies have increasingly become a major focus of attention (12,100,157,200). Of great concern to many policy makers have been the incentives engendered by payment based on costs that have already been incurred. The general failure of such payment mechanisms to distinguish between cost-saving and cost-raising technologies has offered little incentive for hospitals to include efficiency among their capital investment objectives (100,200). Consequently, hospitals' decisions to acquire new technology have placed little emphasis on the comparative cost effectiveness of technology use in clinical practice,

The cost-based system of payment has also tended to reward institutions that increase their definable costs without necessarily improving quality of care, while simultaneously penalizing those that improve care with a concomitant reduction in operating expense (151,198). In view of these concerns, the Medicare program is beginning to pay hospitals according to a *prospective* payment system, with rates set in advance of the period during which they apply. This change has new implications for technology adoption and use.

This chapter addresses third-party payment policies and how they apply to NMR imaging devices. The first section addresses the types of policy decisions made by the major third-party payers and the processes by which they determine coverage and payment levels for new technologies. The second section discusses the history and current status of third-party payer decisions regarding NMR imaging. Readers familiar with the operations and policymaking processes of the major third-party payers may wish to read only the second section. Otherwise, the first section provides a foundation for understanding how policy decisions are made.

THIRD-PARTY PAYER DECISIONS

In setting policies for the payment of hospital and medical services involving the use of new medical technologies, third-party payers must wrestle with three questions:

1. Should they pay for such services?
2. If so, under what conditions or circumstances should they pay for them?
3. How much should they pay under specified conditions?

The first and second questions relate to policy decisions regarding coverage of new services and the specific conditions that may apply, The third question pertains to policy decisions involving the *reimbursement or payment level* permissible under specified conditions of service coverage. Together, these three questions represent a sequence through which all third-party payers must pass when formulating comprehensive policies toward medical technologies. Payers tend to differ, however, in their general procedures, methods of assessment, and decision criteria. Nevertheless, the end product in each case is a determination or policy statement intended to *guide* policymaking within the program or within member plans or companies.

Coverage Policies

When a new medical technology moves from the laboratory into the hospital, third-party payers must decide whether or not to pay for its use. For a device such as NMR that requires the Food

and Drug Administration's (FDA) approval before marketing, the coverage question often arises before or concurrently with FDA review, as manufacturers or providers contact insurers about coverage policy before reimbursement claims are submitted. In the period prior to FDA premarket approval, the technology or device is considered "investigational," and third-party payers tend not to reimburse for clinical services performed with it. The critical decisionmaking period, therefore, is the time just after FDA premarket approval has been granted, when hospitals and other providers anxiously await third-party payers' decisions on both coverage and reimbursement level.

Medicare

The Medicare program may reimburse for only those devices, services, or procedures that are determined to be both "reasonable and necessary." In making this determination, the Health Care Financing Administration (HCFA), which administers Medicare, first considers whether FDA has found the device "safe and effective. " In practice, HCFA generally does not approve coverage of a new device unless FDA has already approved it. HCFA considers it to be a necessary but not sufficient condition that a technology be "safe and effective" in order for it to be "reasonable and necessary." HCFA, however, will not necessarily approve coverage for all devices that FDA has approved, largely because the two agencies differ in their respective definitions of "effectiveness. " FDA deems a technology "effective" if it does what the manufacturer claims it will do, whereas HCFA considers the effectiveness of the technology with respect to health outcome. Another important consideration in HCFA's decision is the stage *or* level of acceptance of the innovation by the medical community—i.e., the extent to which the technology has become an accepted part of clinical practice.

In the absence of a centrally established HCFA coverage policy for a particular medical technology, the fiscal contractors for the Medicare program may make their own coverage policy decisions. When questions regarding the safety and clinical effectiveness of a technology arise in the field, however, fiscal contractors may request that HCFA perform an assessment. Requests for technology assessments may also originate from outside groups, such as medical specialty societies and manufacturers (192).

Within HCFA, a coverage question is directed first to the Bureau of Eligibility, Reimbursement, and Coverage and its Office of Coverage Policy. HCFA may in turn seek the advice of the Public Health Service. This advisory role rests with the Office of Health Technology Assessment (OHTA) in the National Center for Health Services Research. The full assessment process generally requires *8* to 18 months to complete (106,107). The assessment process frequently coincides with the FDA premarket approval process and the two agencies often share available data and information. In making its coverage policy decision, HCFA is not bound by the Public Health Service recommendations.

HCFA does not give consideration to the cost effectiveness of a technology when formulating its coverage policy decision, but may do so later when making policy decisions regarding reimbursement or payment levels. ' At its discretion, HCFA may place restrictions on the coverage of a technology rather than grant "blanket approval" for the technology as a whole. In the past, restrictions have sometimes been application-specific—i.e., reimbursement is provided only when the technology is used for specific clinical applications or diseases. In other instances, coverage restrictions have centered on specific service settings (e.g., only inpatient) or providers or practitioners (e.g., physicians only), or even manufacturers and their devices. For example, coverage of CT scanners was, at first, limited to only specific models produced by certain manufacturers (106,107).

Medicaid

The HCFA decisionmaking process, as described above for Medicare coverage policy, generally does not apply to the Medicaid program. Responsibility for making Medicaid coverage policy decisions rests with the individual States, which, at their own discretion, may choose to cover cer-

[1]HCFA sometimes sets charges or allowable rates for a new technology based on previous charge experience with technologies that are clinical alternatives to the innovation in question (see discussion on reimbursement level decisions).

tain technologies or services not covered by Medicare. States may also devise their own coverage restrictions on technology use. In cases where a State program extends Medicaid coverage to technologies not covered by Medicare, the program may initiate its own internal technology assessment, utilizing its own staff and possibly a panel of outside experts. Alternatively, States may opt to refer technology-related inquiries directly to HCFA for potential assessment.

As with current Medicare policies, Medicaid will pay only for services and technologies judged "reasonable and necessary. " Noncovered technologies receive no reimbursement under Medicaid.

Blue Cross and Blue Shield Plans

Although the national Blue Cross and Blue Shield (BC/BS) Association plays an important role in assessing new technologies on behalf of its member plans, each plan reserves the right to make its own coverage policy decisions regarding specific medical technologies or services. In making such determinations, individual plans generally require that a technology receive FDA premarket approval before considering reimbursement coverage for its use (47). FDA approval, on the other hand, does not automatically ensure BC/BS coverage; nor does HCFA approval of the technology as "reasonable and necessary" for Medicare beneficiaries. HCFA decisions, nevertheless, are scrutinized carefully by the plans.

When questions arise regarding coverage of a new technology (i .e., an individual BC/BS plan receives an inquiry, claim, or letter of intent from a participating hospital or physician), the plan will often contact the national Association and request assistance. An internal technology assessment process then begins to develop recommended coverage policy for plans to consider when making their respective policy decisions. The assessment process generally requires 4 months to 1 year to complete (47).

Unlike the policy *decisions* of HCFA regarding Medicare coverage, the policy statements issued by the national BC/BS Association are strictly rec*ommendations* or guidelines. The thrust of the BC/BS assessment process, therefore, is not to formulate policy with carefully delineated conditions of coverage, but rather to identify the important issues that plans must address and to present useful information that will aid local decisionmaking. An important aspect of this "information clearinghouse" function is the clarification of technical and clinical details relating to a specific technology's safety, effectiveness, clinical status, and appropriate use.

BC/BS employs a three-level scale of clinical status: 1) experimental—the technology has been used only in animal studies, 2) investigational—the technology has entered preliminary clinical use, and 3) accepted medical practice—the technology has gained general use in medical practice. Some BC/BS plans write broad exclusionary clauses in their contracts for "experimental/investigational" devices. Others prefer to deal with emerging medical technologies on a case-by-case basis, making it possible, but not likely, that some investigational devices may receive coverage, albeit for specific clinical applications or uses.

When formulating policy recommendations on coverage of new technologies, the internal review committees of the BC/BS Association take cost-effectiveness information into account. The information does not affect the recommendations directly, but rather is transmitted along with the policy statement to member plans. Plans are then free to weigh the information accordingly in their respective coverage policy decisions. Some plans engage in sophisticated assessment activities of their own. BC/BS of Massachusetts, for example, convenes an Interdisciplinary Medical Advisory Committee to assist it in making coverage decisions for new technologies (47). Other plans may instead conduct their own assessments or surveys of available information on new technologies. In addition, since many plans serve as Medicare fiscal contractors (i. e., administer Medicare claims for HCFA), they may either closely observe or participate in the HCFA assessment process.

Commercial Insurance Companies

Commercial insurance companies operate independently of one another and, therefore, make independent decisions regarding coverage of new or emerging medical technologies. When a question arises concerning payment for a technology

whose safety and effectiveness may not be known, individual companies contact the Health Insurance Association of America (HIAA), a private organization that represents and serves the commercial insurance industry. HIAA membership includes 338 companies, which collectively provide approximately 85 percent of all non-Blue Cross, private health insurance coverage in the Nation (112).

The HIAA inquiry and assessment process is frequently conducted concurrently with the FDA premarket approval process, as well as with the technology assessment activities of other third-party payers, most notably HCFA and the BC/BS Association. Individual commercial insurance companies may, of course, supplement the information obtained from the HIAA process by undertaking their own assessment activities. Such independent efforts tend to be of a limited nature, often involving direct solicitation of expert opinion from the most relevant medical specialty groups.

In making coverage policy decisions, companies face the same choices encountered by other third-party payers—i.e., coverage without restrictions, coverage with restrictions, or no coverage at all. As with HCFA and BC/BS, commercial insurers view FDA premarket approval as a necessary but not sufficient condition for coverage of a new technology. Companies examine closely the policy decisions rendered by HCFA and by various BC/BS plans, but will not necessarily adopt them.

Reimbursement or Payment Level Policies

Once the question of coverage policy has been decided by a third-party payer, attention is focused next on the issue of appropriate or "reasonable" payment for provision of covered services. Although "reasonableness" is a concept with intrinsic meaning to all third-party payers, its operating definition in practice will vary among payers. Complicating the picture is the need for each payer[2] to set separate reimbursement or payment rates for the hospital or facility in which the technology will be employed and for the professional service fee of the physician. Both rates can vary by geographic area, by service setting (e.g., hospital versus physician's office), by physician specialty, by clinical application of the technology, and by the past experience and fee history of the individual practitioner.

Medicare

HCFA sets reimbursement rates for *covered* physician services based on what it considers to be "customary, prevailing, and reasonable" charges. In making these determinations, HCFA staff in the Office of Reimbursement Policy consider such factors as:

- Where the technology will be used—in the hospital, in the physician's office, or in some other setting?
- How the technology will be used—for what clinical applications or disease conditions?
- *By whom* the technology will be used—by physicians with what type or level of specialty training and/or experience?

"Customary and prevailing" charges imply that consideration is also given to: 1) the customary or usual fees charged by a given practitioner for similar or related services in the past, and 2) the prevailing fee (or market price) charged by physicians in the same geographic area and with similar training/experience for similar or related services. In the case of many new or emerging technologies, customary and prevailing charges are impossible to document since little clinical experience, if any, has been gained in the general medical community by the time an HCFA policy decision is made. In such instances, HCFA staff or individual Medicare contractors look to similar technologies and base their reimbursement or payment rates, at least in part, on past experience with established services. For example, assuming Medicare coverage is granted for NMR imaging, policy decisions on reimbursement level will likely be based, in part, on the previous history of charges for X-ray CT scanning.

Since October 1, 1983, HCFA has begun to pay hospitals prospectively for inpatient services on the basis of diagnosis related groups (DRGs).

[2]Medicare does ***not*** set technology-specific payment rates for prospectively paid inpatient hospital services under Part A, but does set rates for physician services under Part B.

The payment for utilizing a given technology for a specific DRG is thus embedded within the established DRG cost per case. For the time being, Medicare is continuing to pay for the capital costs (e.g., acquisition expense, interest, rent, land costs, and other expenses) incurred for major equipment. The capital allowance will be based on the proportion of total hospital charges in some base year that is attributable to Medicare patients. Capital expenses will be treated in this "pass-through" manner for the next 3 years, or until capital costs are brought into the DRG payment rates. For *uncovered* services, HCFA would refuse to pay such pass-through capital costs.

Thus, a hospital that chooses to invest in new technology under the prospective payment system is at risk that the added patient-management costs induced by the new technology will result in financial losses. More specifically, if use of a new technology (either as a substitute for, or as an add-on to, some other modality) increases the average operating cost of a given DRG (or DRGs) to a level above the prospective payment rate established for that DRG (or those DRGs), the hospital will not recover its costs.[3] In addition, hospitals adopting and using an uncovered technology would not be reimbursed for associated capital costs, and would also stand to lose should their average operating costs in the DRGs that use the new technology exceed the approved DRG payment rates.[4] A decision to acquire and to use new technology under the Medicare prospective payment systems, therefore, may have serious implications for the financial well-being of a hospital.

Although HCFA will not need to establish a reimbursement rate for use of a new technology in the inpatient setting, it will need to establish payment rates for outpatient usage and for the professional fee associated with both inpatient and outpatient usage. The level(s) at which these payments are established could have a tremendous impact on the rate at which new technology is adopted in both inpatient and outpatient settings.

[3]Conversely, adoption of cost-saving technology that decreases the average operating cost of a given DRG (or DRGs) relative to the prospective payment rate would benefit the hospital, which is entitled to keep the savings that would be generated,

[4]Costs could potentially be recovered if payments exceeded costs for other DRGs or if costs were shifted to non-Medicare payers,

Medicaid

Medicaid reimbursement policy for new technologies generally is not tied to that of the Medicare program (107). Although Medicaid rates for *both* hospital care and physicians' services are set using many of the same criteria described above for Medicare, the relative weights of such factors will differ by State program, resulting in considerable variation in payment levels across the Nation.

Blue Cross and Blue Shield Plans

Once coverage for a new technology has been approved by a BC/BS plan, the criteria of "usual, customary, and reasonable" (UCR) fees are employed to set physician charges for services. Under this approach, considerable weight is given to past history and to the plan's experience with particular physicians (47), Individual plans differ, however, in their approach to payment for hospital services; some plans reimburse hospital charges; others pay only for costs. With emerging technologies, the lack of relevant technology-specific data or past experience often requires the plan to examine charges or costs for related technologies or services from which they can impute likely costs and set "reasonable" charges for the new service.

Commercial Insurance Companies

The general procedures and criteria used by independent commercial insurance companies in establishing allowable hospital rates and physician fee schedules are essentially similar to those described above for Blue Cross and Blue Shield Plans. Commercial insurers, however, tend to deal directly with the insured rather than with providers. ' Within a given company, therefore, the reimbursement for a specific service is more likely to be standardized than it is within a BC/BS plan (112).

General Observations

These cost-based reimbursement policies for hospitals and fee-for-service payments to physi-

[5]This may be changing, as more commercial insurers begin to participate in the development of preferred provider arrangements with hospitals and physician groups.

cians have been criticized for their retrospective nature and for their inherent biases toward increased technology adoption (198,200). Because physician fees for new technologies cannot easily be tied to historic or prevailing charges, and because UCR fee schedules are not likely to be established until after such technologies have been introduced, payment for new procedures is often set high and rewards technology adoption. Retrospective cost- or charge-based reimbursement systems also give providers little incentive to distinguish between cost-saving and cost-raising technologies and may influence private physician groups to acquire new technologies without regard to their cost effectiveness. The widespread acquisition of X-ray CT scanners by private radiology groups, for example, may find its parallel in large-scale purchases of NMR imaging devices by such groups. In addition, the continuation of historical reimbursement policies for physician fees may provide physicians with incentives to overutilize technology even in the hospital setting.

HISTORY AND STATUS OF COVERAGE POLICY DECISIONS FOR NMR IMAGING DEVICES

During early 1984, increasing numbers of third parties began paying for NMR. By June 1984, at least 10 commercial insurers were paying for NMR as part of "generally accepted practice, " and at least three Blue Cross plans had accepted NMR for payment.' Assessments of NMR imaging are being undertaken by HCFA/OHTA and by the BC/BS Association. The status of each payer's policy regarding NMR imaging is summarized below.

Medicare

HCFA became involved in the assessment of NMR imaging as early as January 1982, when the agency received literature pertaining to NMR from the General Electric Co., together with a request for comments, but no request for an assessment (17). In May 1982, HCFA received a formal query regarding Medicare coverage policy for NMR imaging from a Blue Cross plan in California, which had itself received an inquiry from a neurosurgeon (17). Acting on this inquiry, staff from the Office of Coverage Policy performed a literature review, contacted other Federal agencies (including FDA), surveyed NMR imaging manufacturers for information, and prepared a presentation to the HCFA Physician Panel in August 1982 (17). Later that month, the Physician Panel requested that OHTA perform a full assessment of NMR imaging. In September 1982, OHTA began to look at NMR but delayed a complete assessment pending FDA premarket approval. Recently, following FDA approval of the first manufacturers' applications, OHTA initiated efforts to assess NMR imaging. A decision by HCFA on Medicare coverage of NMR imaging is not expected during 1984.

Medicaid

Presently, it is not known whether State Medicaid agencies have conducted their own assessments of NMR imaging. It is possible that the current HCFA/OHTA assessment process may satisfy the information needs of the individual State Medicaid programs.

Blue Cross and Blue Shield Plans

In October 1982, national Association staff formally requested an assessment of NMR imaging. Later that month, the Medical Advisory Subcommittee reviewed the request and decided to initiate an assessment. At that time, the Subcommittee also designated NMR imaging as an "investigational device" for which no reimbursement should be provided. The staff then performed an assessment and reported its findings to the Subcommittee in March 1983. The Subcommittee reviewed the report and approved its submission to member plans as a "Medical Policy Newsletter. " The newsletter provides information on the current

'Mobile Technology Inc , unpublished data, Lo\ Angeles, CA, June 1o, 1984.

status of NMR imaging as an investigational device, with a view toward clinical applications, technical considerations, and charges (18). The newsletter also offers advice to plans based on current evidence from the literature, from the FDA, and from the American College of Radiology. It is not intended, however, as a uniform medical policy statement, since the issue of NMR imaging is still under consideration by the Association.

Commercial Insurance Companies

Through December 1983, the HIAA had not received any inquiries from member organizations regarding NMR imaging (112). HIAA staff were also not aware of any claims for NMR services that might have been received by member companies. Therefore, the staff had not solicited an opinion on NMR imaging from the Council on Medical Specialty Societies.

According to a survey of *30* commercial companies that provide health insurance, by February 1984, five had determined that NMR was part of "generally accepted practice" and were paying for its use. In February, six other companies had acknowledged the clinical usefulness of NMR, but were reviewing each case before payment. By mid-June 1984, 10 of the 30 companies deemed NMR generally accepted and were paying for procedures, and 11 other companies had provisionally accepted NMR and were paying after review of each case. [7]

[7]Ibid.

CONCLUSIONS

Since FDA has granted premarket approval to an NMR device, third-party payers now have major influence over the rate at which NMR imagers are acquired by hospitals. This influence derives not only from their decisions regarding whether to cover use of NMR, but also from their decisions regarding the circumstances in which use will be covered. Third-party payers such as HCFA, for example, will first need to decide whether they will reimburse for use of only those manufacturers' NMR devices that have gained PMA, or whether they will reimburse for use of any manufacturer's NMR device. Such a decision could have a major impact on the market share achieved by manufacturers in the short run.

Third-party payers will also have to decide whether to make a broad or narrow coverage decision. In the case of NMR, at least in the short run, this will come down to deciding whether to approve reimbursement for some applications of NMR imaging of the head only (the applications in which NMR has so far proved most efficacious), or whether to approve reimbursement for all uses of NMR, regardless of their stage of development. To the extent that the narrow strategy is followed, hospitals may be restrained in the speed with which they acquire NMR devices. To the extent that the latter strategy is followed, HCFA and other third-party payers will likely be subsidizing research on NMR applications that are less well developed.

The third major decision to be made by HCFA and other third-party payers is the monetary level at which outpatient use of the NMR imager will be reimbursed. How much of a difference in reimbursement is established for outpatient use of NMR as compared to outpatient use of X-ray CT will have a major impact on the rate at which NMR imaging systems diffuse into the outpatient setting. HCFA is beginning to pay hospitals prospectively on the basis of inpatient diagnosis, but will need to set an inpatient fee for physicians. Other third-party payers, such as Blue Cross and commercial insurers, may set inpatient rates, depending on their payment methods. Because it is likely that the outpatient rates set by HCFA will influence the inpatient rates established by Blue Cross and commercial insurers, HCFA's outpatient rate takes on even greater importance.

Another important decision to be made by third-party payers is the level at which professional fees for NMR imaging are set. At least in the near future, it can be expected that more pro-

25-341 O - 84 - 8 : QL 3

fessional time will be required for NMR scans than for X-ray CT scans. The level at which professional fees are established, therefore, may well have a significant impact on the level of interest that radiologists and other potential users manifest with regard to acquisition of NMR imaging devices.

Prospective systems of payment may have a major influence on the rate at which NMR diffuses throughout the medical system. With the introduction of DRG-based prospective payment under Medicare, hospitals will have to respond to different incentives from those to which they have been accustomed. Technology acquisition is one area of hospital operations in which change is likely to result. Hospitals, in theory, will have to weigh financial considerations against patient-care benefits more carefully when acquiring technologies. The constraints imposed by prospective payment on hospital budgets will likely deter some institutions from acquiring medical technologies that raise operating costs. In such instances, prospective payment may supersede State certificate-of-need regulation as a constraining influence on hospital investment decisions. In addition, hospitals may need to become more discriminating about deciding how acquired technology is used. Whether and how such rationing decisions will be made remain uncertain.

One potential concern about the advent of prospective systems of payment is whether some hospitals will be so financially constrained that they will be unable to acquire valuable new technology. If or when capital costs become included in the Medicare DRG payment rates, hospitals may be further constrained in their technology acquisition decisions. It is also important to realize that Medicare's DRG payment may vary among hospitals in its effect on their financial condition and their ability to acquire and use new technology. For some institutions, such as municipal hospitals serving large Medicare and Medicaid populations, the DRG payment system may exacerbate an already financially troubled state, impeding hospital capital formation necessary for the acquisition of high-cost but beneficial new technologies. The net effect may be to weaken further those institutions that are the primary sources of care for disadvantaged populations.

How much of an impact the prospective payment system will have on technology acquisition is likely to depend on HCFA decisions regarding updating and recalibration of DRG payment rates when new technologies become available *(186).* *New* technologies such as NMR are likely to be used across multiple DRGs. If NMR proves to be beneficial but not cost-saving in certain DRG applications, hospitals will be confronted by conflicting patient care and financial considerations. Periodic recalibration of DRG payment rates may thus be required as technological change in medicine occurs, In the absence of such recalibration, patients may be restricted from access to potentially beneficial new technologies.