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Reimbursement of Tumor Marker Tests

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The diffusion of new technology is significantly affected by coverage and reimbursement decisions. A variety of agencies (public and private) make decisions as to which technologies or treatments will be covered and what the levels of reimbursement will be. Recently, these agencies' coverage decisions have tended to be strongly affected by whether a technology is cost raising or cost reducing. Historically, a common effect of medical innovation has been improved quality of health care but with a corresponding increase in cost of delivery. The Medicare program has significant influence on the coverage policies of public and private third-party payers. This influence is especially visible in coverage and reimbursement decisions for cancer-related diagnostic procedures and systems. Coverage for these procedures and systems is not widespread because payers have not been convinced of the clinical usefulness of the assays. The industry must take the responsibility of working through the issues surrounding coverage and reimbursement of cancer-related diagnostic procedures with the payers. The ability to successfully negotiate payment for assays requires knowledge of Medicare coverage policies and a grasp of the reimbursement system.

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The Payment Environment

The rate of diffusion of new technology is significantly affected by coverage and reimbursement decisions. Prior to prospective payment, most health care was cost reimbursed, including the cost of new technology. This method of reimbursement stimulated technological innovation and development because the costs, for the most part, were largely passed on to third-party payers. Providers of health care supported this growth because of malpractice concerns, and a technology-oriented society with an attitude that "when it comes to health, cost is not a concern" demanded the latest contemporary medicine could offer. These factors provided an environment whereby the development and spread of technology was unabated until the advent of the prospective payment system in 1983 (*1*).

Because the financial incentive of prospective payment systems is to minimize cost per inpatient admission, many high-cost technologies, along with many other services, were rapidly moved to the outpatient setting, where payment incentives were more favorable. Many outpatient services are completely or partially paid, based on retrospective costs or charges. As a result, between 1980 and 1990, the proportion of personal health expenditures attributable to outpatient hospital care almost doubled, from 4.8% to 8.7% (*2*). This favorable outpatient payment climate has allowed the continued proliferation of new technologies, which is expected to continue to grow until a prospective payment system for outpatient service is implemented.

Citing technology as the principal contributor to our rapidly escalating health care costs is not a new theme. For the last several years, health care economists have been debating the degree to which technologies are driving up health care costs (*3*). However, regardless of whether technology is a major or minor source of rising costs, clearly it is viewed as a major contributor by the government. A recent Project Hope study for the Prospective Payment Assessment Commission on the cost of major technologies predicted that monoclonal antibodies, advances in computer technology, and automatic implantable cardiovascular defibrillators would have the greatest impact on cost in 1993 (*4*). In addition to this study, the General Accounting Office, the auditing and investigative arm of Congress, issued a report on September 9, 1992, citing the adoption of new medical technologies as the single most important factor driving hospital cost increases. The report concludes that, without the adoption of new policy initiatives, moderation of cost growth in the 1990s will be difficult to achieve (*5*). However, as we in the clinical laboratory field are well aware, there appear to be some attempts to control costs by a somewhat slow and cumbersome process for determining coverage of new clinical laboratory procedures.

National Coverage Decisions

A variety of agencies (public and private) make decisions as to which technologies or treatments will be covered and what the level of reimbursement will be. These agencies' coverage decisions now, more than ever, tend to be strongly affected by whether the technology is cost raising or cost reducing. The Medicare program, because of its sheer size, has become the major leader in the coverage process. Moreover, because of its significant effect on the coverage policies of private third-party payers, Medicare has implications beyond the confines of the program as it influences the major portion of US health care delivery.

The Social Security Amendments of 1965, the statute that created the Medicare program, provides the Health Care Financing Administration (HCFA) with the authority to make national coverage decisions.[1] However,

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[1] Nonstandard abbreviations: HCFA, Health Care Financing Administration; FDA, Food and Drug Administration; CEA, carcinoembryonic antigen; CPT, *Current Procedural Terminology*; AFP, α-fetoprotein; and PSA, prostate-specific antigen.

the coverage/assessment process is essentially passive, in that the process at the national level must be prompted by an initial inquiry. Most questions regarding coverage for clinical laboratory assays are resolved at the local level on the basis of Medicare guidelines. Many institutions have been successful in receiving reimbursement for new technology because they have taken the time to work with their local carrier/intermediary to obtain payment by documenting that the quality of care is increased or that the assay has a positive cost-benefit relationship.

The Medicare coverage provisions in the law clearly prohibit payment for any items or service not considered "reasonable and necessary" for patient care. However, the statue does not define "reasonable and necessary." HCFA has, on at least one occasion, attempted to further define these terms, although substantial gray areas still exist and many decisions are made on a case by case basis. In general, if the service or treatment is one that is not yet generally accepted, or is rarely used, novel, or relatively unknown, then authoritative evidence must be obtained to establish it as safe and effective before Medicare may make payment.

To a large extent, for a technology to be found "reasonable and necessary," it must *first* be determined to be "safe and effective." Therefore, products that have not received Food and Drug Administration (FDA) approval as safe and effective or procedures that are not generally accepted may not be appropriate for payment. It also is important to note that payment is allowed for only indicated uses of FDA-approved procedures. For example, carcinoembryonic antigen (CEA) or CA-125 is approved for monitoring tumor recurrence in patients who have had a tumor irradiated or surgically removed. When these tests are used for other purposes, however, payment may be denied. Medicare also excludes from coverage any procedures used for routine screening and procedures that are not of a diagnostic nature.

As stated previously, the coverage process is essentially passive and must be prompted by an initial inquiry. Inquiries may come from a wide variety of sources, including HCFA staff, regional offices, manufacturers, providers, and others. Most inquiries, however, come from a Medicare-designated contractor in situations where the new technology does not clearly fall under existing Medicare payment guidelines and (or) the private side of the contractor's business has not established a payment policy. When a payment inquiry occurs, HCFA initiates a formal process to resolve the issue, essentially to determine whether the service is considered reasonable and necessary.

The inquiry is directed to the Bureau of Program Policy's Office of Coverage Policy. Most of the inquiries can be resolved by this office. If not, an inquiry may be referred to the Office of Health Technology Assessment. This assessment process is time consuming and can take >2 years from initial inquiry date to the final disposition of a coverage issue (*6*).

HCFA has not published final regulations governing the coverage/assessment process (*7*). A proposed rule that would establish generally applicable criteria and procedures for making medical service coverage decisions was published in the *Federal Register* in 1989. However, the proposed rule was never finalized because "cost-effectiveness" was one of the determining criteria, and there is lack of agreement whether this should be a factor. The environment in the federal government has now changed considerably; with the current emphasis on health care reform, this rule may now become final and the cost impact of a technology may become a determining criterion for coverage.

The Clinical Laboratory Fee Schedule

Another factor limiting reimbursement is the clinical laboratory fee schedule. The Deficit Reduction Act of 1984 instituted major changes in the payment of clinical laboratory outpatient (Part B) services by requiring the establishment of area-wide fee schedules for clinical laboratory services. Prior to July 1984, independent and physician office laboratory services were reimbursed under Medicare Part B at 80% of reasonable charges, except for 12 high-volume tests. After this date, fee schedule rates were to be computed by using 1983 reasonable charge data maintained by Medicare carriers. The 75th percentile of area prevailing rates was to be the basis for calculation of the first-year's fee schedule rates. The fee schedules were set at 60% of the 75th percentile of the prevailing rate for independent laboratories and physician offices and at 62% for hospitals. The additional 2% was to compensate hospitals for presumed greater overhead costs. This 2% advantage was later repealed in 1988, except for sole community providers.

For purposes of the fee schedule, clinical laboratory services include laboratory tests listed in the 80000 series of the *Current Procedural Terminology* (CPT), a listing of descriptive terms and identifying code numbers for reporting medical services and procedures performed by physicians. A different code is assigned to every service and every procedure a physician performs. In this way, each procedure or service can be identified by a number instead of a lengthy written description.

The CPT is a result of efforts by the American Medical Association, the California Medical Association, the College of American Pathologists, and other specialty societies, insurance groups, and the federal government, which wanted a system that provided a uniform language that would simplify the reporting of diagnostic and therapeutic procedures provided by physicians to patients (*8*).

The CPT accomplishes this. By having a code for each individual procedure, payers are able to (*a*) more effectively communicate with each other; (*b*) compare reimbursable amounts; (*c*) speed claims processing; and (*d*) compare local, regional, and national utilization (*8*).

The CPT is revised annually by the American Medical Association to reflect new procedures, delete obsolete procedures, and modify existing procedures to reflect changes in medical practice. Because many payers, in addition to Medicare, reimburse laboratory services based on CPT codes, it is important for laboratories to

update their codes each year. However, it is also important to understand that *inclusion of a service in the CPT does not automatically qualify a procedure or service for coverage or reimbursement by any payer (public or private).*

The Pathology and Laboratory section was significantly revised in the 1993 edition of the CPT. The number of changes is so extensive that the coding revision in the Pathology and Laboratory section did not become effective until August 1, 1993. The reason for the delay was that national limitation amounts for many of the codes needed to be recalculated and the individual carriers needed to set payment amounts for the new codes at the local level.

National Payment Limitation

The Consolidated Omnibus Budget Reconciliation Act of 1985 required that national limitation amounts be applied to the payments for outpatient clinical diagnostic laboratory services. For services rendered on or after July 1, 1986, the national limitation amount was set at 115% of the median of all the fee schedules established for a test for each laboratory code. Since 1986, the national limitation amount has been continually lowered and is currently at 88%. Many new codes are not subject to the national limitation amounts because fee schedule amounts have not been established. *Most of the new procedures and services added to the 80000 series of the 1993 CPT will have payment levels established at the local (carrier) level.*

1993 Payment Opportunities

The changes in the Pathology/Laboratory section of the 1993 CPT may offer some payment opportunities for laboratories performing tumor marker testing. In the past we have had very few CPT codes for coding tumor marker tests. The following CPT codes were frequently used through 1992:

- 86316 "Immunoassay for tumor antigen (e.g., prostate-specific antigen [PSA], cancer antigen 125)" (*9*)

The 1992 cap or national limitation amount for this code was $31.90.

- 86149 "Carcinoembryonic antigen (CEA); gel diffusion" (*9*)

The 1992 cap or national limitation amount for this code was $28.87.

- 86151 "Carcinoembryonic antigen (CEA); RIA or EIA" (*9*)

The 1992 cap or national limitation amount for this code was $28.90.

- 86244 "Feto-protein, alpha-1, RIA or EIA" (*9*)

The 1992 cap or national limitation amount for this code was $24.90.

The 1993 CPT has renumbered the codes for CEA and AFP and added new codes for PSA and cathepsin-D: 82378 CEA; 84153 PSA; 82105 AFP, serum; 82106 AFP, amniotic fluid; 82387 cathepsin-D. Only PSA and cathepsin-D will require payment levels to be established at the local (carrier) level. The other codes can be crosswalked to their previous CPT code; therefore, the cap for these procedures should be listed on the national limitation schedule. Code 86316 has been revised to "Immunoassay for tumor antigen (e.g., cancer antigen 125)" (*10*) and may no longer be used to bill PSA tests because a more specific code for PSA now exists.

The most encouraging addition in the 1993 CPT is the addition of the molecular diagnostics codes. The following codes are for molecular diagnostic techniques for the analysis of nucleic acids (*10*):

- 83890 Nuclear molecular diagnostics; molecular isolation or extraction
- 83892 Enzymatic digestion
- 83894 Separation (e.g., dot blot, electrophoresis)
- 83896 Nucleic acid probe, each
- 83898 Nucleic acid probe with amplification, e.g., polymerase chain reaction (PCR), each

According to the instruction in the CPT, these services are coded by procedure rather than analyte and each procedure in the analysis is to be coded. For example, a procedure requiring isolation of DNA, restriction endonuclease digestion, electrophoresis, and nucleic acid probe amplification would be coded 83890, 83892, 83894, and 83898 (*10*). Coding by procedure allows for more flexibility as the field expands and procedures change.

These codes, though new, have had a national limitation payment amount established by HCFA. HFCA has informed its Medicare contractors that "multiple billings of these codes may be made if multiple services are performed" (*11*). Because a study may consist of multiple probes, HCFA has priced 83912 at one-fifth the former price and will allow for multiple billings of 83912 up to the total number of probes performed.

Summary

Payers recognize that new technologies may bring large benefits for some patients; however, because common medical procedures are often not subject to hard scientific validation, it is difficult for the payers to determine in which cases the procedures will produce the expected benefits (*12*). It is up to us to document which tests contribute to the quality of care and are in the best interest of the patient. We must communicate this to payers and work with the local carrier Medical Director in obtaining payment for new technologies. Equal access to a technology is not possible until the technology is fully reimbursed.

In addition, we must keep informed and become part of the process as we move toward a capitated system. The question then will be, Can we continue to afford to perform these procedures if they are included under a negotiated capitated plan? It remains to be seen whether firms that develop and bring to market these new technologies will be able to survive in a market where the cost of providing services is fixed regardless of the actual cost.

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