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The focus of the American Association for Clinical Chemistry’s 11th Clinical Chemistry Forum, held in Alexandria, VA, on November 15, 2001, was on current and future direction of Medicare reimbursement. Reimbursement issues involve coverage policies, particularly as they relate to new tests, and coding system changes, with the continued influence of the Office of the Inspector General (OIG) in subtly defining laboratory policies. The speakers included representatives from the Centers for Medicare and Medicaid Services (CMS), the profession of clinical chemistry, and experts on new test approval and coding issues as well as members of the legal profession with interests in laboratory-related fraud and trends in reimbursement.

Appropriately, the lead-off speaker was Jeffrey Kang, Chief Clinical Officer and Director of Office of Clinical Standards and Quality, CMS. Kang, who envisages an expanded role for clinical laboratories in providing physician performance monitoring, discussed CMS’s priorities for clinical laboratories. These include coverage for tests, coding and reimbursement, medical review, enforcement of CLIA, and using laboratory data to measure physician performance. Coverage defines which items or services are eligible for reimbursement. Medical review defines when covered services are deemed medically necessary. CMS is moving toward an evidential approach to coverage and, therefore, expects evidence from those seeking coverage that use of a new technology leads to a health outcome at least as good as, if not better than the outcome with existing technology. Coverage defines which items or services are eligible for reimbursement. Medical review defines when covered services are deemed medically necessary. CMS is moving toward an evidential approach to coverage and, therefore, expects evidence from those seeking coverage that use of a new technology leads to a health outcome at least as good as, if not better than the outcome with existing technology.

Although CMS expects laboratory tests to have clinical validity and utility, it also recognizes that it is more difficult to demonstrate for laboratory tests than for medications or treatments. In response to the Balanced Budget Act of 1997 and the negotiated rule-making it required, CMS expects to implement 23 national coverage policies embracing 66 Current Procedural Terminology (CPT) codes covering ~60% of laboratory tests currently billed to the Medicare program. These negotiated coverage policies describe the medical conditions for which a laboratory test is covered and establish frequency limitations on coverage of the same test for an individual. The negotiated rule-making regulations define who is responsible for what documentation. Laboratories should be reassured by the assignment of the responsibility for medical record information to the ordering physician and the lack of the need for a physician’s signature on a test order.

CMS accepts that Food and Drug Administration (FDA) premarket approval assures that a test has clinical validity and that CLIA certification of laboratories leads to adequate test quality. However, CMS continues to be concerned about waived tests. Not only must these have clinical validity and utility, they should be extremely accurate and simple. CMS believes that laboratory tests can be used to assess whether good care is being delivered by physicians, both for diagnosis and to demonstrate adequate treatment. CMS already captures data nationally and is able to show, for example, how frequently hemoglobin A1c and lipid profiles are performed on diabetic patients or the proportion of patients receiving hemodialysis who have desirable hemoglobin concentrations. CMS envisions capturing laboratory values electronically to assess adequacy of care and views the Health Insurance Portability and Accountability Act (HIPAA) of 1997 as an opportunity to standardize the collection and transmission of laboratory values.

Robert Christenson, Director of Clinical Chemistry, Toxicology and Rapid Response Laboratories at the University of Maryland Medical Center in Baltimore, discussed the practice of evidence-based medicine (EBM). To ensure optimal patient care, EBM needs to be incorporated into everyday practice. Christenson emphasized the importance of diagnostic sensitivity and specificity, ROC curves, positive and negative predictive values, and efficiency as the core of evidence-based assessment of laboratory tests. These parameters are important in determining clinical impact, which may lead to more cost-effective use of laboratory tests. EBM involves the use of the strongest available data to make informed, unbiased decisions about the diagnosis and treatment of patients, but the clinical impact and cost-effectiveness of laboratory tests are difficult to determine.

The crux of EBM is the systematic review. Such a review is oriented to a specific question or issue and requires extensive literature review with rigorous analysis of all the data to assess their quality, allowing poor-quality data to be discounted. When subjected to this depth of analysis, many studies of laboratory tests have been shown to be poor. Studies with methodologic shortcomings may overestimate the diagnostic accuracy of a test.

David Sheridan, Palmetto GBA, Columbia, SC, a Medicare Contract Medical Director, discussed the use of EBM in policy setting by Medicare contractors. He indicated that contractors are now committed to using well-developed evidence whenever they can. Medicare dictates that no payment will be made for items or services that are not reasonable and necessary for the diagnosis or treatment of an injury or illness or to improve the functioning of a malformed body member. To facilitate compliance, a contractor needs published authoritative evidence from definitive clinical trials or other definitive studies. These studies should have general acceptance by the medical community, and contractors recognize the differences in quality of evidence. The best evidence is gleaned from systematic reviews, with well-designed controlled trials without randomization and well-designed multicenter cohort or case-controlled studies being the next best approach when no systematic review is available. Consensus opinions of recognized medical experts or consultations with medical associations or other healthcare experts, multiple case series, dramatic uncontrolled experiments and the opinions of respected authorities, or reports of expert committees are less compelling. Systematic reviews provide the backbone for defensible decisions for evidence-based policy making. Evidence-based policies have the dual disadvantages of necessary delays before implementation and rigidity. They also are population-oriented and difficult to customize for an individual patient. The information a contractor needs for payment decisions with regard to a specific test includes approval of the test by the FDA, its diagnostic accuracy, its clinical benefit, and the clinical rationale for its use.

Vivian Dullien, the Chief Executive Officer of Biex, Inc., a start-up company, and consultant to other companies on reimbursement and regulatory strategies, discussed the problems in obtaining reimbursement for breakthrough technologies. A breakthrough technology is defined as one for which there is no comparable product currently available. Generally these technologies allow better patient care through increased diagnostic accuracy, safety, speed, or savings. Because it is unique, such a product is not associated with evidence-based studies substantiating its clinical role. Care paths are not established, and insurance coverage is usually sparse at the time the new test is launched. In effect, access to a new technology is restricted because of the absence of payers. It is difficult to assess the cost/benefits of an entirely new product because there are no products on the market with which to compare it. The FDA approval process measures safety and efficacy, but not cost/benefit. The latter is difficult to determine when a test is used to screen for disease risk or to diagnose a disease, compared with the cost of not treating the disease.

Typically, reimbursement follows evidence showing a test’s usefulness. For a start-up company, at least, conducting an extended cost/benefit trial to gather evidence is prohibitively expensive. It is particularly difficult to acquire evidence when it is difficult to define an endpoint, when the targeted disease has a low prevalence, or when a lengthy timeframe is involved in determining an outcome, as in the case of cancer or heart disease. A new test does not qualify for category I coding by CMS, which enables reimbursement, and will be considered a category III, or investigational test, which currently does not qualify for reimbursement. Although a breakthrough test should receive its own CPT code, it may be possible to demonstrate enough equivalency with an existing test that the new test can be reimbursed using a CPT code that already exists. This “mapping” process facilitates reimbursement, although not necessarily at an adequate level. To establish the clinical usefulness of a new test, it is relatively easy to demonstrate its negative predictive value, but it is often much more difficult to demonstrate its positive predictive value, particular when the targeted disease is uncommon.

Various strategies may enable a company to recoup some of its substantial costs when a test is first made available. Dullien proposed several options, including having a patient pay up front and letting the patient try to obtain reimbursement from his or her insurance company. However, this deprives low-income patients access to the test. Similarly, the test could be sold to hospitals, pharmacies, or laboratories, letting them attempt to obtain reimbursement from insurance companies. An alternative approach would be for the manufacturer to partner with physicians and their patients, with the manufacturer collecting cost/benefit data concurrently during its FDA trials. The company would most likely collect outcome data as well during the year after the product’s launch.
Payers, after review of the FDA data and peer-reviewed literature, should then initiate a 1- to 3-year pilot reimbursement phase, at the end of which the outcome data would be reviewed to determine the appropriateness of continued reimbursement.

Grant Bagley, a partner in Arnold and Porter, a law firm that assists drug and device manufacturers in regulatory and reimbursement issues and represents providers in health policy matters, discussed the current move to establish uniform payment policies. In passing, he noted that one of every six federal dollars is spent on Medicare, which receives 1 billion claims per year.

Medicare’s Medicare Coverage Advisory Committee has devised criteria different from the negotiated rule process described by Kang for covering diagnostic tests, and CMS may adopt or adapt some of these guidelines. Nevertheless, more effective tests may not be covered if the additional information has no demonstrable clinical utility, i.e., tests must demonstrate better outcomes. Medicare’s current orientation is to look at safety, effectiveness with benefits greater than risks, improved outcomes, and added value in new tests.

A national laboratory fee schedule may be implemented soon, but there will also likely be continued carrier discrepancies in gap-filling methodology. “Gap-filling” is the process whereby new tests that are dissimilar to any other tests are reimbursed. Reimbursement is based on a formula related to the rate at which Medicare’s local carriers are paying for the new test.

Currently, assignment of new CPT codes for new tests may take years and delay expedient processing of claims. New category III codes, previously nonreimbursable, will be reimbursed if they are not experimental and are safe and effective. However, the procedure to obtain a billing code is cumbersome. Applications for new codes must be submitted by a specific date each year and are reviewed quarterly by a committee comprising representatives of CMS, Blue Cross/Blue Shield, and the Health Industry Assurance Association. For consideration, a test must have FDA approval and a minimum of 6 months of postmarket data. Applications are denied frequently, and coding decisions become, in effect, decisions on cost-effectiveness. Nevertheless, the process is not used consistently as a tool for implementing program policy and processing claims.

Charles Root, President of MCF Compliance, a healthcare consulting company concerned with Medicare reimbursement and regulatory issues, spoke on approaches to reforming the coding process. He distinguished between the American Medical Association’s (AMA) CPT-4 codes, which generally correspond to a fixed fee schedule amount and are used to report tests and procedures, and the Health Care Financing Administration Common Procedures Coding System (HCPCS) codes of the CMS Common Procedural Coding System. The HCPCS level I codes are the same as the CPT-4 codes. HCPCS level II codes are used for equipment, supplies, and services not included in level I.

International Classification of Diseases (ICD-9) codes, initially created by the WHO to report mortality statistics and then modified by the US National Center for Health Statistics to report morbidity statistics within the US, differ from CPT-4 and HCPCS codes in an important way. The US’s clinical modification of ICD-9, called the ICD-9-CM, includes codes that refer to diseases and clinical states.

Medicare requires that all services be medically necessary and uses ICD-9-CM codes to identify why a procedure was done and CPT-4 codes to identify the specific procedure. Another modification of the ICD-9 procedural coding system is under development. This ICD-10-PCS could potentially replace the CPT system for coding procedures. In ICD-10-PCS, for each procedure a composite five-component code is applied. For a laboratory test, this code would include the Section (Laboratory); the class of analyte, e.g., chemistry or microbiology; the specific analyte; the fluid in which it was measured; and the method. Because of the complexity of the system and the difficulty in mapping these codes to existing CPT-4 codes, it is unlikely that this system will be implemented. Concurrently, the AMA is working on a revision of its CPT-4 code, CPT-5, with changes intended for implementation in 2002 and 2003.

The current problems of implementing reimbursement for a new test have already been described. Root and others have proposed a reimbursement process that compares a new test with an existing test and CPT code. If the current reimbursement is not adequate to cover the cost of a new test, a new CPT code should be sought from the AMA. To assign a new code, AMA requires that a test be approved by FDA. If the new test represents a significant change, its use must be supported by the medical literature and it must have potential broad application. CPT codes are published annually in November and become effective at the beginning of the following year. Reimbursement is established by CMS either by gap-filling or by mapping to the payment amount for the CPT code of a similar test.

Root believes that the current HCPCS coding system lacks coherence and is error prone. There is no established procedure to obtain new HCPCS codes, and decisions are often arbitrary. The entire process is closed, requiring frequent follow-up to monitor progress or obtain a decision about a new test. The current fee schedule is based on the prevailing rates in 1984 with arbitrary modifications, and there is little relationship between payments and the costs of providing the services. Gap-filling for new tests is cumbersome and may yield unworkable results.

A possible solution is the assignment of a temporary code after approval of a test by FDA, with a temporary payment amount assigned based on the test cost and resources required. In this scenario, the AMA would assign a new CPT code as appropriate, and CMS would
set a permanent charge and HCPCS code, if no CPT code were appropriate, within 2 years. Furthermore, a national laboratory fee schedule should be adopted. The payment system should also accommodate different sites and different intensities of service, e.g., point-of-care testing or stat tests. Discontinuation of the use of ICD-9 codes to determine medical necessity should be pursued as recommended by the Institute of Medicine.

Laboratories must also be cognizant of current activities in investigating fraud and abuse. S. Craig Holden, an attorney specializing in Medicare fraud and abuse, provided guidance on this issue. Claims for reimbursement and the relationship of a laboratory with referral sources are regulated by statute. The Civil False Claims Act, enacted during the Civil War, established grounds for determining false and fraudulent claims. There is no need to demonstrate intent to defraud, only a determination that a claim was filed with reckless disregard of its truth. The Act spells out a fine equivalent to three times the determined damages plus $5,500 to $11,000 for each individual claim. Because multiple claims are usually involved when Medicare targets a hospital’s practices, the fines can be substantial. The Civil False Claims Act also includes a qui tam provision that enables anyone to function as a “private attorney general” suing on behalf of the government, even if the government declines. If the suit is successful, the individual is entitled to up to 30% of the recovered amount.

The Medicare Anti-Kickback Statute spells out prohibited conduct in the relationships between physicians and laboratories. The provisions basically refer to conflict-of-interest issues. The Stark law applies to Medicare and Medicaid patients and “designated health services,” under which laboratories have been included since 1992. Again, substantial fines may be levied, and exclusion from participation in any Medicare and Medicaid programs may be imposed on laboratories found to have violated the law. The Department of Justice is likely to intensify its enforcement of the law. The OIG has developed a model compliance plan for laboratories that includes both standard procedural provisions and laboratory-specific guidance. The plan specifies rules regarding requisitions, billing, and the use of diagnosis codes.

OIG’s work plan for 2002 will focus on whether a facility’s CLIA license is appropriate for the tests it performs, billing for cholesterol tests, and ensuring that a laboratory’s proficiency testing performance meets CLIA requirements.

Gordon Schatz, an attorney who represents drug, device, and diagnostics manufacturers on technology reimbursement issues, discussed future trends in Medicare reimbursement for clinical laboratories. Although CMS is already reviewing the amount of payments for laboratory tests and has published its clinical laboratory fee schedule for 2002, substantial changes are likely in how CMS determines payment for new tests. The old process involved a combination of “cross-walking” and gap-filling. CMS has various options with regard to determining payment for new laboratory tests. These include (a) substantive criteria such as costs (equipment, reagents, and staffing), charges, and relative resources (time and complexity); (b) linkage to CLIA complexity; and (c) procedural criteria such as resource-based relative value units or having open meetings and using the world wide web to solicit comments. CMS continues to iterate that certain tests may be used for screening that may not be covered by Medicare and that payment for such tests must reflect the diagnostic reason for the test. CMS needs to continue the reforms it has begun, with procedural openness and improved quality of decision feedback. This will concentrate on new tests. At the federal level, there is a need for legislation for across-the-board reform, with recalculation of all laboratory test fees, based on relative resource units. However, there remains a risk of payment cuts with increasing pressure on the federal budget. Some efficiency may be gained by reducing the number of carriers.

In summary, CMS is developing a more open approach to the reimbursement of laboratory tests. It continues to attack fraud and abuse in the sphere of clinical laboratory testing and has begun a process of reforming the approach to payment for laboratory tests. Various strategies to pay for radically new tests have been suggested because the current system does not facilitate their accessibility and introduction into clinical practice. Reimbursement is increasingly being oriented to an evidence-based strategy, and opportunities are now evolving for clinical laboratorians to acquire the evidence that would demonstrate the usefulness of individual clinical laboratory tests.

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