



## Reimbursement Challenges with *In Vitro* Diagnostic Tests: Fitting a Square Peg into a Round Hole

by Paul Radensky

**P**ayers—those financially responsible for the cost of healthcare—are critical market regulators much like the Food and Drug Administration (FDA) and other public health authorities. Although payers do not determine whether a product may be lawfully marketed, payers’ policies can determine which products are successful in the marketplace and which are not. Through coverage policies, which determine for which patients and when items and services will be eligible for payment, payment policies, which determine the rates at which providers furnishing items and services will be paid, and coding and billing policies, which determine the details about billing for items and services, payers play an increasingly important role in regulating the marketplace for new products.

Many payer coverage, payment and coding and billing policies apply comparably to drugs, biologicals, medical devices and *in vitro* diagnostic tests, but there are also substantial differences in the application of these policies among different types of products and services. For example, drugs and biologicals that are administered by physicians tend to be paid on a per-item basis at rates related to reference prices; drugs and biologicals that are self-administered by patients are typically paid on a per-item basis at rates negotiated

among various stakeholders in the distribution chain; and payment for medical devices is often included as part of the rate for the procedure in which the device is used.

Manufacturers of *in vitro* diagnostic test kits and clinical laboratories that perform these tests face specific hurdles in trying to convince payers to cover *in vitro* diagnostic tests and to set payment rates that are adequate to cover the costs of performing these tests. In the sections below, the author explores some of these specific hurdles.

### Coverage for Novel *In Vitro* Diagnostic Tests

The standard for coverage of items and services under Medicare is set out in statute simply as “reasonable and necessary.” Attempts to expand on the brief statutory criteria through regulations have met with significant controversy. Private



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payers have similar criteria although the specific terms may be different. Typically, when dealing with drugs or biologicals, coverage will be extended for those indications for use included in the package labeling approved by FDA. Coverage for off-label uses of drugs and biologicals varies, but is generally provided for those uses supported by citations in accepted drug compendia. In addition, other uses may be covered if supported by results from clinical trials published in peer-reviewed clinical journals.

By contrast, FDA clearance or approval is no guarantee of coverage for medical devices or procedures involving the use of these devices. For products cleared under FDA's 510(k) substantial equivalence standard, payers will often consider the scope of coverage for the predicate device to which the new device refers. For novel uses or technologically different devices, payers may consider FDA clearance to be a necessary criterion for coverage—but FDA clearance or approval is often not sufficient in and of itself to obtain coverage.

Coverage for *in vitro* diagnostic tests generally follows the criteria for medical devices. For those tests that involve the use of test kits cleared or approved by FDA, FDA clearance or approval is generally a requirement for coverage. However, many *in vitro* diagnostic tests are developed and performed as laboratory-developed tests (LDTs)—i.e., tests developed in-house by laboratories certified to perform high complexity testing under the Clinical Laboratory Improvement Amendments (CLIA)—and do not involve FDA-cleared or approved test kits. LDTs are often cutting-edge tests introduced to test for new infectious diseases or for diagnostic or prognostic

use as genetic/genomic tests for cancer. Although FDA has maintained that it has the authority to regulate these tests as medical devices, it has generally followed a policy of enforcement discretion and has not required FDA clearance or approval for LDTs. This has occasionally caused confusion among payers who may ask for proof of FDA clearance or approval for novel diagnostic tests.

Applying criteria for coverage of therapeutic products to diagnostic tests can be challenging. With therapeutic products, payers look for impact on health outcomes—e.g., survival, symptoms, disability and quality of life. With diagnostic products, the output of the test is information. This information does not directly impact survival, symptoms, disability, or quality of life. The impact of diagnostic tests on health outcomes flows through the intermediate steps of treatment decisions based upon the diagnostic results and the health outcomes resulting from those treatment decisions. This often involves many steps and may be quite difficult to study and involve endpoints that can be observed only many years after the performance of the diagnostic test.

With diagnostic tests, it can be very helpful to consider a continuum of outcomes as shown in the table below:

Outcome	Description
Technical accuracy	How accurate is the test in measuring what it says it measures? For example, blood glucose levels.
Diagnostic accuracy	How accurate is the test in diagnosing a condition or disorder? This includes sensitivity, specificity, positive and negative predictive values.
Change in patient management	How does the information provided by the test impact the mix of diagnostic or therapeutic procedures that will be ordered in the management of the patient?
Health outcomes	How does the information provided by the test and the resulting management impact survival, symptoms, disability or quality of life?
Societal outcomes	How does the information provided by the test and the resulting management impact both clinical and economic outcomes (from a societal perspective)? Includes cost-effectiveness/cost-utility.

Along this continuum, the outcomes build upon each other. A test cannot show diagnostic accuracy without first meeting standards of technical accuracy. Diagnostic accuracy, in turn, is required for a test to be useful in patient management decisions. A key outcome to support coverage for a novel *in vitro* diagnostic test is showing that the test can impact patient management. This is necessary to meet Medicare requirements for coverage of diagnostic tests that these be capable of being used by the treating physician in the management of the patient.

Note, however, that *in vitro* diagnostic tests that are used for screening purposes—to detect disease or condition among a population without signs or symptoms—are generally not covered under Medicare unless the type of test is specifically covered under the Medicare statute, such as Pap smears for cervical cancer screening or prostate-specific antigen testing for prostate cancer.

### Payment for *In Vitro* Diagnostic Tests

Under Medicare, *in vitro* diagnostic tests may be paid under one or more of several different payment systems. Tests used during inpatient admissions are generally included under

the inclusive, per-admission payment for the Diagnosis-Related Group to which the admission is assigned under the Medicare Inpatient Prospective Payment System. Similarly, tests performed during stays in a skilled nursing facility are packaged into the per-diem payments under the Skilled Nursing Facility Prospective Payment System. Tests performed in outpatient laboratories (independent laboratories, physician offices, hospital outpatient laboratories) are paid under the Clinical Laboratory Fee Schedule (CLFS) or, if each test requires the individual interpretation by a pathologist, under the Medicare Physician Fee Schedule (MPFS). By contrast, home blood glucose monitoring is furnished as durable medical equipment and paid under the Durable Medical Equipment Prosthetics, Orthotics and Supplies Fee Schedule.

For most novel outpatient tests, obtaining an adequate payment rate under the CLFS is a critical step. Unfortunately, the CLFS is an out-of-date payment system that does not fit well with the scientific advancements of the genomic age. The CLFS is based on historical charge levels that were in place in the early 1980s. In order to limit growth in overall payments for laboratory testing, the CLFS reduced historical charge profiles through formulas setting fees at 60 or 62-percent of historical rates. Unlike most other Medicare payment systems, rates set under the CLFS have remained fairly static over time—in the 15 year period from 1994 through 2008, there has been an update to the CLFS only three times.

When new tests are introduced, there is an established process for assigning new rates under the CLFS.

In the late spring/early summer, the Centers for Medicare & Medicaid Services (CMS) publishes an announcement of a public meeting at which it will accept recommendations for setting rates for new laboratory test procedures under the CLFS. New tests are identified based upon the approval by the American Medical Association's (AMA's) Current Procedural Terminology (CPT) Editorial Panel of new or substantially revised codes to become effective the following year. CMS accepts recommendation to set rates either through a cross-walk to rates established for one or more existing laboratory test procedures or through a local gap-fill process. Under gap-filling, local contractors set rates by reference to (1) charges for the test and routine discounts to charges; (2) resources required to perform the test; (3) payment amounts determined by other payers; and (4) charges, payment amounts and resources required for other tests that may be comparable or otherwise relevant. When payment rates are set by cross-walk, the new rates are effective starting January 1 of the following year based upon the rate in each locality for the test or tests to which the novel test is cross-walked. When the rates are set by gap-fill, each regional Medicare contractor must set rates for the localities within its jurisdiction and report those rates to CMS. CMS then determines a national limit (the National Limitation Amount) at 100-percent of the median of the local fee schedule rates, which then becomes effective January 1 of the second year. Local rates are then the lower of the local rate or the NLA.

Given the need to work with multiple contractors under a gap-fill process, the gap-fill process is time consuming, resource intensive and

uncertain. Therefore, many stakeholders recommend cross-walk for most new tests. Controversy over setting rates for new tests is usually related more to the identification of the test or tests to which the rate for the novel test will be cross-walked rather than the recommendation of cross-walk versus gap-filling.

## Coding & Billing Issues

Clinical laboratory tests are procedures and are billed to payers using CPT or Healthcare Common Procedure Coding System (HCPCS) codes. The HCPCS code system is maintained by CMS. The system includes CPT as Level I of HCPCS, supplemented by alpha-numeric codes approved by the HCPCS Workgroup as Level II codes, for instances where there may be no CPT codes that accurately describe a procedure. Most clinical laboratory tests are billed under the Pathology Section of CPT comprising codes in the 80000 series of CPT.

The process for seeking new codes or revised code descriptors under CPT takes 14 to 26 months to complete. For example, applications for CPT 2010 will be accepted until early November 2008; applications after that time will be considered only for CPT 2011. CPT sets the following requirements to obtain new codes:

- “that the service/procedure receive approval from the Food and Drug Administration (FDA) for the specific use of devices or drugs;
- that the service/procedure is performed across the country in multiple locations;
- that many physicians or other healthcare professionals perform the service/procedure; and
- that the clinical efficacy of the service/procedure has been well established and documented.”

Procedures involving products subject to FDA clearance or approval that have not yet obtained such clearance/approval and procedures not yet performed by many healthcare professionals across the country may be assigned temporary tracking codes called Category III codes. According to AMA, “Category III CPT codes are intended to facilitate data collection on and assessment of new services and procedures. These codes are intended to be used for data collection purposes to substantiate widespread usage or in the FDA approval process ....” Unlike standard CPT codes (Category I codes), Category III codes are assigned an alphanumeric identifier with a letter in the last field (e.g., 1234T). Unlike other novel laboratory tests assigned new CPT codes, those assigned to Cat-

egory III codes do not have national payment rates assigned under either the CLFS or the MPFS. Payments are assigned locally by regional Medicare contractors. Many payers automatically deny coverage for procedures reported under Category III codes.

Requests for new codes are submitted to staff at the AMA and are considered at the next upcoming meeting of the CPT Editorial Panel, an independent body comprising representatives from major medical societies as well as payers. Prior to the CPT Editorial Panel meeting at which a new code application will be considered, AMA staff send out an application to advisors from the AMA CPT Advisory Committee for comments and recommendations. This Committee, which comprises represen-

tatives from nearly all national medical specialty societies, does not actually meet in-person, but rather each professional society individually considers applications and submits recommendations back to AMA staff. For clinical laboratory tests, however, there is an advisory committee, the Pathology Coding Caucus (PCC) that meets prior to the CPT Editorial Panel meeting and makes recommendations on clinical laboratory coding petitions to be considered by the Editorial Panel. The PCC comprises representation from the pathology and laboratory community, including representatives from the College of American Pathologists, the American Clinical Laboratory Association, the Advanced Medical Technology Association (AdvaMed) and other interested groups.

The CPT process can be difficult for manufacturers of novel test kits or clinical laboratories offering new LDTs to understand and navigate successfully. Requests for codes that are made too early are likely to result in adoption of a Category III code. Requests for new codes that do not reflect appropriate discussion and interaction with professional groups are unlikely to be successful.

For some new clinical laboratory tests—in particular complex genetic, genomic or proteomic assays—established CPT codes or code combinations do not adequately describe the assays. Because these tests may be offered as LDTs at one site, it may be difficult to meet the requirements to obtain specific CPT codes. Therefore, many of these tests are reported to payers using non-specific unlisted service codes. Such codes require submission of a “special report” to payers to describe what test was performed

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and to support coverage and payment for the test. Regional payers to whom these laboratories submit their claims can adopt system edits that allow such tests to be covered and paid on a semi-automated basis for more efficient and certain claims processing.

In addition to coding issues, there are other important billing considerations that developers of new tests should consider, such as: (1) the date of service rule and (2) billing for the technical component of physician pathology services furnished to hospitals. Under the date of service rule, laboratory tests ordered within 14 days of discharge from a hospital inpatient admission or hospital outpatient encounter that require use of a tissue specimen obtained during the previous hospital admission or encounter are related back to the prior hospital stay and must be billed by the hospital that performed the biopsy procedure to obtain the specimen. This can be problematic for laboratories since the hospitals may have no relationship with the laboratory performing the test or the treating physician ordering the test and, therefore, may not be willing to assume financial or professional responsibility for the test. Laboratories impacted by this rule have found hospitals nearly uniformly unwilling to agree to provide these tests under arrangements, as required under Medicare rules. Those laboratories are working to have the rules revised so that the laboratories can bill for these tests.

Under special billing rules for technical components of physician pathology services, hospitals that referred such tests to independent laboratories as of July 1999 may continue to refer such tests to outside laboratories and the laboratories are then permitted to

bill for these tests rather than having the payments packaged into the inpatient or outpatient hospital prospective payment system payments paid to the hospitals under Medicare. This “grandfathering” provision has been extended for limited periods of time since 1999, and is set to expire once again in July 2008. Hospitals and laboratories have sought to make this exception permanent, but as of now, it will expire unless Congress extends it once again as part of anticipated Medicare legislation to address the automatic reduction in physician payments under the MPFS that will go into effect in July 2008.

### Conclusion

Developers and marketers of *in vitro* diagnostic test kits and LDTs must

work through time consuming and resource intensive regulatory requirements in order to bring their tests to market. However, the hurdles to clear for successful commercialization of complex tests do not end with FDA clearance or approval or with certification under CLIA. *In vitro* diagnostic test manufacturers and clinical laboratories must also work their way through payer requirements to obtain coverage and payment for these tests. Planning for reimbursement takes time and resources and should not be left to the period after FDA clearance or approval or CLIA certification is obtained—planning should start early in the product or assay development period. ▲

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1. "Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services— which, except for items and services described in a succeeding subparagraph are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, ... ." Soc. Sec. Act § 1862(a)(1)(A).
2. 54 Fed. Reg. 4,302 (Jan. 30, 1989) (Notice of Proposed Rulemaking); 64 Fed. Reg. 22,619 (Apr. 27, 1999) (formal withdrawal of Notice of Proposed Rulemaking); 65 Fed. Reg. 31,124 (May 16, 2000) (Notice of Intent to Publish a Proposed Rule). No further rulemaking has been proposed, but CMS has issued certain guidance documents on coverage requirements and procedures.
3. See, e.g., the national Blue Cross and Blue Shield Association's Technology Evaluation Criteria: "1. The technology must have final approval from the appropriate governmental regulatory bodies. ... ." "2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes. ... ." "3. The technology must improve the net health outcome. ... ." "4. The technology must be as beneficial as any established alternatives. ... ." "5. The improvement must be attainable outside the investigational settings." Although not coverage criteria per se, "the Blue Cross and Blue Shield Association uses the five criteria below to assess whether a technology improves health outcomes such as length of life, quality of life and functional ability." <http://www.bcbs.com/blueresources/tec/tec-criteria.html> Many private payers look at the TEC assessments in formulating their own coverage policies.
4. Soc. Sec. Act §§ 1860D-2(e)(1)(with cross-reference to 1927(k)(6)), 1861(t)(2)(B)(ii)(I), 1927(k)(6)(with cross reference to 1927(g)(1)(B)(i).
5. See, e.g., Soc. Sec. Act § 1861(t)(2) (B)(ii)(II).
6. Federal Food, Drug, and Cosmetic Act (FDCA) § 510(k), 513(i)(I).
7. Public Health Service Act (PHSA) § 353.
8. ASR preamble 11/21/1997. *But see*, IVDmia guidances 9/2006 and 7/2007.
9. See, e.g., G.H. Guyatt, P.X. Tugwell, D.H. Feeny, R.B. Haynes, M. Drummond, *A Framework for Clinical Evaluation of Diagnostic Technologies*. CAN MED ASSOC J. (1986); 134:587-594.
10. "(a) *Ordering diagnostic tests*. All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. 42 C.F.R. § 410.32.
11. Soc. Sec. Act §§ 1861(s)(14), (s)(2)(P).
12. Soc. Sec. Act § 1833(h)(2)(A)(i).
13. Soc. Sec. Act § 1833(h)(2)(A)(ii)(IV).
14. Soc. Sec. Act § 1833(h)(8).
15. 42 C.F.R. § 414.508.
16. 42 C.F.R. § 414.508(b)(1).
17. Note: Applications requesting establishment of CPT codes for vaccine products may be considered prior to submission of the Biologic License Application (BLA) to FDA, but will not be considered until evidence substantiating completion of Phase III Clinical Trials and review of unblinded data is submitted to AMA.
18. Coding Change Request Form Instructions Category I CPT Codes. <http://www.ama-assn.org/ama/pub/category/12888.html> (accessed May 26, 2008).
19. *Id.* Coding Change Request Form Instructions. Category III CPT Codes—Emerging Technology (accessed May 26, 2008).
20. 42 C.F.R. § 414.510.
21. Sec. 542 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (P.L. 106-554).
22. Sec. 104 of the Medicare, Medicaid SCHIP Extension Act of 2007 (P.L. 110-173).