Personalized Medicine: Reimbursement Changes Loom for Molecular Laboratory Tests

One of the vexing problems for personalized medicine in the US is how Medicare and other payers will reimburse high-tech laboratory tests that are used to diagnose or guide therapies for conditions that may be due to genetic causes. (See examples below.) With the development and introduction of high technology tests examining human DNA, RNA, or other key cellular components such as proteins, the deficiencies of current coding and reimbursement policies for advanced laboratory tests have come into stark relief. Changes in billing codes are in the offing that will, in turn, lead to changes in reimbursement in 2012 and 2013. This advisory describes these changes and attempts to place them in a wider context of needed reforms.

Examples of molecular diagnostic tests include:

- Tests for mutations of BRCA1 and BRCA2 genes: Women with a family history of breast or ovarian cancer are tested to determine whether the BRCA1 and BRCA2 genes have a harmful mutation that increases their risk of developing cancer. Patients who test positive for the mutation have several options for managing their risk including the use of drug therapies as chemoprevention.
- Tests for mutations of the KRAS gene: Colorectal cancer patients are tested to detect whether their KRAS genes are normal (wild-type) or mutated. If the mutation is present, studies indicate the patient will not respond to drug therapies (e.g., cetuximab) that target the epidermal growth factor receptor.
- Tests for CYP: Patients are tested for genetic variants in Cytochrome P450 (CYP) enzymes to aid in individualizing treatment selection and dosing for drugs metabolized through this pathway, including certain antidepressants, antiepileptics, and cardiovascular drugs.

All US payers use the same billing codes to describe clinical diagnostic laboratory services: the bulk are on the Current Procedural Terminology (CPT) code set.[1] Determination

1 CPT is a national standard code set designated under the Health Insurance Portability and Accountability Act and is used by all payers. CPT is maintained by a multi-specialty panel convened by the American Medical Association. CPT is a registered trademark of the American Medical Association.

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of payment rates is largely dominated by Medicare's methodologies because private payers, although not required to do so, frequently follow Medicare's lead on payment rates. Medicare payment rates for new tests are determined, in most instances on a prospective basis, by a set of arcane rules described in more depth below.

Contrasting the reimbursement picture for lab tests with that for pharmaceuticals can be revealing. While a new single-source drug will receive, in due course, its own billing code, CPT codes for new lab tests are not assigned automatically, and new tests frequently fit within existing analyte-specific codes or are billed using one or more method codes (described below) or miscellaneous codes for unlisted procedures. Lab code descriptors are usually stated in general, non-product specific terms that identify what is being studied (the analyte) rather than the inputs (such as specific machines or kits). Unlike pharmaceuticals, where reimbursement for a specific product is frequently set by reference to a measure that is supposed to reflect market activity, such as average sales price, Medicare sets reimbursement to lab providers for a given test directly using its own procedures, which tend to emphasize costs rather than market prices. Thus, manufacturers of in vitro diagnostics generally have less influence over applicable payment rates than do pharmaceutical manufacturers.

Current Coding for Molecular Tests

Unlike tests for most analytes (such as sodium, atrial natriuretic peptide, or human papilloma virus) that are described by a single code, complex molecular pathology tests that investigate human genes or genetic variants are now reported using multiple "method" codes that describe different steps of the tests. These codes are sometimes referred to as "stacked" codes, since—in contrast to most tests, where usually only one code is used—several codes (or a "code stack") delineating the test's various steps are needed to capture a single test. Steps, for instance, may include extraction, amplification, or identification of genetic material, depending on the test, and these steps may be billed in multiple units.

This methodology was introduced a number of years ago by the CPT Editorial Panel when the number of commonly performed molecular tests was much smaller. It was apparently regarded as a temporary measure to be used until a more refined approach could be adopted. At present, use of these codes presents a number of difficulties.

- Payers have difficulty identifying what test is performed and what gene is being identified when attempting to determine whether a particular test is medically necessary in a particular situation or whether the payment is what the payer thinks appropriate.
- Claims data cannot be used to determine the extent to which particular genetic tests are being performed or how their use may relate to other services being furnished.
- Labs performing the same test may employ different steps or report steps differently and, therefore, are paid differently.

Proposed New Codes

To improve the coding for molecular diagnostic tests, the American Medical Association (AMA) CPT Editorial Panel created the Molecular Pathology Coding Workgroup (MPCW) in December 2009. The goal of the MPCW was to develop new codes and descriptors that are based on current technology and that allow users of the codes to more accurately identify the service performed. The MPCW focused on molecular assays in cancer, genetics, and histocompatibility, and did not revise the codes for other types of tests.

On March 10, 2011, the MPCW released for comment a set of 100 draft molecular pathology codes, divided into two tiers.[2] Tier 1 codes are gene specific and are for high-volume tests. The nine Tier 2 codes consolidate less-common tests (e.g., those for rare conditions) according to the technical

2 *See* "Request for Molecular Pathology Code Review and Feedback," *Available at:* http://www.ama-assn.org/ama1/pub/upload/mm/362/request-for-molecular-pathology-code-review-and-feedback.pdf. This document provides a specific description of the area of concern: "The MPCW constructed codes to describe non-infectious disease, non-microscopic, nucleic acid-based analyses to detect variations in genes that may be indicative of germline (e.g., constitutional) disorders, somatic (e.g., neoplasia) conditions, or histocompatability alleles indicative of antigenic differences (e.g., HLA)."

resources required to perform the test and, presumably, the level of interpretive work required by the physician or other qualified health care professional. Although the Tier 2 codes are not gene specific, each includes a list of specific genes, tests for which must be billed using that level. For genetic tests included in this schema, a laboratory will not have discretion regarding coding but will be required to use the appropriate Tier 1 or Tier 2 code for the tests it furnishes.

The new codes are open for public comment through April 15, 2011. The MPCW's comment request is quite specific regarding the areas on which it seeks input and does not ask for comments on broader subjects, such as the merits of the overall approach. In particular, the MPCW is interested in concerns regarding the wording used in the code descriptors and in instances where a specific gene or genetic variant is not identified among the proposed new codes or where a currently used test is not included.

The new codes are expected to be available for use January 1, 2012. At that time, the CPT Editorial Panel expects that the new codes—instead of the existing stacking codes—will be required for reporting all analytes identified in the code set.[3] In 2012, the current method codes will remain available, presumably to accommodate any tests that fall outside the new codes, but they are expected to be retired on January 1, 2013. Miscellaneous codes will remain available, but they will only be applicable for tests not described by one of the more specific codes.

Medicare Payment

A critical question now is how will the Centers for Medicare & Medicaid Services (CMS) set Medicare payment rates for the new codes? The pricing effort is expected to be a challenge for CMS. The volume of codes is significantly greater than the number of new lab codes that CMS usually prices in a typical year, and these codes represent highly complex procedures. At this point it is not clear the extent to which CMS will assign new codes to the Clinical Laboratory Fee Schedule (CLFS), the system currently used to pay for most lab services, or the Medicare Physician Fee Schedule (MPFS), which pays for a broad array of physician services including pathology services and a small number of lab tests. The methodology for determining payment rates is significantly different under the two systems, and important policy considerations, such as effect on beneficiaries, may influence the choice.

Clinical Laboratory Fee Schedule (CLFS)

Independent, hospital, and physician office labs bill Medicare under the CLFS. Payment rates are based on the rates set by Medicare contractors in 1985 and updated periodically for inflation.[4] Rates may vary by geographic location but are subject to an upper limit—called the national limitation amount (NLA)—based on the historic median of the contractor-specific rates. Payment for most tests in most areas is at the NLA.[5] No practical mechanism is available to allow CMS to refine lab payment rates relative to one another over time;once a payment rate is set under the CLFS it cannot be easily adjusted to reflect changes in technology.[6] As a result, payment rates are relatively stable over time, with occasional across-the-board updates reflecting inflation or other factors but little or no movement in the relative rate of one test versus others. Labs receive 100 percent of payment from the Medicare program; beneficiaries are not liable for coinsurance.

CMS uses one of two approaches for setting rates for new lab codes: "cross-walking" and "gap-filling". Under cross-walking, CMS sets the payment rate for the new code at the rate applicable to a test that is determined to have some clinical similarity and comparable resource use to the new test.[7] Under gap-filling, each of the Medicare claims processing contractors gathers data on cost and other factors and determines a payment rate for the new code in its jurisdiction.

3 Ibid.

4 *See* MedPAC Payment Basics, "Clinical Laboratory Services Payment System", *available at:* http://www.medpac.gov/documents/MedPAC_briefs_Payment_Basics_10_clinical_lab.pdf (October 2010).

5 Ibid.

6 The statute provides for across-the-board updates reflecting inflation, but Congress not infrequently reduces or eliminates those updates.

7 In some instances, cross-walking is to fractional or multiple units of existing codes.

The contractor-specific rates are then used by CMS to establish a NLA, which affects payment in subsequent years.

While gap-filling is in theory to be used for "breakthrough" technology, in recent years CMS has almost exclusively set payment rates for new codes by cross-walking. For each year's set of new codes, CMS' decision about whether to cross-walk or gap-fill and the recommended cross-walk amounts are subject to comment at an annual public meeting held in the summer and through subsequent website postings; CMS finalizes them in the fall through instructions to the contractors.

Using either approach for this new cohort of codes raises concerns. Since the tests represented by these codes are currently paid based on a combination of several existing codes (and multiple units of those codes) that may vary from laboratory to laboratory, it may be difficult to cross-walk the new codes and arrive at an appropriate payment rate. Gap-filling, on the other hand, relies heavily on the contractor's accurate understanding of the test and the costs involved in performing it. Use of gap-filling has fallen out of favor, both because it is resource-intensive for the contractors and because it has produced wide variations in payment rates for some tests.[8]

Medicare Physician Fee Schedule (MPFS)

Medicare pays for office visits, surgical procedures, and other diagnostic and therapeutic services under the MPFS. The Medicare program pays 80 percent of the fee schedule amount and the beneficiary is liable for the remaining 20 percent. Medicare law defines who is considered a physician[9] and thus who may bill for certain types of services. MPFS rates are based on the relative cost of performing a service compared to the cost of performing other services under the fee schedule. The MPFS is updated annually through rulemaking to reflect changes in payment policy and the introduction of new codes. In addition, the relative value units upon which payment is based are subject to a broad review every five years. The MPFS is subject to a budget neutrality requirement, so if the rate for a particular service increases, the rates for all other services must decline to keep total payments constant. In addition, the MPFS includes a formula called the Sustainable Growth Rate (SGR) that is intended to limit overall increases in total spending under the fee schedule. Over the last decade, the SGR formula has called for steadily increasing, across-the-board cuts, which Congress has generally forestalled.[10] The vagaries of this process have subjected physicians to uncertainties about payment rates that have not been experienced by other providers.

CMS sets payment rates for codes added to the MPFS based on the physician work and practice expenses, such as the equipment, supplies, and non-physician labor, needed to perform the service. CMS relies on recommendations from the AMA/Specialty Society Relative Value Scale Update Committee (RUC), a group of representatives of national medical specialty societies, in determining the appropriate inputs for new codes. The RUC experience in evaluating practice expenses (staff time, disposables, equipment) of laboratory services is not extensive, however, since the RUC is not involved with setting payment rates for the CLFS, where most lab services are currently paid.

How Will the Choice of Fee Schedule Be Made?

The decision about which fee schedule the new codes will be assigned to for Medicare purposes, at least, will be made by CMS. At this time, the criteria that CMS will use to make this choice are not clear. CMS does not appear to have made public its reasoning in making such choices in the past. The most obvious likely factor is the extent to which any given test requires physician work for its interpretation. Even this factor is not fully dispositive, since it appears that

8 Unlike the Medicare physician fee schedule, the CLFS has no budget neutrality requirement (see discussion of MPFS). Thus, the addition of new tests, even though they may be expensive, to the CLFS does not affect payment for existing tests. Budget neutrality concerns would thus not affect either the proposed codes (since the services in question are presumably already paid for on the CLFS) or new tests that might be added to the CLFS in the future.

9 Social Security Act § 1861(r)

10 *See* MedPAC Payment Basics, "Physician Services Payment System," *available at:* http://www.medpac.gov/documents/MedPAC_Payment_Basics_10_Physician.pdf (October 2010).

the physician activity could be paid on the MPFS while the technical aspects of the test might be paid on the CLFS. Other factors might include the imposition of copayments for services on the MPFS versus their absence on the CLFS; the ability to revise payment rates over time; and the effect on other physician services.

The SGR is based on the aggregate of both MPFS and CLFS services, so insofar as the tests in question are now being paid under the CLFS, moving payment for the new codes to the MPFS would not increase the across-the-board cuts already expected as a result of the current SGR law. However, to the extent that existing services were moved to the MPFS, the MPFS budget neutrality requirement noted above could operate to reduce payment rates for all other services paid under the MPFS in order to compensate for the addition. Although spending on the CLFS would presumably go down, under current law that reduction could not be used to offset an increase in MPFS spending. Thus, absent other changes, and depending to some extent on the payment rates established for individual tests, total Medicare spending could go down.

Timing

CMS' approach to the pricing problem should be revealed this summer. CMS has already scheduled a public meeting on the new CLFS codes for July 18, 2011, so its proposed approach may be clear by then. Insofar as CMS prefers to place codes on the MPFS, the normal course of events would mean that the relative values for these tests might not be available until about November 1, 2011, when the final regulation updating the MPFS for 2012 will be posted. (Those values would be treated as interim for the first year and open to comment.) For new codes on the CLFS, CMS is likely to post proposed rates for cross-walked tests during the fall and finalize them late in the calendar year. Gap-filled tests would be priced by individual contractors in the first year, and CMS would establish NLAs for the following year.

Broader Concerns

The new codes now in development will improve the ability of the payment system to describe and understand the use of high technology molecular pathology tests. Whether the resulting payment rates will be more accurate than currently available or will improve availability of these tests is unclear at this writing.

We can anticipate additional coding activity along the same lines. The currently proposed codes do not describe any tests that use genetic data to predict disease prognosis or response to therapy (for example, Genomic Health's Oncotype DX® test). Such tests may involve the application of proprietary algorithms to large quantities of genetic, and sometimes non-genetic, data in patients with diseases associated with multiple genes, genetic variations, mutations, or single nucleotide polymorphisms. As with the genetic tests previously described, these tests are reported by using either the "stacking" codes discussed above or a non-specific code. The MPCW is likely to expand its work to encompass coding of these tests, and proposals in this area may be forthcoming. Among the issues that will confront the workgroup are the appropriate level of coding granularity (e.g., whether a single code should describe all tests that predict prognosis in breast cancer, or should each test have its own code, or something in between); whether to consider proof of clinical utility as a criterion for granting a code; and whether to assign codes in the absence of an application from the manufacturer or other stakeholder. Aside from the coding issues, the complexity of many of these tests may make establishing appropriate payment rates under either the CLFS or the MPFS even more problematic than for those subject to the current MPCW proposal.

These developments highlight more general concerns about how the government reimburses for clinical laboratory tests, particularly new ones. Test developers have pointed to significant problems with how the payment system reflects the "value" of tests—or rather the extent to which it does not. Medicare's fee-for-service payment systems, including the MPFS and the CLFS, are basically structured to reflect the average resources consumed in the delivery of services, not the value of those services. Improving the situation without the effort being estimated

as costing the Medicare program money, considering the budget conventions used by the government, has proved to be a frustrating problem, one which the new codes, by themselves, will not address.

If you have any questions about any of the topics discussed in this advisory, please contact your Arnold & Porter attorney or any of the following attorneys.

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