How will it impact the delivery of personalized medicine?

MDx REIMBURSEMENT ON THE THRESHOLD OF CHANGE

By Rina Wolf

The reimbursement process, CPT codes and current debate regarding which fee schedule new molecular and genetic services should be assigned—the clinical lab fee schedule (CLFS) versus the professional fee schedule (PFS)—are at the center of decisions affecting molecular diagnostic (MDx) laboratories and the future of personalized medicine. Input from lab companies regarding reimbursement issues has traditionally been limited, but the recent CMS listening session on code pricing and fee schedules, as well as the stakeholder workshop on In Vitro Diagnostic Multivariate Assays (IVDMIA) held by the AMA Molecular Pathology Coding Workgroup in Chicago, represent the first open opportunities for stakeholders to comment and participate in the process.

DAVE PERILLO

The agencies and organizations controlling the decision process are fairly numerous, with new changes occurring almost daily. MDx labs must understand the issues and players to affect positive change wherever possible. For example, the FDA is enhancing its presence in the laboratory MDx test development space, offering new draft guidance on companion diagnostics and RUO/IUO (research use only and investigative use only) classifications. These and other issues could have serious implications for MDx test development and reimbursement for labs.

Coding Issues

The CPT system has limited space for new codes, and the AMA traditionally has been opposed to utilizing proprietary brand names in their CPT test descriptors. This inability to support necessary coding granularity may impede growth of robust testing creation and reimbursement for labs by forcing tests into potentially inappropriate codes—especially if they are relegated to Category III status or are captured in a code originally intended for a different test.

The AMA Workgroup strongly recommended that stacking be eliminated for all MDx tests by Jan. 1, 2013, and payors are supportive of this effort. Additionally, it is possible that some, if not all, of these molecular tests may be placed on the Medicare Physician Fee Schedule (MPFS), where the payment rules are substantially different.

As CMS solicits a contractor to assist in updates to the CLFS by analyzing these

new molecular codes, it remains uncertain whether they will be included in that schedule. Interestingly, the new codes were issued with vignettes for physician professional components and laboratory technical components, which indicates that AMA intended for them to go on the PFS. This would negatively impact the reimbursement potential for laboratory developed tests (LDTs).

The College of American Pathologists (CAP), as well as some other physician groups, support listing MDx codes under the PFS. Other stakeholders maintain that fee schedule assignments should be made on a test-specific basis since the need for additional interpretation varies greatly from test to test.

Pricing Issues

The AMA has approved a total of 92 genetic codes for Level 1, as well as established nine new complexity-defined "buckets." The AMA editorial panel will decide which tests will be assigned to each of these buckets. Currently, no plan for stakeholder input exists for this process.

The CMS Demonstration Project for the Date of Service (DOS or 14 day rule) is another area of concern. Tests that meet demo eligibility requirements but are currently billed utilizing Not Otherwise Classified codes (NOC) will be assigned one of six G (temporary) codes by CMS to assign prices for demo utilization. There are also 36 existing CPT codes that may be submitted for the DOS demo project that will be assigned new national pricing for this purpose.

Since these tests already have carrier-assigned pricing, there is concern that potentially lower pricing may result. In that case, it is likely that many of the laboratories that have fought hardest for this project may choose not to participate.

CMS maintains that participation is voluntary, although laboratories unhappy with newly assigned test pricing have no avenue for redress. By requiring the submission of heretofore confidential pricing, payment and cost information for the G code pricing, CMS has essentially repurposed this demo as a re-pricing exercise. In fact, a CMS employee stated that some laboratories view the current pricing modalities as unacceptable and inappropriate for these new tests. Consequently, the collection and analysis of this information by an outside contractor may lead to a new way of pricing these tests in the future.

Additional pricing pressures include CMS assigning arbitrarily low prices for new MDx tests. Recent prices have been in the $1,470–$2,100 range as opposed to the previous $3,000–4,000 range seen for the earlier tests in this space. G codes for drug screening have been established with prices set around $102, negating the stacked code billing configuration.

Coding Application Challenges

Medicare Administrative Contractors (MACs) now charged with handling claim payment contracts in their specific geographies will have significant sway over the MDx reimbursement landscape. California's MAC, Palmetto GBA, states it aims to determine fair reimbursement values for services within current CMS guidelines.

In an attempt to provide clarity, Palmetto has published its Molecular Diagnostics Services Program article.[1] The program will affect diagnostic services that use multiple, methodology-based stacking, microarray, cytogenetic and NOC CPT codes. Palmetto's MDx program is intended to further clarify coverage and reimbursement requirements. Industry stakeholders like the California Pathology Society, California Clinical Laboratory Association and American Clinical Laboratory Associations and others have commented on this article in hopes of revisions to correct regulatory inaccuracies and provide a more realistic but appropriate path to coverage.

The Palmetto MDx program includes a test compendia submission process and requires labs to discuss coverage with Palmetto before submitting claims using stacked codes. This is tantamount to denying labs their rights to the appeals process. The California CMS contractor is also pressuring labs to use NOC codes in place of stacked codes. Their proposed "one code/one test" stance and

bundling definitions is adversely affecting pricing, and may also be a misinterpretation of the coding requirements.

Palmetto's submission process requires extremely high levels of peer-reviewed publication evidence that far exceeds coverage policy requirements for many currently covered assays. With clinical utility definitions still not clearly defined, meeting the requirements may be especially difficult. Consequently, utilization is difficult to sustain when reimbursement is so uncertain.

CMS Listening Session and AMA Workshop

The CMS and AMA meetings held in July have left as many questions as answers. CMS was not able to assign prices to the new molecular codes that will be finalized for the 2012 code year, which has left the pricing and utilization of these codes for 2012 still in question.

Many are saying, however, that the RUC (Relative Value Scale Update Committee) has already begun to assign PFS pricing to some of these codes, which would allow them to be utilized by payors effective Jan. 1, 2012. It remains to be seen which of these codes have been assigned PFS pricing and what private payors and regional Medicare carriers do with these codes and prices in 2012. It's unclear whether the "stacking" option will remain viable for these molecular tests until Jan. 1, 2013 and which, if any, of these codes will still be available for assignment to the CLFS and pricing by CMS next July.

The AMA stakeholders meeting did allow for a comment regarding how the current CPT process could potentially be adjusted to incorporate these new tests and how best to incorporate previously titled IVDMIAs—which may now potentially be called MAAs—into the CPT infrastructure. (For a synopsis of the AMA meeting, visit http://www.ama-assn.org/resources/doc/cpt/cpt-in-vitro-diagnostic-multivariate-assays.pdf)

We can expect ongoing changes in the coming months—hopefully accompanied by insights into how these new tests will be coded and valued. Ideally, it will allow the concept of personalized medicine to continue to thrive by providing for greatly improved patient-specific care, gaining better utilization of payor resources and delivering a viable return on investment for test providers. ■

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Reference

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