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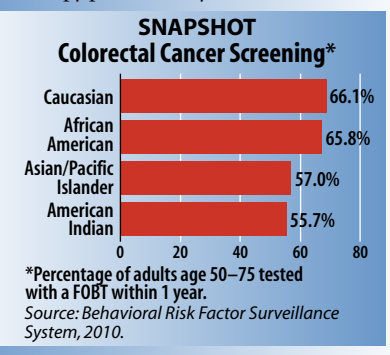
NEWS BRIEF

Colorectal Cancer Screening Rate Remains Low

A new report released by the Centers for Disease Control and Prevention (CDC) found that in 2010 one in three adults age 50 or older, roughly 22 million people, did not get recommended colorectal cancer screening tests. In 2007, more than 142,000 people were diagnosed with colorectal cancer, and more than 53,000 people died from the disease.

Even though the number of colorectal cancer cases and deaths is decreasing across the U.S., CDC officials stress in the Vital Signs report, "Colorectal Cancer Screening, Incidence, and Mortality—United States, 2002–2010," that too many adults do not follow the agency's recommendations.

The agency recommends that all adults 50 to 75 years old get screened for colorectal cancer by one of the following tests: a fecal occult blood test (FOBT) every year; flexible sigmoidoscopy performed by a healthcare provider every 5 years; or a colonoscopy performed by a healthcare provider every 10 years. Adults at higher risk for colon cancer, including individuals who suffer from Crohn's disease, inflammatory bowel disease, some genetic disorders, or who have a personal history of either polyps or colorectal cancer, should undergo more frequent testing.



New data in the report underscore the value of screening for the disease. Between 2003 and 2007, approximately 66,000 colorectal cancer cases were prevented and 32,000 lives were saved compared to 2002. The percentage of adults screened for colorectal cancer increased 13% from 2002 to 2010.

Reducing the number of deaths from the disease would also relieve a significant burden to the healthcare system. In 2010, the estimated direct medical cost of colorectal cancer care was $14 billion. According to the report, this cost could be reduced if health insurance plans would cover colorectal cancer screening tests at no cost to participants.

CDC officials estimate that if the 2020 target for colorectal cancer screening—70.5% of adults age 50–75—is met, nearly 1,000 additional colon cancer deaths will be prevented annually.

The full report is available at www.cdc.gov.

Big Changes Coming to Molecular Dx Reimbursement

Will New Codes Affect More than Just Billing?

By Bill Malone

Molecular testing, long heralded as the key to personalized medicine in the 21st Century, not only fuels the growth of the in vitro diagnostics market, but also puts clinical laboratories at the leading edge of this revolution in the delivery of healthcare. However, even as the wealth of data from genetic studies has pushed this field forward at a rapid pace, reimbursement for tests has become increasingly mired in an outdated coding system. Many molecular tests are underpaid, and others overpaid, according to coding experts.

Under pressure from government and private payers, the Current Procedural Terminology (CPT) Editorial Panel of the American Medical Association (AMA) has now nearly finished a complete overhaul of how molecular tests will be coded for reimbursement. AMA, which controls the nation's coding system with its proprietary CPT structure, is literally rewriting the book on how labs and payers will communicate with an entirely new set of molecular codes for 2012 that, for the first time, will be analyte-specific.

Despite the expected benefits of a cleaner and more straightforward coding framework, AMA's move also has many in the lab community nervous about unintended consequences. After being released for public

See **Molecular Coding**, *continued on page 3*

The MRSA Challenge

Which is Better: Targeted or Universal Surveillance?

By Genna Rollins

After years of discouraging news about both the prevalence and virulence of methicillin-resistant *Staphylococcus aureus* (MRSA), recently there has been cause for optimism. Of note, the Centers for Disease Control and Prevention (CDC) reported in 2010 across-the-board decreases in six categories of MRSA infections in nine metropolitan areas that are part of the agency's long-term, population-based surveillance program. Hospital-onset invasive infections declined by 28% during the 3-year study period, while MRSA bloodstream infections dropped by one-third (JAMA 2010;304:641–48). These findings complement data from the National Healthcare Safety Network showing an almost 50% decline in MRSA bloodstream infections between 1997 and 2007.

Promising though these figures may be, experts warn that it's way too early to declare victory over the pathogen, and that labs and clinicians will need to continue the close collaboration that's been a hallmark of successful MRSA control efforts. "Though we've been making headway, it's mostly attributable to increased attention to healthcare acquired infections in general. Even with reductions like those cited by CDC, that still leaves a sizable portion of infections still occurring," said Daniel Diekema, MD, professor and director of the division of infectious diseases at the University of Iowa Carver College of Medicine in Iowa City. "Labs are key to all of this. Their major role first and foremost is to promptly and accurately identify MRSA. They also need a seamless notification program so clinicians know where infections are occurring and can intervene quickly, and they need to provide support during outbreak investigations."

See **MRSA**, *continued on page 5*

IN THIS ISSUE

Clinical Laboratory News
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New Codes Will Add Clarity

Molecular Coding, *continued from page 1*

comment this spring, the AMA has finished writing most of the codes that cover the vast majority of molecular tests. Now a number of big decisions lie with the Centers for Medicare and Medicaid Services (CMS). The new codes are slated to take effect January 1, 2012, and CMS must decide how they will reimburse labs for each code and whether to keep the codes on the clinical lab fee schedule or move them to the physician fee schedule—a decision it has put off for now.

"The stated purpose of these coding changes was merely to provide more coding transparency for these services," said David Mongillo, vice president for policy and medical affairs at the American Clinical Laboratory Association during a CMS public meeting on the new codes held in July. "To be consistent with this stated purpose, implementation of the changes should be administrative in nature, not a means by which CMS reallocates market share or otherwise seeks to alter the economics of molecular genetic testing services. Failure to adhere to these standards could result in unintended consequences, such as significant disruption of clinical laboratory operations or disservice to non-physician doctoral providers—both of which would have negative implications for Medicare beneficiaries."

The End of Code Stacking

For over a decade, the bane of coding for molecular tests has been the infamous issue of stacked codes. Unlike traditional assays, molecular tests do not have single, analyte-specific codes that labs can use to bill Medicare or private payers. Rather, a list of codes that signify each procedure involved in performing the assay are listed together. Each code describes a separate step or methodology performed to complete the test, such as gene amplification, nucleic acid extraction, or nucleic acid probes. For some tests, these codes must also be multiplied if the lab uses a step more than once to perform the test, especially in those tests that look at multiple markers.

Stacked codes have done a fair job of describing the methods used in performing a test, but offer little hint of what is being measured or why, a critical shortcoming that has made it nearly impossible for payers to know what tests they are paying for or how the tests are being used. It has also resulted in labs coding tests differently, complicating research into how physicians are using molecular diagnostics. The AMA's new coding scheme reverses this approach, giving each test its own code without regard to the method used.

This shift alone changes the coding landscape for molecular tests, said Mark Synovec, MD, co-chair of AMA's Molecular Pathology Coding Workgroup that developed the new codes. "I can't imagine any coding system being changed more radically," he said. "We're going from a system that had a lot of granularity in the procedures with the use of the stacking codes that provided no granularity on what was actually being analyzed, to a new system where all of the emphasis is the analyte. This is a huge change."

With payers closely watching what they pay for, providers and payers can now work together more closely to make sure patients receive appropriate care, Synovec emphasized. "Under the current system, when a set of stacked codes is submitted, the payer doesn't know if it's something medically appropriate or not, and some payers, out of frustration, globally don't cover molecular stacking codes," he said. "On the other side, patients are having experimental tests done that are not part of the patient's insurance plan, but cannot be teased out of the current coding stack submitted for payment. The greater granularity will allow for a better understanding of the analytes being tested, test ordering patterns, and it will allow payers to determine how and which tests should be incorporated into the insurance plans for their beneficiaries."

Under the new coding scheme, tests that make up the majority of the volume of molecular diagnostics fall into the first of a two-tier system. Tier 1 contains 92 codes that together represent more than 90% of the volume of molecular tests currently performed. Tier 2 is reserved for low-volume, and esoteric tests, within which are nine buckets based on test complexity. As novel genetic tests become available and providers request placement in the CPT, AMA will likely assign most of these to one of the nine levels. Tier 2 is not analyte-specific, but each level contains the specific analytes within each level. Self-assignment of an analyte to a Tier 2 code level, outside of the CPT process, will not be allowed. When a particular analyte within the Tier 2 code set is shown to have a high volume of use, it could transition to a Tier 1 code.

"Tier one is going to provide fine granularity, so there will be a specific descriptor that gives a very well-defined picture of what is being tested for," explained Synovec. "Ideally we would not have a Tier two, and we'd have an individual code for every analyte, but with the size of the human genome, that's just not possible."

A Move to the Physician Fee Schedule?

Although few in the lab will miss the uncertainty and confusion over how to code and bill for molecular tests, several thorny issues lie in this coding transition, including possibly moving molecular codes off of the clinical lab fee schedule and onto the physician fee schedule. CMS announced at the public meeting in July that the codes will not be assigned to a fee schedule until next year; however, several people at the meeting expressed concern that the way AMA developed the codes sent a signal they should be on the physician side. A separate AMA committee that provides exclusive reimbursement advice to CMS, called the Relative Value Scale Update Committee (RUC), has already reviewed a large number of the new codes and forwarded the committee's value recommendations to CMS for the 2012 physician fee schedule. According to AMA, CMS adopts 95% of the RUC's recommendations.

In addition, both the College of American Pathologists (CAP) and the Association for Molecular Pathology (AMP) recommended all the new codes be placed on the physician fee schedule. AACC submitted comments supporting placement of tests on the physician fee schedule that require pathologist interpretation, but with a way

See **Molecular Coding**, *continued on page 4*

CMS Turns Gains into Losses

Fix for 14-Day Rule May Hurt Some Labs More than it Helps

The healthcare reform package signed into law last year included a 2-year demonstration project meant to help independent labs performing advanced molecular tests make sure they were paid when a patient had recently been hospitalized. However, it now appears that the once-lauded provision may not be a winner for many labs, according to Rina Wolf, vice president of commercialization strategies, consulting and industry affairs at XIFIN, a revenue cycle management solutions company that services the diagnostic providers market. "It seems that CMS has repurposed this into a re-pricing opportunity," she said. In other words, the program will make it easier to get paid, but CMS will lock some tests into a lower price for purposes of the demo.

Under current Medicare regulations, the date of service for a test ordered fewer than 14 days after a patient's discharge from a hospital is considered the date on which the specimen was collected, and must be covered under the hospital diagnostic-related group (DRG) payment for that stay if the specimen was obtained during an in-patient encounter. If the specimen was obtained during an out-patient encounter, it becomes the responsibility of the hospital to bill for the test, which is usually extremely difficult. Essentially, the rule treats tests ordered fewer than 14 days after a patient is discharged as having been performed when the patient was actually in the hospital. Beginning January 1, 2012, the demonstration program allows labs to receive separate and direct reimbursement under Medicare Part B even when the sample has been collected during a hospital stay.

The problem, Wolf said, is that CMS has proposed that some tests be assigned new special codes and prices in order to participate in the demo. "We've heard from CMS that if these companies already have prices that have been assigned to them by the carriers, then those prices are at risk," she said. "There has been a lot of consternation at CMS and the carrier level, especially Palmetto, at the high prices that some of these older tests were assigned and they've been looking for means to lower these prices, and this could be a perfect opportunity to do that."

CMS has published a list of codes that will be available for reimbursement under the demonstration project. If the codes used for a test do not show up on the list, and are currently billed using not otherwise classified codes, CMS will assign a special new code and make its own decision on how the test should be paid. Many of the newer and most expensive tests performed will fall into this category, Wolf said.

However, some labs will not face this dilemma, as long as the coding they use for the test matches those codes CMS decides to allow for the program. "We expect that hospital laboratories and others who have a lot of tests that can be captured with the code stacking methodology will participate in the demo, and the group of companies that were the most concerned and worked the hardest on this probably will not put themselves at risk," Wolf said. "The companies not using the stacking codes could face lower pricing."

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Fee Schedule Questions Create Uncertainty

Molecular Coding, *continued from page 3*

to continue recognition for non-physician laboratorian interpretation as well.

Moving molecular diagnostics onto the physician fee schedule would help pathologists receive better compensation for interpreting tests. At the same time, it could also cut out PhD-level laboratorians since CMS does not have a mechanism for recognizing PhDs for interpretive services on the physician fee schedule.

Both the reasons for and the possible solutions to this problem are complex. Currently, a molecular code stack also includes a code for the interpretation of the test. The lab can bill for this in addition to the technical work when a qualified non-physician laboratorian performs the interpretation, typically reimbursed to the lab at between $3 and $5 depending on the state where it's located. If a pathologist interprets the test, a special modifier is added to the code and the pathologist is paid directly according to the physician fee schedule, about $18, and the lab is reimbursed for only the technical component. Under the new AMA scheme, the code for the lab to bill for a PhD's interpretation will disappear, and only the special modifier to indicate a pathologist's interpretation will remain.

On the one hand, some stakeholders at the CMS meeting voiced concern that placement on the physician fee schedule, which would boost pathologist reimbursement compared to the lab fee schedule, is necessary to encourage greater pathologist participation in the field. "No payment for professional involvement will kill pathologist participation and deny CMS and other payers the service delivery and consultative participation of the only physician group which understands the lab," said Jeffrey Kant, MD, PhD, chair of AMP's economic affairs committee. "Lack of pathologist involvement will impede new payment models like accountable care organizations and medical homes. Clinicians do not understand these assays well, especially integration with other laboratory data."

The physician fee schedule would also provide for regular revision of the professional and technical costs involved in performing a test through regular review by AMA's RUC. This could save money for payers and beneficiaries over time as efficiency increases, Kant noted. In contrast, the clinical lab fee changes far less frequently.

At the same time, unless a change is made to allow labs to bill for a PhD's interpretation of molecular tests in the new scheme, a host of problems awaits the majority of labs, Mongillo noted. "Laboratories that currently rely on qualified PhD healthcare professionals for interpretation of molecular tests currently reimbursed under the clinical lab fee schedule will have difficulty receiving reimbursement for these services if they are assigned to the physician fee schedule," he said. "Unless an exception is made—as CMS has done with microarray testing—services placed on the physician fee schedule arguably might require performance of the professional component by a physician in order for either the professional or technical components to be reimbursed. Unless addressed by CMS, this could lead to the untenable result that those laboratories currently providing the bulk of molecular testing may be left without a mechanism for receiving any payment for their services."

To prove his point, Mongillo cited a recent ACLA survey of its member labs that asked about who was providing the interpretation service. The survey included all 180 Tier 1 and 2 codes that have been finalized by AMA, and ACLA members provided results for 93% of the 180 codes surveyed. The responses indicated that 99% of the time, the technical component of the test was performed by a laboratory technician. The results also showed that there was always a separate interpretation performed: 90% of the time that interpretation is performed by a PhD, 10% by a pathologist, and 1% computer-assisted. The ACLA data conflicts with a survey performed by CAP, in which the association determined that a large number of the new codes required physician services.

Unless CMS comes up with a fix to allow continued PhD interpretation, a move to the physician fee schedule would be extremely disruptive for labs, said Rina Wolf, vice president of commercialization strategies, consulting, and industry affairs at XIFIN, a revenue cycle management solutions company. "This could really be a staffing issue for labs. If these new codes end up on the physician fee schedule, then many of the functions that are being performed right now by PhD-level people are going to have to be moved to the MD level and that's going to require a lot of operational, organizational changes," she said. "I'm very concerned that CMS does not understand the full extent of that." Placement on the physician fee schedule would also automatically require a copay for the tests and a physician signature, two burdens advocacy groups have struggled to resist for labs over the years.

CMS has several options to avoid this scenario if it decides to put some or all of the new codes on the physician fee schedule. The agency could decide, one by one, which codes really need a pathologist interpretation and which do not; some codes could go on both fee schedules; or CMS could place most or all of the codes on the physician fee schedule but also recognize qualified PhD laboratorians to bill for interpretation. The agency has indicated it will hire an outside consultant to help make these decisions.

However, there may also be legal and regulatory barriers that keep molecular codes on the clinical lab fee schedule, according to Bruce Quinn, MD, PhD, senior health policy specialist at Foley Hoag, LLP. After policy debates over pathologist pay in the early 1980s, Congress passed a law that allows CMS to define exactly what services are payable to a pathologist: surgical pathology, cytopathology, and hematopathology. "Outside of traditional pathology, pathologists can also get paid for interpreting lab tests, but only under some fairly sophisticated rules," he noted. "There has to be a specific request from the clinician and a narrative report that's justified using medical judgment. Based on that, I don't believe CMS should put genetic tests on the physician fee schedule because they don't fall into the test categories CMS has defined so far."

Concern over Lower Reimbursement

Another major concern over how CMS will deal with AMA's new codes is that reimbursement will fall for molecular tests and discourage new investment in the field. Wolf noted that CMS has a track record of using changes in coding or other systems to make cuts (See Box, p. 3). Moreover, by delaying its decision until next year, CMS may be resigning itself to the outcome of continued AMA work on the subject. The RUC has already begun work on evaluating the potential physician and technical component costs of the new molecular codes. "Then the question is, if the RUC does assign prices, and then we have legitimately ordained codes and potentially pricing, private payers and individual CMS carriers could use them next year instead of waiting until January 1, 2013," Wolf said. "These payers probably won't go to that effort to do so, but it could happen."

Wolf also noted that recently, when companies have worked with CMS carriers on coverage determinations for their molecular tests, the carrier has mandated that the tests be billed using not otherwise classified (NOC)s codes and assigned payment levels significantly lower than that obtained through the use of a legitimate stack. Other companies that have sought or been assigned test-specific codes through the AMA process have also seen their reimbursement drop significantly with the use of those codes. "AMA is concerned that companies are not proactively coming forward and participating in the existing coding process, and one of the reasons is that, should a company be successful in getting a code, then it faces great pricing uncertainty and the likelihood is very high that the price will go down. So it's a catch-22," she said.

According to Quinn, who at one time served as the contractor medical director for the California Medicare Part B program, moving molecular codes to the physician fee schedule would almost certainly mean lower prices for tests. "On the physician fee schedule for lab tests, you have something paid by the minute for physician time and technologist time, and a few dollars for capital equipment, so it may be hard to get over the first $100–200 dollars." Quinn also warned that the current pricing of infectious disease tests might eventually be in danger. "If CMS sees the price for human genetic tests drop, they'll probably want to drop the price for infectious disease tests, too, saying they're too high because it's the same chemistry," he said.

CMS and the AMA will have to handle these new codes wisely, said Wolf, in order to ensure that innovation in molecular diagnostics and personalized medicine continues. "The heart of the question is, will personalized medicine fail because these initiatives dis-incentivize the development of these tests and the return on investment becomes untenable from a business perspective? Companies that are being assigned these low prices, especially compared to their development costs and costs of goods, ultimately have to make the decision as to whether that business model works." CLN

For More Information

The draft of the new codes is available on the CMS website, www.cms.gov/ClinicalLabFeeSched/Downloads/Lab_Pub_Mtg_2_2012_060911.pdf.