

A Truer Way To Measure Value of Diagnostic Tests

Helping payers track advanced diagnostics is a must in a health reform environment

A conversation with Matthew Zubiller, VP, Decision Management, McKesson Health Solutions

A \$7 billion business growing at a rate 15 percent to 20 percent annually, advanced diagnostics includes molecular diagnostics and genetic, genomic, and transcriptomics testing — the technological tools that make personalized medicine possible.

The first commercialized advanced diagnostic — the HER2 companion diagnostic for trastuzumab (Herceptin) therapy — became available in 1998. But, 15 years later, payers still have no way to comprehensively track which diagnostic tests their network providers are ordering, whether they're being ordered appropriately, how much they cost, and whether these tests reduce overall costs of care and improve patient outcomes.

Test manufacturers, laboratories, and payers have been making do with code stacking, a process that describes a test by each of the steps — and the corresponding Current Procedural Terminology (CPT) Code — required to perform the test.

Code stacking is labor-intensive and does not address the needs of stakeholders in the advanced diagnostic business sector that powers personalized medicine — it just keeps reimbursement streams flowing along with hundreds of millions of dollars in avoidable expenses for keystroking, paper shuffling, and, eventually, suboptimal care. Even the most creative code stacking can't begin to reflect the true economic



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value of a \$400 advanced diagnostic that could save \$50,000 for a course of chemotherapy that is unlikely to be effective. That means that test developers and venture capitalists have little incentive to get into personalized medicine as long as there is a lack of granularity in how advanced diagnostics are reimbursed.

Bob Carlson, who writes about personalized medicine for BIOTECHNOLOGY HEALTHCARE, spoke with Matthew B. Zubiller, MBA, vice president, Decision Management, McKesson Health Solutions, about the McKesson Diagnostics Exchange, a system that assigns a unique five-digit alphanumeric Z-Code Identifier to each advanced diagnostic test so that it can be accurately tracked.

Bob Carlson: What has delayed a

more efficient approach to tracking advanced diagnostics?

Matthew Zubiller: Providers, payers, laboratories, and patients are just beginning to understand the magnitude of the coding issues, so they can't discuss solutions. It's incredibly difficult to measure what real utilization of testing looks like within the context of care and, thus, to establish the value of a diagnostic test.

BC: Can Z-Code Identifiers and CPT codes coexist?

MZ: Certainly. Z-Code Identifiers were not created to replace CPT codes, which is a common misconception. They don't classify tests, they *identify* tests. I hold the work of the AMA's CPT Molecular Pathology Coding Workgroup in high regard. Their efforts and our efforts are complementary.

The problem is there's no unique identifier of diagnostic tests — the analyte, the genes, the proteome, or whatever is being assayed. McKesson serves many hospitals, providers, laboratories, and health plans and we've built solutions to support them. In doing so, we realized we could provide a standard way of identifying a diagnostic test and sharing it across the industry. So, we created the McKesson Diagnostics Exchange, which is a registry of all the Z-Code Identifiers along with reference information about the tests and how they're performed. Our ultimate goal is to provide decision support to providers, labs, and payers regarding diagnostic tests.

BC: Where does the information about the tests come from?

MZ: If you're a laboratory, you would go online to enter your test information in the McKesson Diagnostics Exchange registry. You can indicate what is public information and what information you want to keep private but share with selected entities

in a way that makes the most sense. In other words, laboratories have control over what information gets shared when and with whom.

BC: What does the McKesson Diagnostics Exchange include?

MZ: The Z-Code Identifiers, the registry, and the test assessments. The test assessment tool uses the information in the registry for coverage determinations. By uniquely identifying the diagnostic tests and providing registry information about them, we create a common language and shared tools for payers, laboratories, and providers to better communicate information about these tests and to better understand their value.

BC: Is this going to help reform the current reimbursement mechanism for advanced diagnostics?

MZ: I believe that the reimbursement mechanisms will reform over time. Our current healthcare system doesn't pay for value — it pays for volume. If we're going to reduce costs and get better quality healthcare, we have to understand the value of the care that's being prescribed and delivered. You're seeing glimpses of this with ACOs [accountable care organizations], PCMHs [patient-centered medical homes], and global payments. If you can measure the utilization of a diagnostic test in conjunction with the therapies, surgeries, admissions, and drugs associated with that test, then you can begin to see the impact that it has on those services. And you can begin to measure the value of a diagnostic test and make the case for getting reimbursed for that value.

BC: Are private payers expressing interest in McKesson's service?

MZ: Yes, many — private payers are one of the drivers. We're also seeing interest from diagnostics manufacturers and some of the best diag-

nostic labs who see that by going down this path they can move more quickly to getting positive coverage decisions and appropriate reimbursement that reflects the value of their tests.

BC: It sounds as if payers really have to be the first movers.

MZ: They are one of the first movers. Private health plans are very interested in figuring out how to determine that the right tests are being done. I think there's a misperception that the private healthcare industry is all about figuring out how not to pay for these tests. The reality is that payers see the value of advanced diagnostics in helping them deliver and pay for better healthcare.

BC: What does it take for a payer to implement Z-Code Identifiers?

MZ: From a systems perspective, there's not a lot of work needed to get started. With a couple of minor modifications, payers should be able to accept the Z-Code identifiers in their claims system. It's about being able to engage your labs and your providers in a way that's fundamentally different from the way you have in the past. The big message is that the entire system will benefit — diagnostics labs, payers, providers, and patients. It's a matter of creating transparency and change. If you can give the healthcare system a method that is an adjunct to the claims system and is implemented before a test is ordered, then you have the ability to make an impact on decisions.

BC: With the medical loss ratios mandated by the Affordable Care Act, paying for the right tests sounds like an opportunity for payers to save money, which translates directly to the bottom line.

MZ: Health plans will be held to medical loss ratios in the 85 percent range, so there's going to be a

greater emphasis on reducing the administrative burden and expense of traditional utilization management. If a health plan can say to its providers, "I'm going to pay you more to help make sure that the right tests are being done," and then say to the laboratories, "I'm going to pay you more per test if you can show me that you are demonstrating clinical utility and taking on the function of utilization management with the provider," then everybody wins.

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