Managed Care Update

Getting Payer Coverage for New Tests Continues to Be Difficult

One secret to winning coverage is to provide extensive data on the test's accuracy, clinical value

EVERY YEAR, IT BECOMES TOUGHER FOR CLINICAL LABORATORIES WITH NEW GENETIC AND OTHER TESTS to obtain favorable coverage decisions by government and private payers.

Not only does it take longer to get a decision from a payer, but payers today want to see more complete data on the analytical and clinical validity of the test before making a coverage decision.

Another change in recent years is that private payers often move faster than the Medicare program to make a coverage decision for a lab test. Historically, private health plans would wait until Medicare agreed to cover a test.

Flood of New Lab Tests

But the flood of new genetic and molecular entering the market assays—with most being laboratory-developed tests (LDTs)—is causing private payers to make faster coverage decisions, often long in advance of Medicare's determination for the same assay.

Soaring utilization of new assays and the corresponding increase in money paid for test claims motivates payers to act. "Private payers tend to examine their coverage requirements where they see significant growth of new technology or utilization of services," said Deborah Godes, Senior Director of **McDermott+Consulting**.

"A payer will not necessarily establish a new coverage policy for a diagnostic assay simply because there is a new assay," she continued. "There must be a reason why they evaluate coverage and usually it's because there has been a significant increase in volume or cost. Not every lab-developed test will go through a coverage review—payers simply don't have the resources for that."

Lab Benefit Managers

As has been regularly reported by THE DARK REPORT, payers increasingly are turning to third-party benefit administrators to manage laboratory test utilization. **United Healthcare**, **Anthem**, and **Blue Cross Blue Shield** plans all use laboratory benefit managers (LBMs) to manage utilization of laboratory testing.

Clinical labs can improve their chances of getting a laboratory-developed test covered by providing payers with extensive data showing the clinical utility of an assay.

While federal programs such as Medicare like to see preliminary data from pilot studies, Godes observed that private payers and LBMs prefer to see studies that have already been published in a peer-reviewed journal or that have resulted in approval by the **Food and Drug Administration**.

"Medicare also does not establish coverage policies for every test," Godes explained. "Depending on codes for the tests, claims will either be processed or reviewed on a claim-by-claim basis. When Medicare—in particular a local Medicare Administrative Contractor (MAC)—determines a need, it will review to determine whether a local coverage determination is needed."

Types of testing ripe for review include expensive tests such as molecular diagnos-

tics or assays that have more cost-effective counterparts. While coverage determinations are made on the basis of clinical utility, cost may factor into the decisions.

"We can't make an across-the-board statement about the role that cost plays in payers' coverage decisions," Godes noted. "For some payers, the economic analysis may be a bigger factor. But all payers want to see evidence of improved outcomes when the provider uses the diagnostic test in decision making.

Proving Clinical Utility

"Key to getting a positive coverage decision from payers is making a solid case through good quality evidence," Godes advised. "Clinical laboratories need to demonstrate that a particular assay actually works as it is intended and also that it is used by clinicians to make decisions regarding patient care. Essentially, clinical utility of a test is related to the added value it has for patient management.

"I think to some extent clinical laboratories may underestimate the impact of showing that the test has an effect on decision making and on outcomes," Godes stated. "We hear from payers over and over again that they want proof of clinical utility that shows the test has a positive effect on patient outcomes.

"Payers have a relatively small group of people that make these coverage decisions, and they may not necessarily have the depth of knowledge into specific nuances of the testing, especially around novel testing, that clinical laboratories have," she explained. "That's why showing evidence is so important. Payers tend to give more gravitas to published evidence."

When does a clinical laboratory know that they need to provide evidence that their assay has a positive effect on patient outcomes? Laboratories should focus on demonstrating evidence of clinical utility throughout the development process, Godes said. Timing for engagement with payers will vary depending on how the laboratories are reporting their assay (i.e., an existing code or a new code), the resources of the lab, and the timeline for reimbursement planned, she added.

"At a minimum, laboratories should begin engagement if or when they start to see payers denying claims for a particular test or when the payer publishes a negative coverage policy that covers the lab's assay," Godes advised. "However, developers of novel diagnostic technologies with the resources to do so should seek engagement before the test is on the market, potentially even when studies that can demonstrate clinical utility are being planned."

Additionally, for tests that will be billed under codes for which payers have not previously seen much utilization, proactive engagement with payers to make them aware of a potential rise in utilization, and the medical necessity of the underlying service, may help to minimize the chance of a misunderstanding in the future about the cause of that utilization increase.

"If that happens, labs should start compiling all their evidence—not only on analytical and clinical validity—but also on clinical utility," Godes said. "Pull together a clinical dossier that can be used to have a discussion with payers.

Address Payer Concerns

"If it is a test that historically has been covered but now is not being covered, labs need to have a conversation with payers to understand what has changed," she noted. "Labs need to be able to address the concerns that payers have."

Godes added that each payer has its own coverage determination process and that clinical laboratories should be prepared to deal with each one individually. "Not all payers will be persuaded by the same arguments," she said. "You need to determine what drives that payer's the denials and then present evidence to address those concerns." TDR

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