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Palmetto's Initial MDx Pricing Disappoints Industry; Raises Concerns about Business Impact

by Turna Ray

WHEN THE CENTERS FOR Medicare & Medicaid Services instructed Palmetto GBA to create and administer the MolDx program last year, many labs and test developers feared that the effort was an attempt by the government payor to control rising healthcare costs by slashing payments for molecular diagnostic tests.

After viewing the proposed reimbursement levels for a list of molecular diagnostics released by the Medicare contractor last week, many industry stakeholders are saying that's exactly what's happening.

"Much of this pricing is below the actual costs [for performing testing] when you factor in reagents, administrative expenditures, marketing, and other tools needed to physically run the test," Rina Wolf, VP of commercialization strategies, consulting, and industry affairs at Xifin, told *PGx Reporter.* Xifin helps diagnostic service providers manage their financial performance and efficiency.

"Some companies have expressed the inability to remain in business at these reimbursement rates," said Wolf.

She added that "there's a lot of disappointment" in the industry regarding the MolDx pricing, "because this was supposed to be a coding exercise and not a re-pricing exercise."

The change in reimbursement levels for molecular diagnostics is occurring as part of an effort that CMS instituted a year ago to gain better insights into the specific tests it was paying for. For years, healthcare providers stacked current procedural terminology codes to bill Medicare, but this coding method didn't allow payors to discern which tests they were reimbursing or whether these tests met the evidence threshold for covered tests.

To better track test utilization and ensure that only "medically necessary" tests were being paid for, CMS charged Palmetto with launching MolDx, under which labs and test developers are being asked to submit data on the clinical validity and utility of their tests in order to receive Medicare coverage. Each lab also has to submit a diagnostic claim with a unique identifier to enable Palmetto to track its utilization. Based on the clinical evidentiary data submitted by labs and the utilization information gathered by Palmetto, the contractor determines CMS's reimbursement policy and pricing for molecular diagnostics performed in Jurisdiction E territories — California, Hawaii, and Nevada (*PGx Reporter 11/16/2011*).

However, many test developers are unhappy with the initial pricing determinations that Palmetto released last week for molecular diagnostics described by Tier 1 CPT codes. "There is a lot of concern, especially with the smaller, innovative laboratories, including pharmacogenetic testing labs," Wolf added. "Those are the labs that are most impacted" by MolDx pricing.

The Tier 1 codes, issued by the American Medical Association, are analyte specific (ie. KRAS gene, BRAF gene, BRCA 1 full gene known familial variant) and describe some of the most commonly performed molecular diagnostics. Palmetto has issued prices for all Tier 1 tests, even if Medicare doesn't cover the test.

Another set of codes, Tier 2, includes tests that are performed less often based on the resources required to perform them. Palmetto hasn't yet issued prices for tests that fall under this coding category.

CMS decided last year to utilize the gap-fill method to price newly coded molecular tests. Through the gap-fill method – which experts estimate CMS has applied three times in the last decade – CMS determines payment for molecular di-

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agnostics when no comparable technology exists. The agency more readily has used the crosswalk process to peg payment rates for new tests to existing tests that use comparable technologies, or are already described by stacked CPT codes.

Because the agency doesn't have much experience with the gap-fill process, test developers have been anxious to see how this new pricing methodology would impact payment levels. Initial observations indicate that most tests will see a significant reduction in reimbursement.

Analysis from investment firm Piper Jaffray shows that Palmetto's MolDx pricing is on average 19 percent lower than CPT code-stacked rates from Quest Diagnostics, with some tests hit particularly hard.

For example, MolDx has priced testing for V600E mutations in the BRAF gene – performed to identify responders to Roche's melanoma drug Zelboraf – at $58. This represents a 78 percent cut in reimbursement when compared to the $259 that CMS would pay if healthcare providers were submitting claims based on stacked CPT codes.

Similarly, testing for KRAS gene mutations at codons 12 and 13 – used to gauge which colorectal cancer patients should receive certain EGFR-inhibiting monoclonal antibodies – was being reimbursed at $911 with stacked CPT codes. Palmetto has priced these tests at $226, representing a 75 percent cut from the stacked code pricing.

Stark Reality

It wasn't entirely unexpected that MolDx pricing would be lower than what some labs were receiving in reimbursement under CPT stacked codes. Palmetto had indicated that changes were coming to reimbursement levels.

Elaine Jeter, Palmetto's medical director, noted at a reimbursement conference last year that when healthcare providers use stacked CPT codes to submit claims for tests, pricing varies substantially depending on the different codes in a stack that are used to describe the same test performed at different labs (*PGx Reporter 2/29/2012*). At the meeting, she cited data suggesting that a dozen labs analyzing the same mutations in the KRAS gene use 12 different CPT code stacks to bill CMS, and the reimbursement varies from $172 to $860. "Why would anybody pay 12 different labs 12 different prices?" Jeter posited. "I know where this is going, because I have to feed this into CMS."

Still, with the preliminary prices now printed in black and white, labs have to face the stark reality of how this effort to rein in spending may affect their businesses.

BioTheranostics is an example of small molecular diagnostics shop that is feeling the heat in the difficult reimbursement environment. "The process for [Palmetto's] reimbursement rate calculation was not clear," said CEO Richard Ding. "It's way off from the cost data that labs provided to the Medicare contractors. It's not even in the range."

Calling the MolDx proposed prices "arbitrary" and "capricious," Ding used Palmetto's proposed pricing for EGFR mutation testing to illustrate how the reimbursement that labs will receive from payors under the program won't cover the cost of performing the test.

Qiagen is planning to market an EGFR companion test kit that will predict which NSCLC patients will respond to Boehringer Ingelheim's afatinib, and recently submitted an application to the US Food and Drug Administration for approval of the test. Palmetto, meantime, has issued a price of $116 for tests that gauge common variants in EGFR in non-small cell lung cancer patients.

Ding estimated that depending on whether a lab receives a volume discount for implementing a test kit from the manufacturer, the EGFR kit acquisition cost is approximately $200 per test. After factoring in batch size variations and repeat tests, the actual material costs per test report is likely higher, he said. "Then you have the labor and the pathologist … And [Palmetto] reimburses this test at $116? We're missing a zero here."

The MolDx prices are most worrisome for small labs that are dependent on revenues from molecular diagnostics sales. "Large labs have a broader product spectrum and molecular diagnostics is a small part of their overall business," Ding noted. "So, they basically see this as an opportunity, frankly, to consolidate the industry.

"I just don't understand why [payors] would want to save a few hundred dollars [by cutting reimbursement] for a molecular diagnostic that guides decisions with very expensive therapies, and the drug costs are tens of thousands of dollars," Ding observed.

Xifin is encouraging its clients to appeal the proposed prices from Palmetto for cases where reimbursement doesn't square with the costs of performing the tests, and make a case for why it isn't possible to stay in business at these payment levels. Ding said that BioTheranostics will definitely express its concerns about the proposed prices through the right channels at Palmetto.

"It's very Machiavellian on [Palmetto's] part" to issue new prices for molecular diagnostics through a process that the contractor presented initially as a coding exercise, Ding said.

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"It's just not how business is done in this country."

Unmet Assurances

On a number of fronts, labs and test developers had hoped to strike some middle ground with Palmetto with regard to how it set pricing for the new molecular diagnostic codes. In a Nov. 30 letter to CMS, the American Clinical Laboratory Association suggested that instead of using the gap-fill method to price the new CPT codes, Palmetto should crosswalk them to a weighted median of the prices that CMS was paying for these tests with stacked coding.

According to Xifin's Wolf, conversations with high-ranking Palmetto officials had given labs hope that that this might be the approach the contractor would take. Looking at MolDx's price list for Tier 1 codes, however, it's clear "that doesn't seem to be the case."

In its letter to CMS, ACLA warned that if the agency did not change its approach or provide an interim solution to pricing the new CPT codes, the association's member laboratories "may decide to cease providing these tests until pricing and reimbursement issues are resolved," which in turn would restrict patients' access to care.

BioTheranostics' Ding believes that if Palmetto had used the crosswalking method rather than gap-filling, then the contractor would have been able to present much higher pricing for many of the tests. "But they chose not to do crosswalking, and chose to do gap-filling, with a clear idea to significantly reduce the reimbursement rate," he charged. "That's the only objective they have and that's very worrisome, not just for jobs but for innovation … in personalized medicine."

Meanwhile, developers of companion test kits for pharmacogenetic drugs, such as Roche's BRAF test for Zelboraf or Qiagen's KRAS test for Erbitux, had been under the impression that Palmetto would price FDA-approved diagnostics at a higher level than laboratory-developed tests in an effort to give their hospital and reference lab customers a monetary incentive to adopt the kits.

The MolDx pricing does not distinguish between LDTs and FDA-approved tests, however, giving labs little reason to adopt the regulated kits — and developers little incentive to seek FDA clearance for their tests.

Even if the label of a drug recommends that patients should be tested with an FDA-approved companion test to assess whether they will respond to treatment, it is an added expenditure for labs to implement the new kit if they already analyze the relevant marker through an established LDT — especially if the FDA-approved test is cleared for an analytical system that the lab doesn't have installed. This has certainly been an issue hindering the adoption of Roche's PCR-based Cobas BRAF Mutation Test, where several hospital labs balked at having to invest in a Cobas instrument and the new test kit, which they perceived to be less robust than the standard Sanger sequencing-based LDT they were performing to gauge BRAF mutations.

To encourage more labs to adopt its diagnostic, Roche performed a head-to-head comparison of the Cobas test against Sanger sequencing, and reported that the kit was more sensitive in picking out which patients would benefit from treatment with the melanoma drug Zelboraf (*PGx Reporter 9/28/2011*). Of course, getting FDA approval and then marketing the kit to compete against LDTs are costly endeavors for developers of companion diagnostic kits, and it seems these test makers were expecting Palmetto to recognize these added investments by pricing test kits higher than LDTs.

"Dr. Jeter had given some indication that she was going to look more favorably on FDA-cleared kits," Wolf said. "The BRAF test is a perfect example." Roche decided to reserve comment on MolDx pricing at this time.

Wolf noted, however, that if Palmetto had priced LDTs and companion diagnostic kits differentially, it would have potentially been problematic from a coding standpoint. "The basis of this new coding exercise was supposed to be one test, one code, one price, and the Tier I codes, like BRAF, are supposed to be methodology agnostic," she noted.

In a statement to *PGx Reporter*, Jeter explained that differential pricing for diagnostic kits and LDTs was not possible due to the use of analyte-specific CPT codes. "The current CPT Tier 1 codes make no differentiation as to the test being an LDT or FDA-approved 'kit,'" Jeter said over email. "The gap-fill process required us to use all related test data for all versions of the same CPT referenced test. With the MolDx identifiers, and before the new CPT codes and gap-fill, we were able to make test-specific reimbursements. We acknowledged to industry that this gap-fill process possibly creates a reimbursement-driven bias between LDT and FDA kits."

The AMA, which makes royalties on the use of CPT codes, and certain lab groups have pushed back against Palmetto's efforts to use unique identifiers, which would enable brand-specific pricing.

A long-term aim of the MolDx program, according to Jeter, is to establish pricing that is more commensurate with

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the value that tests provide to healthcare. This initial list of prices from Palmetto, most test providers would agree, illustrates there is a long way to go to achieving this goal.

Qiagen, in a statement to *PGx Reporter*, said that the company wants to work with other stakeholders to move toward a value-based reimbursement system. "This value comes from clinical utility – the proven ability to save lives, improve medical outcomes, and avoid waste in healthcare spending," a Qiagen spokesperson said. "We believe reimbursement needs to be put on a rational basis, established on experts' review of clinical data, including FDA approval."

However, measures of clinical utility and cost savings for a particular medical intervention tend to shift based on the questions being asked and what the payor is willing to spend on a given clinical scenario. Several different cost-effectiveness studies on KRAS testing to administer EGFR inhibitors for colorectal cancer have estimated that the intervention would save the healthcare system between $100 million and $700 million.

A study published in the *Journal of the National Cancer Institute* last year found that while testing for KRAS and BRAF mutations to guide anti-EGFR treatment can save payors around $8,000 per patient compared to administering these drugs without PGx testing, payors who "decide against the use of anti-EGFR therapy" for cheaper treatment alternatives can save approximately $20,000 per patient (*PGx Reporter 11/28/2012*). During lean economic times, as is the case currently, payors may have more conservative thresholds for what they're willing to spend on a particular intervention.

Will Other Payors Follow?

Whether other Medicare contractors will base their pricing determinations on MolDx levels remains to be seen. So far, Medicare contractor Cahaba, with jurisdiction over labs located in Alabama, Georgia, and Tennessee, has not followed MolDx's lead.

According to Piper Jaffray's comparison of contractors' reimbursement prices, Cahaba's average pricing for Tier 1 codes was 10 percent lower than code-stacked prices – better than the 19 percent average reduction that Tier 1 tests would see under MolDx compared to code-stacked rates.

"Palmetto expected many, if not all, the contractors to mimic their pricing. As we've seen with Cahaba, they did their own thing," Wolf said, adding that it's likely that there will be some pricing differentiation between Medicare contractors for Tier 1 codes.

This variability, in turn, makes it particularly difficult for industry observers to predict how private payors are going to react. Historically, private payors have taken CMS reimbursement levels as a guide for what they should be paying for healthcare products.

"We're really waiting with bated breath to see what the private payors are going to do," Wolf said. "We're trying to accumulate that information as our clients have claims that are adjudicated."

By April, all Medicare contractors are expected to submit their pricing for Tier 1 codes to CMS. Stakeholders will likely be able to provide comment on these prices and further discuss them at a July CMS meeting. The contractor prices won't be finalized until the fall and will go into effect in 2014.

However, ACLA Senior VP JoAnne Glisson isn't confident that industry protests will change pricing. While the MolDx and Cahaba prices are preliminary, leaving room for Medicare contractors to change their pricing levels after discussions with industry stakeholders, it remains to be seen "whether they will entertain efforts by laboratories or ACLA … to discuss the prices, the rationale, and the methodology they used," Glisson told *PGx Reporter*.

Although Palmetto and Cahaba have published their proposed prices for these new codes, other contractors – such as Novitas, Cigna, and Noridian – are not obligated to post their reimbursement valuations for the public. If other contractors don't publish their prices, then labs will be left to discover the new reimbursement levels for their tests when healthcare providers perform testing and submit a claim.

"The problem is if all the contactors come up with these painfully low prices, when the prices are amalgamated, the odds are that they will be low," Wolf said. "So, it's a tremendous concern."