

# Low 2013 Molecular Rates May Bankrupt Some Labs

➤ Prices for some high-volume molecular test fails to cover the lab's cost to perform these tests

➤➤ **CEO SUMMARY:** *Many of the recently issued reimbursement rates for molecular diagnostic tests are inadequate and in fact are lower than the cost of running the tests, lab experts say. Smaller laboratories that specialize in developing and selling molecular tests could be forced to close. As many as 20 or more molecular labs operate in California and are facing the prospect of appealing the low rates and awaiting a decision on these appeals.*

**F**OLLOWING THE RELEASE of 2013 pricing for molecular test CPT codes that lab industry experts say are too low and, in some cases, less than a lab's cost of performing these tests, **Palmetto GBA**, the nation's largest Medicare carrier, once again finds itself in the lab testing industry spotlight.

On January 28, Palmetto issued its 2013 reimbursement rates for 79 of the 104 new molecular testing CPT codes. The rates are effective for Medicare Part B Medical Laboratory Tests in Jurisdiction 1, which is California, Hawaii, and Nevada. The dramatically low rates for some of the most commonly ordered molecular CPT codes brought immediate and strong criticism.

"Palmetto Genetic Test Rates Could Bankrupt California Genetic Labs, Force Thousands Out of Work, and Slow the Advances of Personalized Medicine" was

the headline of the press release issued by the **California Clinical Laboratory Association (CCLA)** on February 6.

Experts in clinical laboratory reimbursement say many of the rates are inadequate and some are lower than the cost of running the tests. Also, they predict that a significant number of labs, particularly in California, will be forced to downsize or close if the unexpectedly low prices for these molecular CPT codes are not properly addressed.

"These rates will be particularly devastating here in California because there are so many molecular labs in this state," noted Lâle White, CEO of **XIFIN, Inc.**, a San-Diego based company that provides revenue cycle management services to medical laboratories. "I estimate that more than 20 labs in California are greatly affected by these low rates.

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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“Keep in mind that, since January 1, 2013, no labs have been paid for the 104 molecular tests that the **Centers for Medicare & Medicaid Services (CMS)** has identified,” she explained. “Now add to this news the fact that some of these new Medicare Part B rates for the highest volume diagnostics don’t even cover the costs of performing these tests and you can see the problem.”

On its web page that lists the 2013 pricing for the new molecular CPT codes, Palmetto wrote, “As instructed by CMS, Palmetto GBA has determined a gap-fill allowance for the 2013 MoPath CPT codes. The fees were based on the detailed analysis of multiple lab applications and a standardization of the submitted stacks. All services to produce the assay result, including the work for microdissection, were evaluated and included in the listed fee... We will continue to update this fee schedule as the remaining MoPath services are evaluated.”

### ► **Low Rates, But High Volume**

“Prices for about half of the CPT codes that Palmetto issued are essentially in line with the recommendations of the **American Clinical Laboratory Association (ACLA)** and the large national labs,” observed White. “But the reimbursement for the molecular test codes that make up the highest volume of testing are problematic, such as BRAF and EGFR.

“For example, the rates for BRAF and EGFR are below costs and these tests represent a large portion of the molecular testing volume,” she continued. “This is a major financial problem for all labs, but is particularly true for smaller labs that have a limited and targeted menu. These very common, high volume tests are priced way too low.

“Take those molecular diagnostics labs that have a patented test and may run other tests to round out their menu,” stated White. “With such a limited molecular test menu, these labs could be in

financial trouble, particularly if they have not yet achieved profitability.

“Because these smaller molecular labs are still trying to develop their tests and their markets, they have a big expense base,” White explained. “Their funds are spent on research and development and on educating oncologists and pathologists about the value of these tests.

### ► **Lab Investors Uneasy**

“Another problem for small labs is that, because they are not profitable, they are backed by investors,” she added. “In recent years, those investors have been uneasy because of the uncertainty over pricing, coding, and FDA regulations for molecular and genetic tests.

“All labs that offer molecular testing as part of their broader menu perform these high volume tests: BRAF, KRAS, and EGFR,” stated White. “So technically, most labs are affected.

“However, I can think of at least 20 labs in California that solely perform molecular testing. Will they be forced to close?” asked White. “That’s hard to say because their investors will make that decision. Since these labs typically have negative cash flow, they may have to shut down or down size if their investors don’t pony up.”

### ► **Test Volume Growing**

Donna Beasley, DLM(ASCP), recently the Laboratory Specialty Vice President at **McKesson Revenue Management Solutions**, agreed. She said that molecular testing represents the biggest volume growth in lab testing in recent years.

“Many smaller labs may not survive through the period of any appeals and process rate adjustments,” observed Beasley. “While all labs will feel the effect, the larger labs may continue operations but turn away from developing new molecular diagnostic tests as investor angst increases with the reduced rates. Were this to happen, it would be a big loss

## Website Analyzes Fee Reports and Calculates Losses From Palmetto's New Molecular Rates

**T**O CALCULATE THE FINANCIAL IMPACT of Palmetto GBA's 2013 prices for the high volume molecular CPT codes, a website called **Market Access Analysts** published an analysis. For such high volume molecular tests as KRAS, BRAF, and EGFR, the prior code stack reimbursement was compared to the prices announced on January 28 by Palmetto for the Medicare J1 region.

"While the impact of these [Palmetto] rates is still being determined, a simple analysis seems to suggest a significant reduction in reimbursement for certain diagnostic tests," the site said. "Using the CPT code stacks identified by **Quest Diagnostics Incorporated** for the KRAS, BRAF, and EGFR tests and the CMS 2012 Clinical Lab Fee Schedule (CLFS), we've calculated an estimated 2012 rate for comparison with the newly proposed 2013 MolDx prices."

<u>Molecular Test</u>	<u>Calculated 2012 CLFS Rate</u>	<u>Palmetto 2013 Rate</u>	<u>Difference \$</u>	<u>Difference %</u>
KRAS	\$211.20	\$225.28	\$14.08	+6.7%
BRAF	\$257.34	\$57.51	\$(199.83)	-77.7%
EGFR	\$299.88	\$116.25	\$(183.63)	-61.2%

Source: <http://marketaccessanalyst.wordpress.com>

for physicians and patients who might benefit from the molecular tests."

Michael Arnold, Executive Director of the **California Clinical Laboratory Association (CCLA)**, held a meeting by conference call with his members last week (on February 5). He heard that one lab had already laid off 25% of its staff.

In its press release about this issue, issued on February 6, CCLA wrote, in part, that: "...Palmetto, the outgoing Medicare contract administrator for California and several other states, upended the clinical laboratory industry last week by announcing surprise reimbursement rates that in many instances are below the costs of doing the tests. The impact of this development could force clinical laboratories performing genetic testing to close their doors—reducing patient access to these important new clinical laboratory tests."

"These new reimbursement rates for molecular and genetic testing have no relationship to reality," commented Arnold in the CCLA press release. "They will result in laboratory closures, lost jobs and a reversal of recent advances in personalized medi-

cine. Patient access to many life-saving genetic and molecular tests may no longer be available."

At the national level, representatives from ACLA hope to meet with CMS officials to discuss transparency and reimbursement under the gapfill process for molecular testing, said JoAnne Glisson, ACLA's Senior Vice President. "We will raise these issues. But first we want to see if more pricing information from the other Medicare contractors will be made public," she said.

### ➤ Labs Can File Appeals

Laboratories in Medicare region J1 can file appeals to Palmetto. "Part of the iterative process of setting prices for molecular tests involves the filing of an appeal," stated White. "This can be done if the price for a test does not appear to reflect that the price was appropriately determined under the regulatory guidelines for establishing a rate.

"Through appeals, the reimbursement rates are likely to change," added White, "and in the process, the prices will become more equitable.

"Palmetto is trying to do the right thing. It just didn't have enough time to

do it properly,” concluded White. “But Palmetto has been very good about talking to stakeholders. They listen to what labs say and try to be responsive.”

Palmetto officials did not respond to requests for comment by press time.

### ► California’s Labs Feel Pain

California has a large concentration of independent laboratory companies. Thus, it is no surprise that labs in the Golden State are first to feel the financial squeeze represented by Palmetto’s release of its 2013 pricing for these molecular CPT codes.

Further, because of the advanced biotech research that is centered in California, a significant number of these laboratories have just a few proprietary molecular and genetic tests that make up the majority of their specimen volume. That makes these specialty lab companies particularly vulnerable to financial loss—even bankruptcy—should reimbursement rates be set at rates that may be less than the cost of performing these tests.

For these reasons, the molecular specialty testing labs in California may be useful “canaries in the coal mine.” They give the lab industry a way to gauge the short-term and long-term financial and clinical impact of the pricing decisions made by Medicare officials and the different regional Medicare contractors.

### ► New Molecular CPT Codes

In the meantime, it can be expected that labs will file appeals and lab industry associations will engage in conversations with CMS, Palmetto, and the other Medicare contractors over the issue of rates for the new molecular CPT codes. **TDR**

—Joseph Burns

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## Understanding Gap-Fill and Cross-Walking Processes

**S**EVERAL EXPERTS in laboratory coding, billing, and reimbursement have called attention to the fact that the process of establishing reimbursement for the new molecular CPT codes is in its earliest stages. Additional steps have yet to happen.

“As a starting point, Palmetto GBA has asked stakeholders to provide comments and cost information for reconsideration of the newly-published rates,” stated Lâle White, CEO of XIFIN, Inc., in reference to the newly-published molecular test prices for Medicare region J1. “California labs will be providing data to the contractor,” she noted.

Experts say such data collection is part of what is required to establish pricing through the gap-fill methodology mandated by CMS. However, Medicare pricing instructions indicate that—when a new test is comparable to an existing test—the price of the new test should be cross-walked rather than gap-filled.

What is a challenge to Palmetto and other Medicare contractors is that most of the tests that make up the new molecular CPT codes were previously coded with specific methodology codes that had a fee schedule reimbursement rate. That is why many lab industry comments submitted during the public comment period suggested that the new molecular CPT codes be cross-walked to the prior methodology codes. Then, Medicare contractors could develop a median price to be used where different versions of the test were grouped into one code.

Billing and coding experts say that, for the most part, it appears that Palmetto tried to use that methodology. However, it was handicapped by the lack of cost data to complete a gap-fill analysis. For that reason, the appeals filed by laboratories and the submission of additional data will play a big role in helping Medicare contractors develop fair and appropriate reimbursement levels for each of the new molecular CPT codes.