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October 20, 2017

Ms. Valerie Miller
Director, Division of Ambulatory Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Preliminary PAMA payment rate for 81528

Dear Director Miller:

Two years ago today, I submitted the last in a series of comment letters discussing the proposed payment rate for a new colorectal cancer screening test, which was initially reimbursed under CPT code G0464 and later transitioned to 81528. The crosswalk methodology resulted in a payment amount that significantly exceeded the efficient frontier of cost-effectiveness, based on Medicare's own analyses. Through the public meetings process, you determined that CMS lacked the statutory authority to consider factors such as test purpose and cost-effectiveness in determining payment rates for a new test. At the time, you also noted that the forthcoming PAMA process was intended to establish a market-based rate which would likely incorporate the cost-effectiveness concerns of payors.

Unfortunately, thanks to a loophole unintentionally created during the PAMA rulemaking process, it appears that this will not be the case for code 81528, along with any other tests that were still subject to negotiation with commercial payors during the initial data collection window. After comments from laboratory trade groups, the final PAMA rule incorporated revised data collection requirements that excluded tests that were completed, but not yet paid during the six-month collection window. The exclusion includes, but is not limited to, tests where the commercial payor's payment determination was appealed, *even if that appeal was ultimately unsuccessful*. This provision in the rulemaking created an incentive for laboratories to appeal a large proportion of their test volume, knowing that even delaying payment for a few months could exclude an undesirably low payment from the PAMA data collection process. The incentive is particularly acute for sponsors of tests with unique procedure codes who operate their own labs, as they represent the sole reporting entity in the data collection process.

Additionally, tests that recently transitioned from G codes may have had relevant data excluded from the collections process due to misclassification under the prior G code. Tests billed under the old code are easily associated with the new procedure code. In particular, miscategorized billings under code G0464 during the data collection window should be considered "applicable information" reportable for code 81528. To the extent they were not included in the data submission, additional information should be collected from the reporting laboratory.

Importantly, it is not the case that a lab would necessarily have deliberately omitted information or appealed an unusually large number of tests in order to take advantage of PAMA. I am not suggesting any impropriety on the part of any company. The final adopting release for PAMA was in August 2016, after the data collection window. It is also entirely natural that a relatively new test would still be the subject of commercial negotiation between a laboratory and payors, which might result in delays in payment. Early in a test's market acceptance, it is normal for the proportion of reimbursements subject to negotiation to be higher. However, the resolution of that negotiation process represents real commercial data and payment rates, the very market data PAMA was intended to capture. Ignoring this important information would tend to favor single-source laboratories at the expense of taxpayers.

Although the PAMA adopting release was clear in excluding appeals, there has not been any opportunity for the public to comment specifically on the exclusions, which were suggested by industry commenters and were not proposed in the draft rule. Indeed, until the first preliminary payment rates were proposed this year, it was not clear what impact the exclusions would have. I believe the data collection procedure for PAMA should be revised and the 2018 payment amounts recalculated including tests that were subsequently paid after resolution of appeals. The payment submission deadline fell nine months after the data collection window; there is no obvious practical reason to exclude delayed payments that were resolved during this timeframe. Laboratories should be required to include data on all tests completed during the collection window, for which payment was received prior to the submission deadline.

While I recognize that most public commentary since the preliminary rates were issued has focused on the negative impact to laboratories from reduced payment rates, it is also important to consider data collection limitations that may result in payment rates that are too high, circumventing the cost savings goals of PAMA. With total Medicare reimbursements of $61.2 million in 2016, code 81528 has the highest gross reimbursement of any single-source test. Under PAMA, its preliminary 2018-2020 payment amount of $508.87 is nearly unchanged from the current NLA of $512.43.

This outcome is concerning in light of data that the test sponsor, Exact Sciences, reports in its public filings regarding average reimbursement levels. Exact reported in its 2016 10-K filing that for tests completed during the trailing twelve months ending June 30, 2016, its overall average reimbursement rate was approximately $405 per test. In its second quarter 2017 10-Q filing, Exact reported an average reimbursement of $423 for tests completed during the trailing twelve months ending December 31, 2016. From these two disclosures, it appears that the company's average reimbursement during the data collection window was approximately $414, including Medicare volumes.

For the full year 2016, Medicare (not including Medicare Advantage) represented 60% of Exact Sciences' revenues. Medicare revenues were not explicitly disclosed for the first half of 2016 alone. However, assuming Medicare represented 60% of the company's revenue in the first half of 2016, and that these tests were reimbursed at the NLA, approximately 48% of the 94,000 tests completed during the data collection window were paid by Medicare. This estimate is consistent with the company's disclosure that Medicare covers 46% of patients in the screening population for the test. Mathematically, if 48% of tests were reimbursed at the NLA over $500, the remaining ~48,000 tests must have received an average reimbursement of about $321 per test in order for the overall average to be $414.

CMS staff should consider the considerable discrepancy between the average non-Medicare reimbursement of $321 per test, which includes amounts under appeal, and the data which was reported to CMS and resulted in the weighted median and interquartile data released to the public. What proportion of the tests in the non-Medicare population were excluded from the data reported to CMS? It appears that the final PAMA rule inadvertently caused a great deal of commercially relevant data to be excluded for code 81528. Before finalizing the payment amount, you should ensure that the data you have is complete and correct, and that the collections process provides you with the necessary information to reflect the rates actually determined by commercial payors.

Finally, please note that neither my firm nor any connected person have been compensated in any way for this letter. For more than two years, we have not held any investment, long or short, in Exact Sciences, the sole laboratory reporting under code 81528. I believe Exact Sciences deserves commendation for its significant investment in increasing compliance with colorectal cancer screening guidelines. However, for the reasons discussed in the 2015 comment process and further outlined in this letter, I believe that the proposed payment rate for code 81528 is too high. The company was provided with an opportunity to review this letter before submission.

Thank you once again for providing an opportunity to comment before rates are finalized.

Sincerely,

Jacob Ma-Weaver, CFA