July 3, 2013

VIA Electronic Mail:  MoPathGapfillInquiries@cms.hhs.gov

Mr. Jonathan Blum, Deputy Administrator  
and  
Director, Center for Medicare  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

Re: Interim Gap-fill Payment Amounts for Diagnostic Tests

Dear Mr. Blum:

AdvaMedDx is writing to provide comments on the interim Medicare Administrative Contractor (MAC) payment amounts for diagnostic tests that were posted to the Centers for Medicare & Medicaid Services (CMS) website on May 9, 2013. We have significant concerns regarding the outcomes of the gap-fill process that is currently underway and that will be used to assign payment rates to new codes for a large number of diagnostic tests for CY 2014.

Operating as a division of the Advanced Medical Technology Association, AdvaMedDx represents the world’s leading diagnostics manufacturers by advocating for the power of medical diagnostic tests to promote wellness, improve patient outcomes, and advance public health in the United States and abroad. AdvaMedDx member companies produce innovative, safe and effective diagnostic tests. These tests facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease and often reduce health care costs.

Our comments address the following:

(1) The information provided by CMS is inadequate to inform stakeholders and permit well-informed comments on the posted rates.
(2) The interim payment rates expose limitations in the current gap-filling system.
(3) The gap-filling process needs improved transparency and additional opportunities for stakeholder feedback.
(4) CMS should clarify the role of the MolDx Program, or similar program moving forward, for identifying, covering and rate-setting for molecular diagnostic tests.
(1) The information provided by CMS is inadequate.

The interim payment rates and the “rationale” document that were posted on the CMS website on May 9, 2013, were incomplete and did not adequately inform stakeholders of either the process used to determine the 2013 payment amounts, or the likely amounts for 2014. The interim payment rates did not include an estimate of the National Limitation Amounts (or “NLAs,” the median of the carrier specific amounts), and it is not clear how CMS intends to calculate those medians.

The spreadsheet posted on the CMS website had many missing values; and, if additional information is not provided by the MACs in a timely manner, it is not clear how the missing values will be treated in the calculation of the NLA. Even where values are present, the methodology for establishing the NLA is unclear. CMS did not provide information about whether the NLA for a given test will be established as the median of amounts posted by contractor, by MAC jurisdiction, by State, by regional locality, or (because some sub-state data is shown) by all columns of the table. Not enough is known about the various MACs’ rate-setting processes to ensure they can even be used reliably in any such calculation.

The data posted by CMS indicates that some of the MACs may have used a modified crosswalk approach to establish their gap-fill payment amounts, using some portion of the now-deleted molecular pathology methodology codes (or “stack codes”) as a proxy for the cost of performing a test. Payment rates for the stack codes do not in any way reflect the actual cost of developing, commercializing, or performing these tests.

For stakeholders, having access to the interim payment rate data from all MACs as well as their methodologies for determining those payment rates is critical. Under the circumstances described above, it is difficult for stakeholders to determine the extent to which additional information should be provided, or to whom, to help ensure payment rates are set appropriately.

The limited information provided by several of the MACs, combined with the lack of clarity regarding how CMS will perform its calculations, points to a need for guidance concerning the process and the provision of data. We ask CMS to provide such direction to the MACs in order to ensure consistency in the gap-filling process. We further urge CMS to provide information immediately regarding the methodology it expects to use in calculating the NLAs. Finally, we urge CMS to require the MACs to provide adequate explanations as to how each MAC generated its interim gap-filled amounts, and to post this information on the CMS website as soon as it is available. This information will assist CMS and stakeholders in ensuring that the gap-fill rates can reliably be used to establish the CY 2014 NLAs.
(2) The published interim payment rates expose the limitations of the current gap-filling process.

The use of the gap-filling process for an unprecedented number of codes for highly sophisticated tests, on such a short time line, has exposed the practical shortcomings of this process. Most of the MACs have little experience with setting payment rates for laboratory tests in general or for highly complex molecular tests in particular. There is wide variation in the payment amounts that were issued by the various MACs, and the explanations provided in the “rationale” document offers little justification for those determinations. The current process provides very limited transparency and thus does not engender great confidence in the quality of the MACs’ decision-making, pointing to the need for improvements in the rate-setting process, as discussed in more detail below.

AdvaMedDx believes the gap-fill process would benefit from more specific guidance from CMS about the factors to take into account when establishing gap-fill payment amounts. Specifically, CMS should direct its contractors to consider:
  - The impact of the new test on patient care, patient management, or patient treatment;
  - The technical characteristics of the new test, and the resources required to develop, validate, and perform the new test;
  - Amounts charged by laboratories to self-pay patients for the new test; and
  - Amounts paid to laboratories for the new test by private insurers.

(3) The gap-filling process needs improved transparency and additional opportunities for stakeholder feedback.

As stated above, AdvaMedDx believes that transparency in the rate-setting process is critical. CMS should provide clear justification for the way payment rates are derived so that interested parties, including manufacturers of diagnostic tests, are able to understand the agency’s rationale, and if necessary, provide additional information to CMS or the appropriate contractor. Such information should include the resources required to develop and perform specific tests, such as costs of the development of evidence required by government agencies, costs of regulation (certifications, licensing, obtaining and maintaining approvals, etc.), direct and indirect costs (including equipment, software, materials, labor), and information regarding the value of those tests with respect to patient care management.

We strongly recommend that CMS consider additional processes for improving the transparency of the rate-setting process by providing knowledgeable parties, including AdvaMedDx and its members, better opportunities to provide input regarding MAC-established payment amounts. Such opportunities should include public meetings and appropriate notice and comment opportunities based on adequate information about how proposed rates are set. A more transparent process that accommodates input from manufacturers, laboratories, clinicians, scientists and other interested parties will provide the opportunity for CMS to access and utilize the best available information in determining appropriate payments for these tests.
(4) CMS should clarify the role of the MolDx program, or establish a similarly structured program for specifically identifying, covering and rate-setting for molecular diagnostic tests.

One MAC, Palmetto GBA, which has been operating its Molecular Diagnostics (MolDx) pilot program since 2012, has a more established structure than other MACs for identifying specific tests and assessing those tests for coverage purposes. For several months, stakeholders have asserted publicly and privately to CMS and to the MACs that many of Palmetto’s payment amounts are inadequate, and in many cases are set lower than the cost of performing the test. Yet, judging from the posted amounts, Palmetto’s decisions appear to have helped inform some of the other MACs. If these payment amounts are in fact below the cost of performing the test, and there is no recourse for an appropriate pricing methodology by the MAC or by CMS, labs will no longer be able to offer these tests and manufacturers will exit this sector, potentially reducing access to these tests. The current gap-filling exercise underscores the need for CMS to maintain a well-informed, transparent, and accountable process to assist with coverage and payment determinations for laboratory tests.

We recently wrote to CMS in support of what we view as positive elements of the Palmetto MolDx Program. The MolDx program provides a way for the contractor to identify specific molecular diagnostic tests using test-specific identifiers, allowing the contractor to recognize a specific test, regardless of the CPT codes used, to process claims appropriately, and to make appropriate coverage and reimbursement decisions regarding that test.

Despite some questionable results, the program’s rate-setting methodology appears to consider information regarding the resources required to develop and perform tests. In particular, molecular tests require extensive scientific development and validation efforts, and development of clinical utility evidence. We believe the resources that are required to develop and validate these tests, including clinical studies that may be required for FDA approval or clearance, or to obtain Medicare coverage, should be recognized in the payment amounts set by CMS.

Under the MolDx program, unique test identifiers are used to identify and thus differentiate specific molecular pathology tests sharing the same molecular pathology CPT code. Additionally, Palmetto has provided differential pricing for certain tests based on the contractor’s evaluation of the clinical evidence and costs associated with developing and performing the test (for example, whether the test has been approved or cleared by the FDA or the sponsor can present evidence similar to that required by FDA). AdvaMedDx supports this approach, as it appears to take into account the costs of obtaining and maintaining FDA approvals/clearances and the costs of maintaining FDA registered facilities.

We consider the following elements of the MolDx program to be an improvement over existing processes related to coverage and payment for diagnostic tests, including molecular diagnostics:
- Test identification – assignment of unique test identifiers
- Performance of technology assessments
- Publication of coverage determinations on a website
- Establishment of reimbursement rates based on “enhanced” gap-filling process

The program to date has provided an improved level of transparency over what had previously been available through any of the MACs. We also note that this contractor has been open to discussions with laboratories and manufacturers regarding the provision of additional data that it has used to reevaluate and/or revise payment rates in some cases. We would again urge CMS to provide guidance to all MACs regarding the incorporation or use of these program elements, in order to ensure a more consistent and predictable coverage and rate-setting process.

**Conclusion**

The interim payment rates published by CMS demonstrate a number of inadequacies in the current gap-filling process for the 2013 molecular pathology code set of more than 100 new CPT codes. AdvaMedDx believes that improvements in the process, including greater transparency, more standardized methodologies and additional opportunities for stakeholder input would result in more accurate and appropriate payment amounts for diagnostic tests that are vital to patients and clinicians. Finally, we continue to advocate for continuation of those elements of the MolDx program or similar program that would improve the rate-setting process.

As always, we would be happy to work with CMS toward these objectives. If you have questions regarding these comments, please me at (202) 434-7219 or cbranham@advamed.org.

Thank you for your attention to these important issues.

Sincerely,

Chandra N. Branham, J.D.
Vice President, Payment & Health Care Delivery Policy
AdvaMed

cc: Elizabeth Richter
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