February 5, 2013

VIA Electronic Mail:
Marilyn.Tavenner@cms.hhs.gov
Jonathan.Blum@cms.hhs.gov

Marilyn Tavenner
Acting Administrator
and
Mr. Jonathan D. Blum
Acting Principal 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: Payment for Molecular Diagnostics Services (MolDx) in 2013

Dear Ms. Tavenner and Mr. Blum:

We are writing regarding an urgent issue for the in vitro diagnostics industry and for the Centers for Medicare & Medicaid Services’ (CMS). As of January 1, 2013, Medicare Administrative Contractors (MACs) began receiving claims for over 100 new CPT codes for molecular diagnostic tests. These tests were previously paid by the MACs using methodology-based stacking codes, which were eliminated from the CPT code set as of January 1, 2013. CMS announced in the CY 2013 Physician Fee Schedule final rule that the new CPT codes for advanced molecular diagnostic tests will be paid using gapfilling. AdvaMedDx is concerned about the outcomes of the gapfill process that MACs will use in 2013 to assign payments to these new CPT codes.

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. AdvaMedDx operates as a division of AdvaMed, the Advanced Medical Technology Association.

Our comments address two issues: (1) improving transparency and providing for stakeholder feedback in the gapfilling process, and (2) the MolDx pilot program for identifying, covering and reimbursing molecular diagnostic tests.
1) Improving Transparency in the Gapfilling Process in 2013

AdvaMedDx would like to provide the following comments on the gapfilling process. Gapfilling has not been used frequently in the past; however, in 2013, MACs are required to gapfill an unprecedented number of very complicated molecular diagnostic tests. This task will be difficult for the MACs, and AdvaMedDx members have concerns regarding the appropriateness of the resulting payment amounts, which will factor into the assignment of national pricing amounts in 2014. We believe that the quality of the payment information – and ultimately the quality of the national payment amounts – would be improved if CMS’ process included additional opportunities for input.

Current regulations require that, for the first year of gapfilling, MAC-specific amounts are established using multiple sources of information (charges for the test, resources required to perform the test, payment amounts made by other payers, and payment amounts for comparable tests). In the second year, a national amount is established based on the median of the MAC-specific amounts.

The national payment amounts for the new molecular diagnostic tests will be based upon payment data submitted by the MACs to CMS throughout 2013. As manufacturers, AdvaMedDx members may have additional information that would be useful to CMS in establishing national payment amounts, including information about the resources required to develop and perform specific tests and information regarding the value of those tests with respect to patient care management.

We strongly recommend that CMS consider a process for improving the transparency of the gapfilling process by providing knowledgeable parties, including AdvaMedDx and its members, the opportunity to provide input about the preliminary MAC payment amounts that are submitted to CMS. These input opportunities could take the form of public meetings or appropriate notice and comment opportunities. A more open comment period will be critical for establishing equitable rates, particularly for molecular tests that are not often performed in the Medicare beneficiary population (i.e., tests done primarily in younger patient groups). We believe that a more transparent and interactive process that accommodates input from all interested parties (manufacturers, laboratories, clinicians, and others) will provide the opportunity for CMS to access and utilize the best available information in determining appropriate reimbursement for these tests.

2) Palmetto MolDx Program

During the last several years, one MAC, Palmetto GBA, developed and implemented a pilot program to identify molecular diagnostic tests and to establish coverage and

---

1 42 CFR 414.508(b).
2 Id.
reimbursement specific to these tests. Palmetto’s Molecular Diagnostic Program (or “MoIdx”) introduced a number of positive elements that we believe represent progress in the process by which Medicare evaluates diagnostic technologies for coverage and payment, including the ability to:

A. identify the tests for which claims were being submitted using the stacking codes; and

B. provide a level of transparency that had not been previously available.

AdvaMedDx has paid close attention to the evolution of this program, and while it is still in its early stages, we are generally supportive of these elements of the MoIdx program. In particular, we are pleased with the program’s efforts to review evidence from each diagnostic developer regarding the clinical use of the tests being performed. This review can have a particularly important role when a test has not yet been subject to FDA review, assisting Medicare in determining whether a test can be considered reasonable and necessary for Medicare beneficiaries. We believe that continuation of these program features or a similarly-structured program could be valuable in 2013, particularly for the purpose of providing information to other MACs who do not have similar programs in place and who may not have the same level of experience with coding and payment for diagnostic tests.

These features of the MoIdx program seem to provide a basis for improving test identification, and standardizing evidence-based coverage and reimbursement decision-making.

A) Ability to Identify Tests

The MoIdx program provides a way for the contractor to identify specific molecular diagnostic tests through the development and adoption of test-specific identifiers. Under the program, a unique identifier is assigned to each test. The unique identifier allows the contractor to recognize a specific test, regardless of the CPT codes used, to process claims appropriately, and to make appropriate reimbursement decisions regarding that test.

In addition, the rate-setting methodology that Palmetto has employed for new tests appears to take into consideration the value of those tests, including information regarding the resources required to develop and perform them. AdvaMedDx has urged CMS to consider this type of information in its pricing decisions for a number of years. In particular, molecular tests require extensive scientific development efforts, and we believe that the resources required to develop and validate these tests, including clinical studies that may be required for FDA approval or clearance, or otherwise required to obtain Medicare coverage, should be recognized in the payment amounts set by CMS.
B) Transparency

The MolDx program seems to offer a higher level of transparency than has been found with other in vitro diagnostic test pricing models. The assignment of unique identifiers to specific tests allows the contractor to identify the test that was actually performed. Furthermore, the coverage determinations are posted on the contractor’s website so that interested parties (e.g., laboratory providers) have access to these decisions. This level of transparency appears to be an improvement over practices currently in place among other MACs. The process could be improved by ensuring the program has sufficient resources to allow the contractor to perform timely evidence reviews, make coverage and payment decisions, and avoid unnecessary delays.

While the MolDx program is new and evolving, the elements of the program highlighted in this letter represent improvements over existing coverage and reimbursement practices. AdvaMed urges CMS to improve its processes for determining payment for molecular diagnostic tests in 2013 and in the future.

Conclusion

AdvaMedDx believes that it is essential for CMS to provide opportunities for input on this year’s gapfilling process and continue the MolDx program beyond the pilot stage. We would be happy to work with CMS on the best way to accomplish these steps and welcome the opportunity to meet with you at your earliest convenience to discuss ways that AdvaMedDx and its members can assist in this endeavor.

If you have questions regarding these comments, please contact me at (202) 434-7219 or cbranham@advamed.org.

Thank you for your attention to this important issue.

Sincerely,

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