



**Statement  
Of  
AdvaMedDx**

**Centers for Medicare & Medicaid Services  
Clinical Laboratory Public Meeting for New Clinical Laboratory Test Payment  
Determinations for Calendar Year 2014**

**July 10, 2013**

Good morning. My name is Chandra Branham, and I am representing AdvaMedDx. AdvaMedDx functions as an association within AdvaMed – the Advanced Medical Technology Association. Our member companies produce innovative, safe and effective diagnostic tests that facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease and often reduce health care costs.

AdvaMedDx has long believed that Medicare’s payment rates for diagnostic tests should reflect their value – particularly their impact on care management and patient outcomes. We appreciate this opportunity to make recommendations today regarding the process CMS uses to establish payment rates for new laboratory services paid under the Clinical Laboratory Fee Schedule.

Our primary concerns relate to two key issues:

- **Recognition of the algorithmic component of Multi-Analyte Assays with Algorithmic Analysis, several of which are under consideration (or reconsideration) for CY 2014; and**
- **Improved transparency relating to the preliminary payment determination process, including the provision of complete and accurate justifications for CMS’ preliminary determinations – allowing interested stakeholders to fully understand and comment effectively on the agency’s proposed determinations.**

1) **MAAA Codes**

Multi-Analyte Assays with Algorithmic Analysis (MAAAs) are clinical diagnostic laboratory tests that rely on highly-complex algorithms designed and developed to interpret a number of different inputs resulting in a single score or index that is a probability of some meaningful prognostic clinical outcome or event. MAAAs are used in the diagnosis, screening, prognosis, prediction, and monitoring of disease. They can assess the risk of developing a condition, the risk of a disease or condition recurring (e.g., cancer) or a potential patient response to a treatment, such as a drug therapy. They are discrete tests with distinct results that have been developed and validated as well as ordered and reported to address specific clinical questions for which a multi-analyte result is necessary for patient management.

MAAAs have significant value in terms of the information they provide for both clinicians and patients, and their impact on patient care. By better targeting treatments for individual patients, use of MAAAs can reduce overall health care costs. The development of MAAAs involves substantial investment of time and resources. The development of the algorithmic component of these tests is also complex. But this significant investment is needed to ensure that these tests are scientifically and clinically validated.

MAAAs have been in routine clinical use for years, but have only recently been identified by specific CPT codes. These codes were established by the AMA to provide more granularity so that payers know what they are paying for when a MAAA test is ordered, reported and billed.

Last year, CMS decided against separately pricing the MAAA codes citing that it “uses other codes for payment of the underlying clinical laboratory tests on which the MAAA is done.” CMS currently reimburses clinical laboratory tests, including but not limited to MAAAs, that use calculations, algorithms or similar means to generate results that are used to inform physician practice by providing patient-specific information that improves patient care. Examples of such tests include prediction of HIV phenotype susceptibility using bioinformatics, PT/INR (prothrombin time) testing, and flow cytometry. In fact, nearly all clinical laboratory services involve some type of computation in order to translate raw signals into a patient-specific report that can be interpreted by the treating physician for use in patient management.

MAAA tests require an algorithmic component to produce a patient-specific result following the analysis of multiple analytic assays. The algorithmic component of MAAAs creates the value of the test in clinical decision-making. It is the application of the algorithm that provides the specific results that are useful to a clinician in terms of making treatment decisions for a particular patient.

- **AdvaMedDx strongly recommends that CMS recognize the value of MAAA tests in its payment determinations. Given the unavailability of other appropriate code descriptors, AdvaMedDx further recommends that CMS reimburse MAAA codes included in the CPT® and listed on the CLFS using either the crosswalk or gapfill methodologies, as appropriate.**

## 2) **Limited Transparency Regarding Decisions:**

Each year, manufacturers and other stakeholders develop and present recommendations to CMS regarding the basis for establishing the payment amounts for new clinical laboratory tests under the CLFS. However, CMS has frequently failed to adopt the recommendations it receives, even where it appears to agree on a particular recommendation. Often, the rationales provided by CMS in support of their payment decisions are cursory and provide insufficient detail to permit stakeholders to fully understand the basis for the decision. Furthermore, it is unclear whether and to what extent the agency takes stakeholder comments into consideration in making its determinations.

For example, last year, in its preliminary payment determinations for CY 2013, CMS rejected the industry's recommendation to crosswalk a new code for Galectin-3 to one of two CPT codes (86252 or 83880), and instead recommended a crosswalk to the non-specific immunoassay code. AdvaMedDx is concerned about a decision to cross-walk a new immunoassay to the non-specific code (83520), rather than adopting a crosswalk to a more specific code that is clinically and economically similar to the new test.

The CMS rationale for rejecting the industry recommendation stated in part that providers were currently reporting the unspecified code pending a final coding decision from the AMA for a specific code (which has been assigned – CPT 82777, effective Jan. 1, 2013), and that other commenters had suggested a crosswalk to the other codes without providing adequate rationale.

However, at least one commenter at the public meeting did provide detailed information in support of the recommendation to crosswalk the Galectin-3 code to more comparable CPT codes 86252 or 83880, including technical and clinical comparability information, and a resource-based analysis of the costs required to perform the test. The recommendation was supported by other commenters; yet, the rationale provided by CMS did not appear to consider the more detailed information that was presented.

- **AdvaMedDx recommends that CMS be more transparent in its responses to commenters by providing complete and specific information in its payment determination rationale so that interested parties can readily understand the Agency's reasoning for its decisions.** Additionally, when commenters differ in their views, or when CMS' decisions are not clearly aligned with all comments, we believe it is incumbent upon the agency to provide the public with a detailed rationale regarding how its decision was reached, including discussion of the applicable evidence used to support that decision.

As we have previously stated, an improved process is particularly important given the new and complex diagnostic tests that have recently come under consideration and for which CMS must make payment and fee schedule placement decisions. These tests – which include molecular diagnostic tests and MAAAs – present unique challenges in determining appropriate payment.

AdvaMedDx appreciates the opportunity to make these comments today. We look forward to the agency's proposals regarding payment for these tests, and to participating in the public process.

Thank you.