September 28, 2012

Attn: Glenn McGuirk
Hospital and Ambulatory Policy Group
Center for Medicare
Centers for Medicare & Medicaid Services
Mail Stop C4-01-26
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CY 2013 Clinical Laboratory Fee Schedule Preliminary Payment Determinations and MAAA Codes

Dear Mr. McGuirk:

I am writing on behalf of AdvaMedDx regarding the Centers for Medicare & Medicaid Services’ (CMS) Preliminary Payment Determinations for certain test codes paid under the Medicare Clinical Laboratory Fee Schedule (CLFS) for CY 2013. Our primary concerns relate to CMS’ preliminary proposal to not pay for Multi-analyte Assays with Algorithmic Analysis (MAAAs) and to the lack of transparency regarding the process for making the preliminary payment determinations. **CMS should reverse its preliminary payment determination with respect to MAAA codes and adopt the industry recommendations regarding the payment methodology for these tests. Additionally, CMS should be more transparent in providing information in its rationale supporting its proposed payment determinations.**

AdvaMedDx member companies produce advanced *in vitro* diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and often reduce overall health care costs. Functioning as an association within the Advanced Medical Technology Association (AdvaMed), AdvaMedDx deals exclusively with issues facing *in vitro* diagnostic manufacturers both in the United States and abroad. Below, we raise the following specific concerns:

- **AdvaMedDx urges CMS to withdraw its proposed payment determination for MAAA tests and issue a final payment determination that recognizes the value of these tests.**
- **AdvaMedDx further recommends that CMS reimburse any MAAA code included in the 2013 Edition of CPT® and listed on the CLFS using either the crosswalk or gapfill methodologies.**
Finally, AdvaMedDx again urges CMS to improve transparency relating to the preliminary payment determination process, by taking into consideration input received at the annual Clinical Laboratory Public Meeting and via public comment, and providing more complete rationales for its preliminary determinations that allow stakeholders to understand fully and comment effectively on its proposed determinations.

What are MAAs?

MAAs 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. It is not simply a consolidation of information from a number of equally weighted component analyses. MAAs rely on analyses of substances in the body, as do other clinical laboratory tests. They are used for several purposes, including assessment of the risk of developing a condition, the risk of recurrence of a disease or condition (e.g., cancer), and potential patient response to treatments, including drug therapies. MAAs are not add-on pieces of information to a panel of tests otherwise ordered and reported by a laboratory but are discrete tests with distinct results.

The American Medical Association (AMA) defines MAAs as:

...procedures that utilize multiple results derived from assays of various types, including molecular pathology assays, fluorescent in situ hybridization assays and non-nucleic acid based assays (e.g., proteins, polypeptides, lipids, carbohydrates). Algorithmic analysis, using the results of these assays as well as other patient information (if used), is then performed and reported typically as a numeric score(s) or as a probability. MAAs are typically unique to a single clinical laboratory or manufacturer. The results of individual component procedure(s) that are inputs to the MAAs may be provided on the associated laboratory report; however these assays are not reported separately using additional codes. These codes encompass all analytical services required for the algorithmic analysis (e.g., cell lysis, nucleic acid stabilization, extraction, digestion, amplification, hybridization and detection) in addition to the algorithmic analysis itself.¹

MAAs have been in routine clinical use for years, but generally have not been identified by specific CPT codes. Providers have instead relied on “stack” (83890-83914) or unlisted codes or a combination of stack and unlisted codes to bill for these tests; and payers, including Medicare contractors, have regularly paid for these tests. For 2013, the CPT Editorial Panel, as part of its overhaul of molecular diagnosis codes, created a mechanism for establishing MAA codes to provide granularity and specificity so payers would know what they are paying for when a MAA test is ordered, reported and billed.

The development of MAAAs involves substantial investment of time and resources. Development of an algorithm is complex, and this investment is needed to ensure that these tests are scientifically and clinically validated. Though the cost can be considerable, MAAAs have significant value in terms of the information they provide and the impact they can have on patient care and reducing overall health care costs by better targeting treatments for individual patients. For example, a prognostic test that determines the likelihood of recurrence of breast cancer can assist the clinician in identifying patients who do not need chemotherapy, reducing health care spending and avoiding potential adverse effects for the patient.

**CMS’ Preliminary MAAA Payment Determination**

In comments made in conjunction with CMS’ Annual Clinical Laboratory Public Meeting that was held in July of this year, interested stakeholders recommended that payment for the new MAAA codes be determined using various cross-walks or the gapfill methodology.

In late August 2012, CMS released its preliminary payment determinations for new and reconsidered codes for tests paid under the Clinical Laboratory Fee Schedule (CLFS). In that document, CMS rejected the stakeholder recommendations related to payment for MAAAs and stated that it “uses other codes for payment of the underlying clinical laboratory tests on which the MAAA is done, and does not recommend separately pricing the MAAA codes.” CMS also stated that “Medicare does not recognize a calculated or algorithmically derived rate or result as a clinical laboratory test since the calculated or algorithmically derived rate or result alone does not indicate the presence or absence of a substance or organism in the body.”

We believe that CMS’ statements amount to establishment of a new policy. This change in policy appears to create a distinction between (1) payment for clinical laboratory tests based on the intended use and (2) payment for the process for determining the test result. We do not believe that this is the current policy, and CMS’ proposal would not be an appropriate policy for Medicare.

**The Proposal is Inconsistent with Current Policy**

The proposal not to pay for the algorithms used in an MAAA is inconsistent with current Medicare policy. No existing precedent, regulation, or statute supports reimbursement for clinical laboratory tests if they indicate the presence or absence of a substance but not if they analyze substances in the body to inform medical treatment decisions that affect

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the future health of Medicare beneficiaries, as is the case with MAAAs. CMS’ position as stated in the preliminary payment determination, if finalized, could have widespread implications for payment for other tests, as noted below.

CMS currently reimburses a number of 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 (described by CPT code 87900), PT/INR (prothrombin time) testing, and flow cytometry.

In the case of MAAAs, the algorithm provides a value for the various markers combined together that are, individually, too nonspecific to be clinically actionable. When consolidated and interpreted collectively by the algorithm, these markers enable clear clinical decision-making. The algorithmic component of MAAAs is critical in deriving useful data from the various markers that are part of the test. These algorithms create the value of the test in clinical decision-making. The use and development of MAAAs presents an opportunity for greater efficiency and consistency in diagnosis.

No Underlying Codes for Most MAAAs

The preliminary payment determination represents a radical departure from CMS’s treatment of MAAAs to date and raises significant concerns regarding the future treatment of these and similar tests. We do not agree with the CMS statement that other codes are used by CMS for payment of “the underlying clinical laboratory tests on which the MAAA is done.” MAAA tests have existed for years and providers who performed these tests billed for them using the “stack” codes (83890-83914) and/or unlisted codes, with reimbursement being determined by the individual Medicare Administrative Contractors (MACs).

Contrary to CMS’ assertion that other codes are used to pay for the underlying clinical laboratory tests on which the MAAA is done, in most cases the analytes in a MAAA do not have underlying codes. As a result, they would not be reported individually. Additionally, analysis of the analyte independent of the algorithm does not provide the same level of information, and tests of the individual analytes are frequently not offered because of their lack of independent clinical utility. 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.

Further, as of December 31, 2012, the stack codes describing molecular pathology methodologies that have previously been used to identify MAAA services will be deleted from CPT®. Any provider billing for an algorithmic analysis of the assays/analytes described in one of the new MAAA codes will be forced to use the applicable CPT code in order to conform with the standard CPT coding convention, which requires use of the CPT code that most accurately describes the service performed and instructs against use
of a code that merely approximates the service provided. As a result, providers will be caught between a rule requiring accurate coding and CMS’ failure to pay for that code.

**Recommendation 1:**

A final decision to not pay for MAAA test codes for CY 2013 will have significant and damaging implications for Medicare beneficiaries and a dampening effect on innovation and investment in advanced personalized diagnostics. Therefore, **AdvaMedDx strongly recommends that CMS withdraw its proposed payment determination for MAAA tests and issue a final payment determination that recognizes the value of these tests.** Given the lack of other appropriate code descriptors, AdvaMedDx further recommends that CMS reimburse the MAAA codes included in the 2013 Edition of CPT® and listed on the CLFS using either the crosswalk or gapfill methodologies.

**Process and Transparency**

Finally, AdvaMedDx has previously commented on CMS’ process for making payment determinations for the test codes that are paid under the CLFS, particularly regarding the transparency of that process. While we appreciate the opportunity to provide input – at the annual Clinical Laboratory Public Meeting and in the preliminary payment determinations – it is unclear whether and to what extent the Agency takes such comments into consideration in making its determinations.

For example, in the preliminary payment determinations for CY 2013, CMS rejected the industry recommendation to crosswalk a new code (827XX, Galectin-3) to either CPT code86252 or 83880, and instead recommended a crosswalk to 83520 *(immunoassay, qualitative, not otherwise specified).* The CMS rationale for rejecting the industry recommendation referenced one public meeting presenter who stated that 827XX and 83520 use the same testing methodology. CMS also noted that the CPT code application to the AMA indicates that providers currently report the test using the unspecified immunoassay code. (NOTE: This would make sense if the application for a specific code was still pending.) Finally, CMS stated that “other commenters suggested a crosswalk to code 82652 or code 83880 without explanation of a rationale other than stating without documentation that these codes represent comparable resources.”

However, at least one commenter at the public meeting provided detailed information in support of the recommendation to crosswalk code 827XX to CPT codes 86252. That commenter’s presentation included technical and clinical comparability information, as well as a resource-based analysis of the costs required to perform the test.3 Other commenters provided additional data in support of the industry payment recommendation as well. The CMS rationale does not appear to

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3 See Peter Gardiner, MB ChB, MRCP, FFPM, Medical Affairs Consultant, BG Medicine *(handouts presented at Clinical Laboratory Public Meeting, July 16, 2012).*
consider the more detailed information that was presented to the agency. We urge CMS to consider all stakeholder input, and cross-walk new codes to existing codes that describe comparable tests, based on technical, clinical and resource-use data. 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 it arrived at its decision, including discussion of the applicable evidence used to support that decision.

**Recommendation 2:**

As we have previously noted, CMS has frequently failed to adopt the recommendations it receives, and often the rationales for CMS' payment determinations provide insufficient detail to allow stakeholders to understand the basis for their determinations, as in the case of the codes discussed above. **AdvaMedDx again urges CMS to provide more complete rationales for its preliminary determinations, comparable in content to proposed rule comments. This change will promote increased stakeholder understanding and may improve the effectiveness of comments on the proposed payment determinations.** We also urge CMS to make data and comments associated with the public meeting more readily available to stakeholders via the internet or other means.

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AdvaMedDx appreciates this opportunity to provide these comments. If you have any questions or require any additional information, please do not hesitate to contact Chandra Branham on my staff at cbranham@advamed.org or (202) 434-7219.

Sincerely,

[Signature]

Ann-Marie Lynch
Executive Vice President,
Payment & Health Care Delivery Policy

Cc: Elizabeth Richter
Marc Hartstein
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