October 25, 2013

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 2014 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 New and Reconsidered Test Codes paid under the Medicare Clinical Laboratory Fee Schedule (CLFS) for CY 2014. Our primary concerns relate to CMS’ preliminary determination regarding Multi-analyte Assays with Algorithmic Analysis (MAAAs). **We urge CMS to reverse its preliminary payment determination with respect to MAAA codes and to adopt the industry recommendations, enumerated below, regarding payment for these tests.**

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.

AdvaMedDx recommends that CMS adopt the following recommendations which will be discussed in greater detail throughout these comments:

- **AdvaMedDx urges CMS to withdraw its proposed payment determination and issue a final payment determination that recognizes the value of MAAA tests.**
- **AdvaMedDx further recommends that CMS reimburse any MAAA code included in the 2014 Edition of CPT® and listed on the CLFS using either the crosswalk or gapfill methodologies.**
What are MAAAs?

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 rely on analyses of substances in the body, as do other clinical laboratory tests. However, MAAAs are not simply a consolidation of information from a number of equally weighted component analyses. 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. MAAAs are discrete tests with distinct results.

CMS states in its CY 2014 preliminary payment determinations that “[a]t this time, it does not appear that there is a single, consistent definition for a MAAA.” However, the American Medical Association (AMA) has defined MAAAs 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. MAAAs are typically unique to a single clinical laboratory or manufacturer. The results of individual component procedure(s) that are inputs to the MAAAs 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

MAAAs have been in routine clinical use for years. Until recently, they have not been identified by specific CPT codes. Prior to 2013, providers 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, regularly paid for the tests. Beginning in 2013, the AMA CPT Editorial Panel, as part of its overhaul of molecular diagnosis codes, created a mechanism for establishing MAAA codes to provide granularity and specificity so payers would know what they are paying for when a MAAA test is ordered, reported and billed. Additionally, the stack codes describing molecular pathology methodologies were deleted from CPT®, effective January 1, 2013. Deletion of the stack codes means that providers must now use a specific MAAA code or an unlisted code to bill for these tests.

The development of MAAAs, including the algorithmic component, is complex, and substantial investment is needed to ensure that these tests are scientifically and clinically validated. Though the development costs 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, saving the healthcare system money and avoiding potential adverse effects for the patient.

**CMS’ Preliminary MAAA Payment Determination**

In comments made during the two most recent CMS Annual Clinical Laboratory Public Meetings (July 2012 and July 2013), interested stakeholders recommended that payment for MAAAs be determined using various combined cross-walks to existing laboratory codes or the gapfill methodology.

In August 2012, CMS released preliminary payment determinations for new and reconsidered codes for tests paid under the Clinical Laboratory Fee Schedule (CLFS) that rejected stakeholder recommendations related to payment for MAAAs. In that determination, CMS 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.”

This year, in September 2013, CMS reiterated that it will not recognize certain MAAA codes as valid for Medicare purposes, this time stating that there is no single, consistent definition for a MAAA. The Preliminary Payment Determination for CY 2014 further stated, “An algorithm is not a clinical diagnostic test. The CLFS only pays for clinical diagnostic laboratory tests,” and thus the MAAA codes under consideration are “not payable under the CLFS.”

**The Proposal is Inconsistent with Current Policy**

AdvaMedDx is greatly concerned that CMS’ current position will have widespread implications for other test payments. A blanket policy not to pay for the algorithms used in an MAAA is inconsistent with current Medicare policy. In fact, 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

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3 Id.

HIV phenotype susceptibility using bioinformatics, PT/INR (prothrombin time) testing, and flow cytometry.

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 very clear clinical decision-making. The algorithmic component of MAAs 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 development and use of MAAs present an opportunity for greater efficiency and consistency in diagnosis.

**No Underlying Codes for Many MAAs**

CMS’ current position represents a radical departure from CMS’s historic treatment of MAAs and raises significant concerns regarding the future treatment of these and similar tests. MAAs have existed for years. Prior to 2013, providers who performed these tests billed them using unlisted or stack codes (83890-83914) with reimbursement being determined by the individual Medicare Administrative Contractors (MACs).

Additionally, though codes exist for many of the individual assays/analytes tested via an MAA, the analysis of these assays/analytes independent of the algorithm does not provide the same level of information. In many instances, tests of the individual analytes lack 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.**

Finally, providers who bill for an algorithmic analysis of the assays/analytes described in one of the new MAA codes should 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. Under CMS’ current policy, providers will be caught between a rule requiring accurate coding and CMS’ failure to pay for that code.

**Recommendation**

A final decision not to pay for MAA test codes for CY 2014 has significant implications for advanced personalized diagnostics, including having a dampening effect on innovation and investment in these tests. **AdvaMedDx strongly recommends that CMS issue a final payment determination that recognizes the value of MAA tests. Given the unavailability of other appropriate code descriptors, AdvaMedDx further recommends that CMS reimburse any MAA code included in the 2014 Edition of CPT® and listed on the CLFS using either the crosswalk or gapfill methodologies.**
AdvaMedDx appreciates this opportunity to provide these comments. If you have any questions or require any additional information, please do not hesitate to contact me at cbranham@advamed.org or (202) 434-7219.

Sincerely,

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

Cc: Elizabeth Richter
   Marc Hartstein
   Ann Tayloe-Hauswald