Biotechnology Industry Organization

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Calendar Year 2013 Centers for Medicare and Medicaid Services (CMS) New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes and Preliminary Payment Determinations

Dear Ms. Tavenner,

The Biotechnology Industry Organization (BIO) appreciates the opportunity to submit comments on the *New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes and Preliminary Payment Determinations* published by the Centers for Medicare and Medicaid Services (CMS) on August 31, 2012. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnologies, thereby expanding the boundaries of science to benefit society by providing better healthcare, enhanced agriculture, and a cleaner and safer environment. Specifically related to advanced personalized diagnostic products, a number of BIO companies develop and market *in vitro* diagnostic technologies for a variety of research, investigational, and clinical uses. BIO is deeply concerned with CMS' payment proposal regarding Multi-Analyte Assays with Algorithmic Analyses (MAAAs), and is concerned generally with the lack of transparency in the process through the annual CLFS meeting and publication of the proposed payment methodologies. BIO believes these proposed payments will threaten access to molecular pathology tests by Medicare beneficiaries and have a devastating impact on the advancement of personalized medicine.

1201 Maryland Avenue SW
Suite 900
Washington DC 20024

202.962.9200 P
202.488.6301 F
bio.org

I. Payment for MAAAs Should Be Based on a Rate for the Entirety of the Test, Which Includes the Associated Algorithm

MAAAs are a category of Common Procedural Terminology (CPT) codes created by the American Medical Association (AMA) to describe advanced personalized diagnostic tests that contain an algorithm as a necessary part of the test. These tests produce results from multiple analytes, which taken together may be interpreted to indicate clinically useful information. Importantly, the results of these tests individually are not likely to provide the physician any clinically useful information. The results cannot be separated from the algorithm and be interpreted independently. The benefit provided by MAAAs is the clinically-validated algorithm, which is the critical component of the MAAA diagnostic result that provides value to the individual patient. These algorithms are not simply a calculation on general attributes (*e.g.*, age, stage and grade) then placed in a simple calculation to produce a result, these sophisticated bioinformatics are integrated into the wet lab process and provide individual patient information based on serum, blood or gene/protein expression which is truly personalized to only one patient. Accordingly, MAAAs are distinct clinical laboratory tests, which should be paid based on a payment rate assigned the entirety of the test – the algorithm is not separable from the underlying assays that provide the data.

CMS' proposal to separate the algorithm function of the tests and not provide payment misunderstands the nature of these tests. As a parallel example, consider payment under the Medicare system for magnetic resonance imaging (MRI). CMS' proposal to exclude payment for the algorithm portion of MAAAs is akin to refusal to pay for the software and monitor for a physician to interpret the result. What use would all of the various pieces of data collected by the MRI machine be to a physician without the software and monitor to view the image? CMS clearly provides for payment in these contexts through indirect practice expenses and the inclusion of amortization of equipment. Why is the agency singling out the useful and necessary part of MAAAs (*i.e.*, the algorithm) to deny payment?

II. The Proposal to Separate and Exclude Payment for the Algorithm Component of MAAAs Fails to Account for the Value Provided By These Tests

As stated above, MAAAs are multi-analyte tests that are validated in clinical trials against a clinical outcome (*e.g.*, presence or absence of disease) to produce a single probability score or diagnosis. Many of these tests are proprietary, and substantial investment is made into developing the algorithm, and conducting the studies necessary to validate it in the clinic. Many MAAAs are currently used in the clinic and are recognized as the standard of care for the diagnosis of certain conditions, or for the high-value prediction or monitoring of therapeutic response. The creation of new codes to describe these tests does not mean that these tests are new. Rather, the new codes were created to provide better clarity and specificity in billing practices for providers submitting claims for these tests. Indeed, Medicare contractors have paid for these tests in their entirety for years, and should continue to pay for these tests where demonstrated to be clinically valid.

Notwithstanding whether the proposal is based on a misunderstanding of the nature of MAAAs, CMS clearly pays for algorithms in other contexts. As one example, CMS has for years paid for HIV genotypic drug resistance tests (CPT 87900) -- a test that uses an algorithmic analysis to predict antiretroviral drug response. The proposal to exclude algorithms from payment in MAAAs is inconsistent with the precedent set by the agency's historical practice, and treats these products differently than products that have been paid under the Medicare system for years.

The valuable, clinically-actionable information derived from these clinical laboratory tests is the score provided by the algorithm. The underlying data points are not typically provided to the physician, and would likely not provide any actionable information. Again, the value to Medicare beneficiaries for MAAAs lies in the score produced by the clinically-validated algorithm (*e.g.*, the patient specific clinical laboratory result),, which provides the physician with useful information relating to a diagnosis or clinical outcome. To further a policy that encourages the pricing of these tests in the absence of the necessary interpretive information is scientifically invalid, and threatens the integrity of the application of evidence-based medicine to Medicare beneficiaries.

III. Failure to Account for Algorithms in Payment for MAAAs Will Have a Disastrous Affect on the Advancement of Personalized Medicine

CMS' proposal to not acknowledge value and provide for pricing of algorithms stands juxtaposed to the direction of scientific advancement in the way medicine is practiced for improved patient and health-economic outcomes. Our understanding of the pathogenesis and management of disease is growing exponentially; therefore, algorithms and data management methodologies to assist physicians with patient management will be critical to advancing healthcare for Medicare beneficiaries. As communicated in this proposal, the agency seems willing to pay for a clinically-actionable result only if it is simple, and based on a single analyte. This is simply not consistent with the complexity inherent in science, and our current understanding of biological processes. The wealth of data that will inevitably come with our increased understanding of the pathogenesis and management of disease should be embraced by CMS, and payment systems must be set-up to provide appropriate and adequate reimbursement for the value these products provide to Medicare beneficiaries.

Advanced personalized diagnostic tests are currently in the marketplace and have demonstrated improvements in patient care and saved costs within the overall healthcare paradigm. To categorically exclude payment for them does a disservice to Medicare beneficiaries who will be unable to access these tests. Patients will, for example, be treated with individually-ineffective and potentially unnecessary interventions, or be subjected to needless invasive procedures.

This proposal to not separately price for the algorithm portion of MAAAs will have a devastating effect on innovation in medicine and the advancement of personalized medicine. BIO urges CMS to reverse this proposal and set payment rates for MAAAs based on the value provided by the entirety of the clinical laboratory test, which necessarily includes the algorithm component.

IV. The Lack of Transparency in the Assignment of Payment Determinations to Products Paid Under the CLFS Threatens Patient Access

BIO is also concerned with the lack of transparency in the assignment of payment determinations for products paid under the CLFS. Without adequate stakeholder input, CMS risks undervaluing important tests and services provided to Medicare beneficiaries, which could result in problems with access to these technologies. During the CLFS meeting, interested stakeholders submit proposals on how these products should be priced, based on recommendations to gapfill or via specific recommendations on how to crosswalk the new codes. Typically, the new and reconsidered code payment determinations are published with very little explanation of why the agency decided to take a different approach. These decisions should be explained and justified, or the process created through the annual meeting risks losing its purpose. BIO encourages CMS to provide detailed explanations in future publications of the proposed payment determinations in situations where the agency does not follow the recommendations of stakeholders from the annual meeting.

BIO would also be glad to help the agency identify the critical factors that the contractors will use to determine the payment rates through the gapfilling process.

****

BIO appreciates the opportunity to provide these comments, and would be happy to work with the agency to address any of the concerns raised herein.

Respectfully Submitted,

Paul Sheives, JD
Director, Diagnostics and Personalized Medicine Policy