October 23, 2015

American
Clinical Laboratory
Association

VIA EMAIL

Glenn McGuirk
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Mail Stop C4-04-04
7500 Security Boulevard
Baltimore, MD 21244

Re: Preliminary Determinations on 2016 CLFS Tests: MAAA testing and other issues.

Dear Mr. McGuirk:

On behalf of the American Clinical Laboratory Association ("ACLA"), we are pleased to present these comments on the 2016 Clinical Laboratory Fee Schedule (CLFS) Preliminary Determinations that were released by CMS on September 25. In these comments, we will address the issues of pricing for the tests that qualify as Multi-analyte Assays with Algorithmic Analyses (MAAA). We are filing a separate statement on issues related to the Drugs of Abuse testing. As you know, ACLA represents clinical laboratories across the nation, including local, regional, and national laboratories. Many of the laboratories that have MAAA codes are ACLA members and will be directly affected by the changes made in the Preliminary Determinations.

MAAAs are a category of CPT codes created by the AMA to describe advanced personalized diagnostic tests that contain an algorithm as a necessary part of the test. MAAAs 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 has been made in developing the algorithm, as well as in conducting the studies necessary to validate the patient-specific scores resulting from the analysis and algorithm. Today, many MAAAs are recognized as the standard of care for the diagnosis of certain conditions, or for the high-value prediction or monitoring of therapeutic response. These MAAA tests are exactly the types of significant advances that are the subject of the Precision Medicine Initiative, which was recently announced by the White House.

The algorithms of MAAA tests involve analyses that are integrated into the "wet lab" process and provide individual patient information based on DNA, RNA, or protein information. Importantly, the results of the individual biomarker components standing alone will provide the physician with little clinically useful information. The individual biomarker results of these tests cannot be separated from the algorithm and the algorithm itself is too complex for the physician to apply to the test components on his or her own.

In its Preliminary Determinations, CMS proposed cross-walking these MAAA codes to other tests on the CLFS. If finalized, these cross-walks would result in a payment cut of 30-90

percent, which in many instances will mean that the laboratory offering the test will have to stop doing so. [1] Because many of the laboratories affected offer only a small number of tests, the significant cuts proposed will force many of these companies to go out of business, leaving the physicians and patients who rely on these tests without any means to obtain them. In most instances, the reimbursement levels established by the cross-walk fail to recognize the value of the underlying algorithm and the central role it plays in the utility of the test. While ACLA believes that Medicare should only pay a fair and appropriate amount for any medical service, in this case it appears CMS's proposal will significantly under-reimburse for these very valuable tests.

First, it is inappropriate for CMS to cross-walk these tests, rather than gap-fill them. According to CMS's own regulations, cross-walking is only to be used when a new test is comparable to an existing test, multiple existing test codes or a portion of an existing test code.[2] Gapfilling is to be used if it is determined that no comparable test exists on the CLFS. [3] In this case, CMS has cross-walked to other tests that are totally different from the MAAA tests at issue. These tests used for cross-walking differ in virtually all respects: the indications; the type of testing; the methodology; the equipment used; and the underlying costs. Most importantly, none of the tests that are the basis for the cross-walk include an algorithm. Therefore, it seems difficult to see how they could be determined to be comparable. As a result, CMS's own regulations seem to require that these tests be gapfilled.

Further, CMS's own history supports the use of gapfilling for these tests. In the Final Determinations for 2014, CMS explained that it could not make a categorical determination of how to pay for specific MAAA tests. Therefore, it stated that it would leave it up to the contractors to determine if a test was payable and if so, then the contractor was to gapfill the test. As a result, local Medicare contractors have already established rates for these tests through careful consideration of a number of factors, including market rates and resources required to perform the tests. Just last year, CMS determined that it was appropriate to gapfill another MAAA test, CPT 81519, that is directly comparable to the MAAA codes under review here. It is difficult to see what has changed in a year, which now makes cross-walking more appropriate.

It is also important to note that CMS's Advisory Committee on Clinical Diagnostic Laboratory Tests, which was established to advise CMS on "the establishment of payment rates …including whether to use cross-walking or gapfilling processes…"[4] has twice voted overwhelmingly that these tests should be gapfilled, rather than cross-walked. Given the expertise of this committee, and the specific purpose for which it is established, CMS should give great weight to their recommendations.

Finally, there should no longer be any doubt that CMS is permitted to pay for MAAA tests, including the algorithm. PAMA itself recognizes algorithms as a distinct part of the

[1] A summary of the codes, and the projected cuts, as well as the recommendations of stakeholders is attached in Appendix A.
[2] 42 C.F.R. § 414.508(a).
[3] *Id*. at §414.508(b).
[4] PAMA, §216(f)(1).

definition of an ADLT. [5] The whole purpose of including the language in PAMA was to clarify that Medicare would pay for MAAA tests, including the algorithm. Medicare contractors have paid for these tests in their entirety for years through Local Coverage Determinations, and Medicare should continue to pay for these tests where demonstrated to be clinically valid. Of course, once the new process envisioned by PAMA goes into effect, in most instances these tests will be priced based on the weighted median of private payor rates, rather than on the gapfilling or cross-walking approaches discussed here.

In conclusion, CMS's proposed crosswalks for these MAAAs are inconsistent with past agency precedent, and against the vast majority of stakeholder input, as well as the recommendations of the Advisory Committee. CMS ignored the almost universal recommendations to gapfill, and instead proposed inappropriate and draconian payment cuts. Not only would this decision affect these particular tests, it sets a dangerous precedent for the future payment of innovative tests in the area of precision medicine.

Thank you for your consideration. If you have any questions or need any further information, please do not hesitate to contact us.

Sincerely

JoAnne Glisson
Senior Vice-President

cc: Marc Hartstein

[5] *Id.* at §216 (d)(5).

APPENDIX A

Code	Description	Advisory Panel Recommendation August 26, 2015	CMS Preliminary Determination September 25, 2015	Percent Cuts Under CMS Proposed Crosswalk	Coalition Recommendation October 19, 2015
81490	Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score	Gapfill	Crosswalk	-64%	Gapfill
81493	Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score	Gapfill	Crosswalk	-39%	Gapfill
81525	Oncology (colon), mRNA, gene expression profiling by realtime RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score	Gapfill	Crosswalk	-79%	Gapfill
81535	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination	Gapfill	Crosswalk	-5%	Gapfill
81536	+ Each additional single drug or drug combination (List separately in addition to code for primary procedure)	Gapfill	Crosswalk	-84%	Gapfill

Code	Description	Advisory Panel Recommendation August 26, 2015	CMS Preliminary Determination September 25, 2015	Percent Cuts Under CMS Proposed Crosswalk	Coalition Recommendation October 19, 2015
81538	Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival	Gapfill	Crosswalk	-91%	Gapfill
81540	Oncology (tumor of unknown origin), mRNA, gene expression profiling by real-time RT-PCR of 92 genes (87 content and 5 housekeeping) to classify tumor into main cancer type and subtype, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a probability of a predicted main cancer type and subtype	Gapfill	Crosswalk	-51%	Gapfill
81545	Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)	Gapfill	Crosswalk	-33%	Gapfill
81595	Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score	Gapfill	Crosswalk	-77%	Gapfill