October 26, 2015

VIA ELECTRONIC MAIL: glenn.mcguirk@cms.hhs.gov

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CY 2016 New Clinical Laboratory Fee Schedule Test Codes and Preliminary Gapfill Payment Determinations

Dear Acting Administrator Slavitt:

On behalf of the Coalition for 21st Century Medicine (the "Coalition"), please accept these comments on the preliminary payment determinations for new Clinical Laboratory Fee Schedule test codes for 2016 published by the Centers for Medicare and Medicaid Services (CMS) on September 25, 2015.

The Coalition represents the world's most innovative diagnostic technology companies, clinical laboratories, researchers, physicians, venture capitalists and patient advocacy groups – all linked by a common mission: To develop and commercialize state-of-the-art diagnostics that improve patient health.

The Coalition appreciates CMS' efforts to determine the appropriate methodology to price new or substantially revised codes on the Clinical Lab Fee Schedule (CLFS), but **we disagree with CMS' preliminary decision to use crosswalking as the methodology for determining pricing for the nine recently established codes for eight Multianalyte Assays with Algorithmic Analyses (MAAAs)** that are subject to review for 2016. As you know the codes presented for pricing determinations at this year's July public meeting, and which were subsequently reviewed by the CLFS Advisory Panel, are not new tests; rather, they are merely new codes. In fact, long before being assigned Category I CPT® codes effective January 1, 2016, each of these tests were covered and paid for by Medicare. The rates under which these tests have been and are currently being paid were established by the Medicare's Administrative Contractors (MACs) through extensive discussion with the laboratories and review of substantial information to support the rates adopted. The proposed payment amounts came as a shock to the affected laboratories, and caused substantial disruption in capital markets and among the laboratories, physicians and patient groups who rely on these tests. For the reasons set forth below, **we urge CMS to refer these tests to the MACs to determine payment amounts for these nine codes using the gapfill methodology**.

CMS SHOULD REFER THE MAAA CODES TO MEDICARE CONTRACTORS TO ESTABLISH PAYMENT RATES USING GAPFILL

Crosswalking is not the correct method to price these codes. Crosswalking was established as a method to allow CMS to set Medicare payment rates for tests with similar characteristics. In fact, by regulation, crosswalking is appropriate when "a new test is comparable to an existing test, multiple existing tests, or a portion of an existing test code."[1] In the past, crosswalking has been used to assign the National Limitation Amount (and locality specific fees as well, if lower) of an existing test code to a new test code when the two tests measured similar analytes using similar methodologies, and when CMS determined that the tests required similar levels of technical resources to perform.

By contrast, gapfilling is used when there are no analogous test codes on the CLFS. The gapfilling process allows local contractors to review data addressing test charges and discounts, resources specific to a test, rates paid by other payers for the test, and rates paid by the contractor for similar tests in order to determine an appropriate payment rate. During the gapfilling process, contractors will frequently work closely with laboratories to understand the gapfill factors associated with a particular test, using that information to determine the contractor's payment amount.

In the case of the MAAA codes being reviewed, there are no comparable test codes currently on the CLFS. MAAA tests are unlike any other test on the CLFS insofar as no other lab tests utilize results derived from a number of different assays (many of which have no established codes or rates), processed through an empirically derived algorithm in order to produce a patient specific result. Even the Molecular Pathology tests coded in the 81161-81479 CPT® series do not describe tests that are sufficiently comparable to MAAA tests as to be used as accurate crosswalks.

The American Medical Association (AMA) recognized the unique nature of MAAA tests when it established new codes and the MAAA section of the CPT®. The AMA recognized that there was no other code or groups of codes within the existing coding structure within which MAAA tests would fit, or which were comparable to MAAAs, and that CPT® should develop a distinct category where each code references a distinct, specific test.

CMS has consistently concurred that MACs are best positioned to determine payment rates for MAAA codes, and as such directed that gafilling be used to price these tests. Each of the laboratories that developed the tests subject to review this year have previously worked with local MACs to review their MAAA tests and establish both coverage and payment for their test. In addition, as part of those discussions, the MACs agreed that these 8 tests should be reported using unlisted procedure codes because no established codes alone or in combination described these specific MAAA tests.

At the July 2015 public meeting, the Coalition and other stakeholders with knowledge of and interest in these tests recommended that CMS publish the existing payment rate established by

[1] 42 C.F.R. § 414.508(a).

the MACs that issued the tests' local coverage determination. One presenter speaking on behalf of the American Association for Clinical Chemistry recommended crosswalking for these tests. The AACC has since retracted this recommendation, and submitted comments to CMS saying, "we believe that these MAAA tests are not comparable to the test codes that are currently on the Clinical Laboratory Fee Schedule [and]…gapfill is the most accurate and appropriate methodology for determining payment rates for the MAAA test codes…."[2] The Coalition's July recommendation was premised on our reading of §1834A(e)(2) of the Social Security Act (as added by section 216 of the Protecting Access to Medicare Act of 2014). Specifically, we understand the mandate that CMS "publicly report the payment rate for the test" by January 1, 2016" to mean that CMS must adopt and report for 2016 the payment rate in effect as of the date of enactment. After extensive, productive discussion with CMS, we now understand that the agency does not presently concur with that reading, because it has not yet issued a final regulation defining the term "Advanced Diagnostic Laboratory Test," among other things.

In light of the agency's interpretation, we now recommend that CMS refer the MAAAs to the MACs to determine payment amounts using the gapfill methodology. This recommendation accomplishes the same objective we had with our initial recommendation in July—leaving ratesetting to our local MACs (who have already completed a ratesetting exercise). This recommendation is endorsed by the AMA, the American Clinical Laboratory Association, and the AACC. This recommendation is also endorsed by CMS's CLFS Expert Advisory Panel, which has now twice recommended that CMS use gapfill to price these codes. Congress established this panel through PAMA to provide CMS with expert advice on the use of gapfilling or crosswalking to price new test codes.[3] This panel consists of experts, including pathologists and experts in laboratory medicine and other stakeholders from academia, hospitals and laboratories. This expert panel convened on August 26, 2015, to review the new codes, and after deliberation, recommended that CMS gapfill the MAAA codes in 2016. This panel met again on October 19, 2015, and affirmed its original recommendation.

CMS' PRELIMINARY PRICING DETERMINATION SEVERELY UNDERVALUES THESE TESTS AND WILL NEGATIVELY IMPACT BENEFICIARY ACCESS TO THE TESTS

Under CMS's preliminary determinations, payment amounts for these tests would be significantly cut, in some instances by as much as 90 percent.

Code	Test Name (Laboratory)	Test Description	Medicare Contractor Rate	CMS Preliminary Determination	Percentage Cut
81490	Vectra® DA (Crescendo Bioscience)	Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score	$586.50	$211.44	-64%

[2] Letter from David Kock, President, American Association for Clinical Chemistry, to Glenn McGuirk, October 9, 2015.
[3] Social Security Act §1847A(f)(1).

Code	Test Name (Laboratory)	Test Description	Medicare Contractor Rate	CMS Preliminary Determination	Percentage Cut
81493	Corus® CAD (CardioDx)	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	$1,050.00	$644.64	-39%
81525	Oncotype DX® Colon Cancer Assay (Genomic Health)	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	$3104.00	$644.62	-79%
81535	ChemoFX® (Helomics)	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	$696.92	$664.98	-5%
81536	ChemoFX® (Helomics)	+ Each additional single drug or drug combination (List separately in addition to code for primary procedure)	+ $387.74	$35.48	-91%
81538	VeriStrat (Biodesix)	Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival	$2112.00	$196.64	-91%
81540	CancerTYPE ID (bioTheranostics)	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	$2900.00	$1,434.54	-51%
81545	Afirma® Gene Expression Classifier (Veracyte)	Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)	$3200.00	$2,151.81	-33%
81595	AlloMap® (CareDx)	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	$2821.00	$644.64	-77%

Payment reductions of this magnitude compared to current contractor rates will impede each laboratory's ability to continue to provide these tests, and will impact beneficiary access. Ultimately, this will result in poorer patient outcomes and increased costs to the Medicare

program. In addition, continued innovation in this critical area of precision medicine will be threatened as investors will not commit funds to developing tests where payment is this volatile.

CONCLUSION

By selecting the gapfill process, CMS will be referring these tests to the local contractors that initially established payment amounts. The contractors will recommend payment amounts to CMS that will apply in 2017, unless CMS implements the new ratesetting process established by PAMA on January 2017, as required under the law, and as proposed by CMS on October 1st.[4] In the meantime, during calendar year 2016, the payment amounts established by the contractors, which are currently in effect, should and will remain in effect.

For the foregoing reasons, we strongly recommend that the CMS reconsider its preliminary determination and instruct the MACs to continue to locally price these tests using the gapfill process in 2016.

Please contact me at _____ or at _____ if you have any questions.

Sincerely,

[4] 80 *Fed. Reg.* 59,386 *et seq.* (Oct. 1, 2015).