July 12, 2016

Mr. Glenn McGuirk
Division of Ambulatory Services
Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: 2016 Preliminary Gapfill Payment Determinations for New MAAA CPT Codes: 81493, 81525, 81538, 81540, 81545, 81595

Dear Mr. McGuirk**:**

On behalf of the Coalition for 21st Century Medicine (C21) and the six member laboratory providers listed below, we are pleased to submit comments in response to the 2016 Preliminary Gapfill Payment Determinations for six new Multianalyte Assays with Algorithmic Analyses (MAAA) Current Procedural Terminology (CPT®) codes for existing advanced diagnostic tests.

The Preliminary National Limitation Amounts (Preliminary NLAs), which appear to be based upon the median of rates submitted for these codes for each of the 57 Medicare localities, if finalized, would represent drastic reductions in payment rates for these innovative tests in the magnitude of approximately 30-percent to 90-percent. These Preliminary NLAs are determined by a 29 to 28 locality split among the Medicare Administrative Contractors (MACs) who reported rates for these six tests. Although we have transparency and a clear relationship to the four regulatory criteria for gapfill in 28 of the localities, there is neither transparency nor any apparent relationship to the gapfill criteria among the rates posted for the other 29 localities.

The NLAs must be adjusted in the 2016 Final Gapfill Payment Determinations to comply with the regulatory criteria for gapfill, to avoid substantial fluctuations in payment prior to and with the implementation of Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA 216), and to assure continued access to these advanced diagnostic tests, which the regional MACs where the laboratories are located have determined to be reasonable and necessary and valuable services for Medicare beneficiaries.

Background on New MAAA CPT Codes

In 2015, the AMA CPT Editorial Panel developed test-specific codes to facilitate data collection and reporting for several existing advanced diagnostic tests. These existing advanced diagnostic tests, the laboratories that developed the tests, the CPT® codes adopted for 2016, and the uses of the tests are shown in Table 1, below:

Table 1: Tests and Clinical Uses

Code	Test *Laboratory*	Clinical Use
81493	Corus CAD *CardioDx*	A non-invasive blood test that incorporates age, sex, and gene expression into a single score that can be used, in combination with clinical assessment, to help clinicians identify patients unlikely to have obstructive coronary artery disease as a cause of their symptoms and help determine appropriate next steps for patient management.
81525	OncotypeDx Colon *Genomic Health*	A multi-gene test for predicting recurrence risk in patients with stage II and stage IIIA/B colon cancer to enable an individualized approach to treatment planning.
81538	VeriStrat *Biodesix*	A blood-based predictive and prognostic proteomic test for patients with advanced non-small cell lung cancer who test negative for EGFR mutations (EGFR wild-type) or whose EGFR mutation status is unknown. Assesses disease aggressiveness, classifying patients as either Good or Poor.
81540	CancerTypeID *Biotheranostics*	A molecular cancer classifier that helps identify the site of origin for cancers with indeterminate, uncertain, or differential diagnoses. The test uses real-time RT-PCR to measure the expression of 92 genes in the patient's tumor and classifies the tumor by matching the gene expression pattern of the patient's tumor to a database of known tumor types and subtypes, encompassing 50 tumor types.
81545	Afirma *Veracyte*	The Gene Expression Classifier (GEC) measures the expression of 142 genes to determine if the FNA sample that was originally classified by cytopathology as indeterminate is benign or suspicious for cancer -- enabling patients with benign results to potentially avoid unnecessary surgery.
81595	Allomap *CareDx*	A non-invasive blood test that uses genomic technologies to identify the absence of cardiac rejection. When used in conjunction with standard clinical assessments, may help identify patients with stable allograft function who have a low probability of moderate to severe acute cellular rejection at the time of testing.

In November 2015, CMS assigned these test codes to be gapfilled in 2016 by the MACs. Each of these tests has been covered by the MAC in the jurisdiction where the test is performed and paid under a non-specific CPT code. Coverage and claims for five of these codes are governed by LCDs from Noridian (81493, 81525, 81540, 81545, and 81595). The other test code (81538) is currently covered and paid under a coverage policy from Novitas. The Medicare rates currently in effect for each of these tests under unlisted codes were established by the local MACs considering the four gapfill criteria. These rates have been in effect for a number of years.

2016 Gapfill Pricing Process

During the gapfill pricing process earlier in the year, each of the six laboratories submitted comments and information to the MACs for each test consistent with the gapfill criteria. These data included the Medicare testing volume, rates already established and paid by their local MACs, resources to perform the test, and rates established and paid by commercial payers including Medicare Advantage payers.

The current payment rates for five of the six tests (81493, 81525, 81540, 81545, and 81595) are established in the Noridian regions where the labs reside and all test claims are submitted. These current payment rates were submitted by CGS, Noridian, Palmetto, and WPS which comprise 28 of the 57 localities in the Preliminary Gapfill Determination spreadsheet posted by CMS. The rates posted by these four MACs for the 28 localities are the rates currently in effect and are consistent with the gapfill criteria as noted above and further explained more fully below.

In the case of the sixth test (81538), although its current rate was established by Novitas following the gapfill criteria, the rate posted by Novitas in the Preliminary Gapfill Determination is 87-percent less than the rate Novitas is actually paying for this test – this notwithstanding the fact that the laboratory provided Novitas with information, including Explanations of Medicare Benefits, showing the rate that has been established and paid by Novitas for this test. By contrast, in response to the information provided by that lab to CGS, Noridian, Palmetto, and WPS regions, these four regions did report the rate currently being paid by Novitas for the test.

The current Medicare rate, the Preliminary NLA, the percent reduction represented by the Preliminary NLA, and the rates reported by the MACs under the Preliminary Gapfill Determinations are shown in Table 2, below:

Table 2: Current Rates and 2016 Preliminary Gapfill Determinations

Code	Test/ *Laboratory*	Current Medicare Allowed Amount	Preliminary NLA	Change	***28 Localities*** CGS--*2* Noridian--*14* Palmetto--*4* WPS--*8*	***29 Localities*** Cahaba--*3* FCSO--*2* NGS--*12* Novitas--*12*
81493	Corus CAD *CardioDx*	$1,050.00	$741.01	-29%	$1,050.00 $1,050.00 $1,050.00 $1,050.00	$741.01 $731.49 $741.01 $731.49
81525	OncotypeDx Colon *Genomic Health*	$3,104.00	$848.86	-73%	$3,104.00 $3,104.00 $3,104.00 $3,104.00	$848.86 $848.86 $780.13 $848.86

Code	Test/ *Laboratory*	Current Medicare Allowed Amount	Preliminary NLA	Change	***28 Localities*** CGS--*2* Noridian--*14* Palmetto--*4* WPS--*8*	***29 Localities*** Cahaba--*3* FCSO--*2* NGS--*12* Novitas--*12*
81538	VeriStrat *Biodesix*	$2,112.00	$283.00	-87%	$2,112.00 $2,112.00 $2,112.00 $2,112.00	$283.00 $283.00 $187.21 $283.00
81540	CancerTypeID *Biotheranostics*	$2,900.00	$1,522.17	-48%	$2,900.00 $2,900.00 $2,900.00 $2,900.00	$1,522.17 $1,522.17 $1,268.14 $1,522.17
81545	Afirma *Veracyte*	$3,200.00	$2,240.16	-30%	$3,200.00 $3,200.00 $3,200.00 $3,200.00	$2,240.16 $2,240.16 $1,746.80 $2,240.16
81595	Allomap *CareDx*	$2,821.00	$732.12	-74%	$2,821.00 $2,821.00 $2,821.00 $2,821.00*	$597.31 $732.12 $705.24 $732.12

*WPS reported $2,821-$2,827 across its 8 localities.

As is clearly shown, the Preliminary NLAs would, if finalized, represent drastic cuts for these tests from the rates currently paid by Medicare—rates which have been established through deliberative consideration of the tests by the local MACs who are covering the tests. As is also clearly shown, four of the MACs representing 28 of the 57 localities have established gapfill rates consistent with the current Medicare rates. By contrast four other MACs—MACs that generally have no familiarity with the tests involved—have established rates that are dramatically, and inexplicably, lower than the current Medicare rates. Because the other four MACs represent 29 localities, the Preliminary NLAs are determined by those other MACs.

Applying the Four Gap-fill Criteria Leads to Assignment of the Rates Consistent with the Currently Established MAC Rates

Under Medicare regulations, the MACs are required to consider the following criteria when establishing gapfill rates:

*(b) **Gapfilling**. Gapfilling is used when no comparable existing test is available. (1) In the first year, carrier-specific amounts are established for the new test code using the following sources of information to determine gapfill amounts, if available:*

(i) Charges for the test and routine discounts to charges;

(ii) Resources required to perform the test;

(iii) Payment amounts determined by other payers; and

(iv) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

(42 C.F.R. 414.508(b)(1).)

Our members furnished information consistent with these criteria to the contractors that process their claims to support the establishment of the current Medicare rates for these tests. In addition, as noted above, our members furnished similar information generally to all MACs in support of the 2016 gapfill exercise. We have no transparency into how Cahaba, First Coast, NGS and Novitas may have used the data submitted to calculate the rates shown, but these cannot be based upon the gapfill criteria listed above.

Two of the four criteria relate to rates allowed by other payers. Criterion (i), in referring to charges and discounts, is referring to rates paid for the test by other payers. Criterion (iii) expressly refers to amounts determined by other payers. The current Medicare rates for these six tests are consistent with rates paid by commercial payers and Medicare Advantage payers. These private payer rates and current Medicare rates should be given substantial weight in the gapfill process under these defined criteria.

In terms of resources (criterion [ii]), many of our members submitted detailed information to their MAC comprising financial accounting data on resources expended to develop and run the tests involved and the numbers of tests over which such expenditures are applied. These data reflect the cost of research and development as well as laboratory operations. CMS has repeatedly acknowledged that research and development expenditures are valid and appropriate resources to consider to support rate-setting for clinical diagnostic laboratory tests. These data supported the current Medicare rates established by each laboratory's local MAC at the time of Medicare coverage, and these indicate that the Preliminary NLAs are inconsistent with the resources required to develop and perform these tests.

Criterion (iv) refers to tests that are comparable or otherwise relevant. As the six tests are MAAAs, by definition, they are unique tests for which there are no other comparable tests. It was because there are no comparable tests that CMS choose to gapfill these tests codes rather than crosswalk them to exiting codes on the CLFS.

Although we have no transparency into the basis for the rates submitted by Cahaba, First Coast, NGS and Novitas, it appears that the rates are close to those initially proposed in 2015 for crosswalk for these six tests. As you know, after considerable discussion and presentation of evidence last Summer, CMS rejected crosswalk to such rates for these tests. One cannot allow such rates to return through a backdoor, opaque process by MACs who generally have no familiarity with these tests or who are not considering their own previous pricing determinations.

<u>The Preliminary NLAs are not Consistent with PAMA 216 and Would Result in Substantial Fluctuations in Rates Pre to Post PAMA Implementation</u>

As noted above, the laboratories provided information to the MACs on commercial payer rates to support the establishment of the current Medicare rates. In addition, when we were

engaged with congressional staff on PAMA 216, we provided them information on commercial rates for several member tests. Therefore, we know the commercial payer amounts that will be reported to CMS in 2017 for these tests will support the establishment of rates under PAMA 216 that are consistent with the current Medicare rates. It would be very disruptive – and highly unreasonable – for current rates to be reduced by 30- to 90-percent in 2017 only to rise again under PAMA 216 in 2018.

Although PAMA 216 is not yet in effect, if it were implemented consistent with the statutory timeline, PAMA 216 rates would be in effect in 2017. As you may recall, the only reason the six labs sought new codes for 2016 was to allow reporting of rates this year to support establishment of PAMA 216 rates in 2017. It is clearly inconsistent with congressional intent to impose 30- to 90-percent reductions in rates for tests in the year prior to PAMA 216 implementation when PAMA 216 itself does not permit reductions in rates greater than 10-percent year-over-year for the first three years of implementation.

Failure to Adjust the Final NLAs to be Consistent with Current Medicare Rates Will Jeopardize Continued Access to these Reasonable and Necessary and Valuable Precision Medicine Tests for Medicare Beneficiaries

The laboratories that offer the six tests generally offer only a single test or at most a very limited menu of tests. For several of the laboratories, Medicare-aged beneficiaries are the largest recipients of the testing because of the demographics of the test indication. If reductions in rates are adopted for 2017, it will be difficult for the laboratories to continue to offer these tests, and some of the laboratories may not be able to survive at all. It is little comfort that PAMA 216 rates will be published at the end of 2017 and may reverse such reductions if the laboratories are unable to make it through 2017 due to the drastic reductions.

The tests discussed here are some of the most innovative, clinically valuable precision medicine tests that have been developed over the past 10 to 20 years. They have been shown to help avoid unnecessary chemotherapy, endomyocardial biopsy to identify transplant rejection, thyroid surgery to remove non-malignant glands, and cardiovascular diagnostic testing in patients at low likelihood for coronary artery disease. Health outcomes studies have shown the clinical and economic benefits of these tests. These are exactly the kinds of tests that the President's Precision Medicine Initiative is looking to advance to support the identification of therapies that are personalized to the needs of individual patients. It would be very unfortunate for Medicare beneficiaries and for the Medicare program as a whole if these tests were no longer available because four MACs submit rates for these tests that are inconsistent with the gapfill criteria and inconsistent with the rates that have already been well-established for the advanced diagnostic tests.

* * * *

Thank you for your consideration of our comments. We are happy to discuss this information with you and the MACs at your convenience.

Sincerely,

Coalition for 21st Century Medicine and on behalf of our members:

Biodesix
Biotheranostics
CareDX
CardioDX
Genomic Health
Veracyte