



August 1, 2016

Mr. Andrew Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244

**RE: 2016 Preliminary Gapfill Payment Determinations for New Genomic Sequencing Procedures Test Codes**

Dear Administrator Slavitt:

On behalf of the Coalition for 21st Century Medicine (C21), we appreciate the opportunity to submit comments in response to the 2016 Preliminary Gapfill Payment Determinations for new Genomic Sequencing Procedure (GSP) Current Procedural Terminology (CPT<sup>®</sup>) codes. This letter supplements our earlier comment letter submitted on July 12<sup>th</sup> regarding Multianalyte Assays with Algorithmic Analyses (MAAA) Current Procedural Terminology (CPT<sup>®</sup>) codes. We are concerned with the lack of transparency in the process used to make these Preliminary National Limitation Amounts (Preliminary NLAs), and with the negative impact on beneficiary access that they would have if finalized. The significant variability in the gapfill preliminary payment rates submitted by the Medicare Administrative Contractors (MACs) raises concerns that the MACs are not applying the gapfill factors consistent with the regulations.

C21 comprises many of the world's most innovative diagnostic technology companies, clinical laboratories, physicians, venture capital companies, and patient advocacy groups. Given C21's mission to facilitate development and commercialization of innovative diagnostic tests to inform important patient management decisions, we have a keen interest in the consistency and transparency of the gapfill process.

The Preliminary NLAs for the GSP codes must be adjusted in the 2016 Final Gapfill Payment Determinations to comply with the regulatory criteria for gapfill, and to avoid significant fluctuations in payment prior to the implementation of Section 216 of the Protecting Access to Medicare Act (PAMA) which could drastically limit beneficiary access to advanced diagnostic tests.

**Wide Variations in Pricing Amongst the MACs for GSPs**

We are concerned that wide variability among the MACs for these GSP codes (81412 – 81442) indicates that the gapfill criteria have not been appropriately applied. The differences in

Mr. Andrew Slavitt  
August 1, 2016

pricing among the contractors are inconsistent with established payer rates and the resources required to perform these tests. The rates reported by many of the MACs do not reflect an accurate application of the gapfill criteria and fail to recognize the work required to analyze multiple genes in a single assay. Under Medicare regulations, the MACs are required to consider the following criteria when establishing gapfill rates:

- (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.<sup>1</sup>

The preliminary rates are both inconsistent among the MACs and also with established payer rates. For example, code 81432 for hereditary breast cancer testing of 14 genes has a Preliminary NLA of \$622.53, and a related code 81433 used to describe the additional duplication/deletion analysis has a Preliminary NLA of \$159.48, as shown in the attached chart. In contrast, a code already on the Clinical Laboratory Fee Schedule (CLFS) describing a **combination** of these two procedures for only two genes, 81162, has a current NLA of \$2,485. The Preliminary NLAs represent a reduction of approximately 70% for testing hereditary breast cancer-related disorders when analyzing an additional 12 genes beyond those in 81162. An analysis of the other preliminary pricing amounts for GSP codes in the table below demonstrates no relationship between the length of genomic sequence or number of genes analyzed. In fact, even though the number of genes varies in the sequencing panels from six to fifteen, many of the preliminary rates are identical. These identical rates clearly fail to account for the varying resources required to validate, sequence and interpret increasing numbers of genes.

The Preliminary NLAs are inconsistent with the resources required to perform these tests based on the number as well as the size of the genes. In determining the resources involved in germline next generation sequencing testing, it is critical to look beyond just the number of genes. No two genes are alike or equal. Genes vary in size depending on the number of exons and even size alone is not a complete predictor of the work required. Some genes are far more difficult to analyze than others, regardless of size. Evaluating the number of exons in each gene, however, is an appropriate proxy method to determine the amount of work and complexity required for the full panel analysis. In fact, the Advisory Panel on Clinical Diagnostic Laboratory Tests members voiced support for determining the resources required for hereditary multi-gene panel GSP codes by assessing the number of exons analyzed in the test.

CPT code 81435 (hereditary colon cancer sequencing of at least 10 genes) has 132 exons and has a CLFS price of \$796 which was developed through last year's gapfill process. In contrast, CPT code 81432 which is also a hereditary sequencing procedure (hereditary breast/ovarian cancer sequencing of at least 14 genes) involves nearly twice as many exons with a total of 256 exons required in the analysis. The Preliminary NLA, however, is inexplicably lower at \$622.53. We note that one Medicare contractor (NGS) did provide rates for 81432 and

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<sup>1</sup> 42 C.F.R. 414.508(b).

Mr. Andrew Slavitt  
August 1, 2016

81433 that more closely reflect the codes' resources and complexity of exons at \$1153 and \$614 respectively. Based on the previous gapfilling of similar GSP codes for hereditary conditions (81435 and 81436), MACs should resubmit rates for 81432 and 81433 that align with the resources required as shown below:

<i>CPT Code</i>	<i>Descriptor</i>	<i>Number of Exons</i>	<i>Existing or (Proposed Rate)</i>
81435	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic <b>sequence analysis panel</b> , must include sequencing of at least <u>10 genes</u> , including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11	132	\$796
81436	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); <b>duplication/deletion analysis panel</b> , must include analysis of at least <u>5 genes</u> , including MLH1, MSH2, EPCAM, SMAD4, and STK11	62	\$796
81432	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic <b>sequence analysis panel</b> , <u>must include</u> sequencing of at least <u>14 genes</u> , including ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11, and TP53	256	2 x 81435 (\$1592)
81433	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); <b>duplication/deletion analysis panel</b> , must include analyses for [ <u>5 genes</u> ] BRCA1, BRCA2, MLH1, MSH2, and STK11	97	1.5 x 81436 (\$1194)

The only other previously priced GSP codes (81445<sup>2</sup> and 81455<sup>3</sup>) are not valid as comparable tests since these codes are for somatic testing which require different specimen types and lack variant interpretation work that is required with germline testing. As a result, the only previously priced GSP codes that are relevant comparators to the current germline GSP panel

<sup>2</sup> 81445 - Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed

<sup>3</sup> Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA and RNA analysis when performed, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed.

Mr. Andrew Slavitt  
August 1, 2016

codes are the hereditary colon cancer codes (81435/81436), each of which were gapfilled by the MACs last year at a payment rate of \$796. Since both CPT codes 81435 and 81436 were undergoing gapfill in 2015 they were not available for a crosswalk recommendation at the 2015 CLFS Public Meeting. Given the NLAs are now available for these codes, we urge the MACs to consider their previous gapfill work and use these codes as comparable to this year's new hereditary GSP codes.

Given previous gapfill efforts for similar codes, we believe the preliminary rates submitted by many of the MACs do not reflect a true and consistent application of the gapfill criteria for genomic sequencing procedures and we urge a resubmission of rates.

**The Preliminary NLAs are not Consistent with PAMA and Would Result in Substantial Fluctuations in Rates Pre- to Post-PAMA Implementation**

As we have noted in our earlier comment letter on the MAAA codes, it would be highly disruptive for current rates for these innovative tests to be so significantly reduced in 2017, as proposed by the Preliminary NLAs, only to rise again under when market based rates set the pricing in 2018. Although PAMA is not yet in effect, if it were implemented consistent with the statutory timeline, PAMA rates would be in effect in 2017. It is clearly inconsistent with Congressional intent to impose payment reductions in rates up to 70% for tests in the year prior to PAMA implementation when PAMA itself does not permit reductions in rates greater than 10-percent year-over-year for the first three years of implementation.

Further, PAMA requires that when CMS is using the gapfill approach as an interim step to pricing before market rates are available, the agency must provide a public explanation of the basis for the payment rate, including an explanation of how the criteria to be considered under Gapfill were applied. CMS has provided no such explanation supporting the variability in pricing by these MACs.

**Conclusion**

We are concerned that wide variability among the MAC pricing for these GSP codes (81412 – 81442) is inconsistent with the established payer rates and the resources required to perform these tests based on the complexity and number of exons in the genes in these new GSP codes. For the reasons discussed above, we respectfully request CMS and the MACs to consider their previous gapfill work for both CPT codes 81435 and 81436, and use these codes as comparable to this year's new hereditary GSP codes for determining the resources involved with the tests. This will allow increased transparency into the process, and will ensure a consistent application of the gapfill criteria prior to finalizing the NLAs for the GSP codes.

Mr. Andrew Slavitt  
August 1, 2016

Thank you for considering our comments. We would be pleased to answer any questions you may have.

Sincerely,

A handwritten signature in blue ink, appearing to read "Ann R. King".

Coalition for 21<sup>st</sup> Century Medicine