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October 31, 2016

Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: Reconsideration Request for 2016 Gapfill Final Determinations for Services on the Clinical Lab Fee Schedule (CLFS)

Dear Mr. Slavitt:

On behalf of the Association of Molecular Pathology (AMP), thank you for the opportunity to submit a reconsideration request the 2016 gapfill final determinations for services on the Clinical Lab Fee Schedule (CLFS). AMP is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

2016 Final Gapfill Determinations for Genomic Sequencing Procedure (GSP) CPT Codes

AMP submitted comments on the preliminary gapfill determinations and our comments here remain consistent with our previous comments[1]. AMP appreciates that all Medicare Administrative Contractors (MACs) recommended a price for each GSP CPT code. However we remain deeply concerned about many of the gapfill values submitted. Despite stakeholder outreach to various MACs after release of the preliminary gapfill values, it remains difficult to communicate with the MACs. As a result, with the exception of **81432**, the preliminary and final gapfill GSP values remained nearly identical. We thank those MACs who increased the national limitation amounts (NLAs) of 81432 slightly. However, most NLAs still do not accurately represent the reimbursement value for performing these important procedures**.**

We think it is important to highlight that NGS submitted consistent values that appear reasonable and closely resemble values when gapfill criteria are applied. AMP applauds the obvious effort by NGS to put forth values that are both consistent and reasonable. For the other cases, however, that carried greater weight in the gapfill process the NLAs are both inconsistent and do not reflect reasonable costs. Thus AMP cannot support the GSP pricing as set forth in the final determination.

[1] http://amp.org/publications_resources/position_statements_letters/documents/AMPComments-PrelimGapfillDeterminations2016-FINAL.pdf

By way of illustration, for codes **81412-81442** the Novitas and First Coast Jurisdictions NLAs are the same for each GSP code: $645.26. Submission of $645.26 for all of these procedures implies that essentially the same resources are required to perform each of the procedures. However, that is simply not the case as any laboratory scientist with a knowledge of the procedures will attest to. The procedures not only vary based on the minimum number of genes required but also vary in the size and type of genes. Thus both the amount of DNA being analyzed and the nature of the analysis differs between the different GSPs. There is obviously a difference of required resources necessitating differential pricing. Parenthetically, it should also be noted that even if all of these codes had similar resources, $645.26 is well below the amount needed to cover the cost of these procedures.

Additionally, a number of MACs appear to have submitted values based on the NLA for code 81445[2], i.e. $597.91. Assigning a preliminary NLA rate based on code 81445 or any other somatic code to hereditary GSP codes is frankly unreasonable and belies a fundamental misunderstanding of the underlying science. These codes are not the closest comparator code and therefore are not appropriate as relevant codes. 81445 is a CPT GSP code designed for somatic mutation analysis. The GSP codes undergoing gapfill are codes for *heredity* mutation analysis procedures, not *somatic* mutation analysis procedures. It is inappropriate to compare GSP codes for somatic mutation analysis to hereditary mutation analysis as the procedures are substantially different in numerous important ways including specimen types, processing, depth of coverage, interpretive analysis and reporting.

Reconsideration Request

Based on the concerns articulated above, in accordance with 42 C.F.R. §414.509(b)(2)(iv), we urge CMS to reconsider the final carrier-specific amounts for the GSPs (81412, 81432-34, and 81442), seriously evaluating the recommendations from stakeholders on the best pricing approaches for these procedures. AMP recommends that CMS abandon the gapfill methodology which has failed for these codes and instead consider valuing the codes based on their similarity to and variance from existing hereditary GSP codes already priced on the clinical lab fee schedule (CLFS). More specifically, AMP suggests the following methodology for pricing codes 81412, 81432-34 and 81442.

Our recommendation for codes **81412, 81432-34**, and **81442** uses a formula based on calculating the number of exons required for each procedure. We believe this approach helps maintain the relativity of the resources involved in performing the different procedures. The proposed crosswalk methodology is based on relativity to hereditary mutation analysis codes 81435[3] or 81436[4] and utilizes the number of exons contained in the required genes for each CPT code.

It is important to note that codes 81435 and 81436 are the only two hereditary GSP codes for which NLAs have actually been established. No other GSP code currently priced on the CLFS is a viable comparator. It is also worth reiterating that the GSP codes for somatic mutation analysis are inappropriate for crosswalking to hereditary codes as the procedures are substantially different in numerous important ways including specimen types, processing, depth of coverage, interpretive analysis and reporting.

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[2] 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

[3] 81435 - Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11.

[4] 81436 - Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11

The proposed method to appropriately value **81412, 81432-34**, and **81442** is as follows. First, the number of exons for each gene required by the CPT code descriptor is obtained using the National Center for Biotechnology Information (NCBI) online gene database[5]. Then, for both the 2016 CPT code to be crosswalked and the existing code to be used as the basis, the total minimum number of exons is determined by taking the sum of the number of exons in the minimum gene set for the CPT code. Then, the total minimum number of exons for the 2016 code is divided by the basis code's total minimum number of exons to determine a ratio of required exons. That ratio is then multiplied by the National Limitation Amount (NLA) of the basis code to establish the new codes NLA. The application of this method for each code is described in detail in the chart below.

Comparator Codes (Hereditary GSP Codes currently priced and on the CLFS)

Code	Descriptor	Minimum Genes Sequenced	Minimum Number of Exons	NLA
81435	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11.	10	163	$796
81436	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11	5	76	$796

Recommendations for Insufficiently-priced 2016 Gapfill GSP CPT Codes

Code	Descriptor	Minimum Genes Sequenced	Total Minimum Number of Exons	Crosswalk Recommendation
81412	Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including *ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1*	9	171	Ratio to 81435 = exons for 81412/exons for 81435= 171/163= **1.049** **Crosswalk Recommendation = crosswalk to 81435 * 1.049**
81432	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 14 genes, including *ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11,* and *TP53*	14	297	Ratio to 81435 = Exons for 81432/exons for 81435= 297/163=**1.822** **Crosswalk Recommendation = crosswalk to 81435 * 1.822**

[5] http://www.ncbi.nlm.nih.gov/gene

Code	Descriptor	Minimum Genes Sequenced	Total Minimum Number of Exons	Crosswalk Recommendation
81433	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for *BRCA1, BRCA2, MLH1, MSH2,* and *STK11*	5	106	Ratio to 81436 = Exons for 81433/exons for 81436= 106/76= **1.395** **Crosswalk Recommendation = crosswalk to 81436 * 1.395**
81434	Hereditary retinal disorders (eg, retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy), genomic sequence analysis panel, must include sequencing of at least 15 genes, including *ABCA4, CNGA1, CRB1, EYS, PDE6A, PDE6B, PRPF31, PRPH2, RDH12, RHO, RP1, RP2, RPE65, RPGR,* and *USH2A*	15	331	Ratio to 81435 = Exons for 81434/exons for 81435= 331/163= **2.031** **Crosswalk Recommendation = crosswalk to 81435 * 2.031**
81442	Noonan spectrum disorders (eg, Noonan syndrome, cardio-facio-cutaneous synsdrome, Costello syndrome, LEOPARD syndrome, Noonan-like syndrome), genomic sequence analysis panel, must include sequencing of at least 12 genes, including *BRAF, CBL, HRAS, KRAS, MAP2K1, MAP2K2, NRAS, PTPN11, RAF1, RIT1, SHOC2,* and *SOS 1*	12	170	Ratio to 81435 = exons for 81442/exons for 81435= 170/163 = **1.043** **Crosswalk Recommendation = crosswalk to 81435 * 1.043**

Again, we thank you for the opportunity to submit these reconsideration requests for the 2016 gapfill final determinations for services on the CLFS. We urge CMS to take time to review our recommendations above, giving particular consideration to the crosswalk rationale proposed. We believe it provides a method to accurately and equitably crosswalk the GSP services that have failed to receive consistent or reasonable pricing using gapfill. We are happy to answer any questions about our recommendations and provide follow up information. Please direct your correspondence to Tara Burke, AMP Senior Policy Analyst, at tburke@amp.org.

Sincerely,

Charles E. Hill, MD, PhD
President, AMP