



ASSOCIATION FOR MOLECULAR PATHOLOGY
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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: 2016 Preliminary Gapfill Payment Determinations for New Genomic Sequencing Procedures CPT Codes

Dear Mr. Slavitt:

On behalf of the Association of Molecular Pathology (AMP), thank you for this opportunity to submit comments on the preliminary gapfill determinations. 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.

Since the Centers for Medicare and Medicaid Services (CMS) began utilizing the gapfill process to price services on the Clinical Lab Fee Schedule (CLFS), AMP has expressed concerns about the lack of transparency. It remains difficult to constructively respond to preliminary gapfill values as there is a continued lack of transparency and no discernible rationale as to how the MACs determined preliminary pricing. While we hope the implementation of the Protecting Access to Medicare Act (PAMA) will ultimately improve this process, undervaluation threatens patient access to care if laboratories stop being able to provide these procedures.

CMS relies on the Medicare Administrative Contractors (MACs) to be the primary operational contacts between the Medicare fee-for-service program and providers across the country. Consequently, MACs must serve as equitable intermediaries, thoroughly and conscientiously considering the input of physicians and stakeholders who are practicing in these rapidly evolving fields of research, science, and medicine. Many of our members report attempts to engage with their MAC in this process but their participation is rejected. Having an open dialogue between CMS, MACs, and stakeholders is necessary to ensure that Medicare patients receive the benefit of and access to the most up-to-date clinical science and receive safe and effective care. Transparency and stakeholder engagement are critical to ensuring that the gapfill process results in appropriate and fair pricing assessments.

Based on the limited information released by CMS, we are concerned that most preliminary national limitation amounts (NLAs) do not accurately represent the reimbursement value for performing these procedures.

Analysis of 2016 Preliminary Gapfill Determinations for GSP CPT Codes (81412-81442)

AMP appreciates that all MACs recommended a price for each GSP CPT code, however we remain concerned about many of the gapfill values submitted. Under 42 C.F.R 414.508(b)(1), Medicare regulations state that 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.

From our analysis, only NGS submitted consistent values that closely resemble values for which gapfill criteria were applied. However, in the remaining cases, the preliminary NLAs are inconsistent with a number of the gapfill criteria and thus AMP cannot support pricing at this level. We encourage the remaining MACs to consider the approach that NGS used. Below, we provide a few examples of such inconsistencies.

For codes **81412-81442**, Novitas and First Coast Jurisdictions submitted the same value for all codes - \$645.26. Submission of \$645.26 for all of these procedures implies that the same amount of resources are required to perform each procedure. However, that is not the case. These procedures not only vary based on the minimum number of genes required but also vary in the size and type of genes, which result in different analysis being required and thus necessitating differential pricing. 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 81445¹, which is \$597.91. Assigning a preliminary NLA rate based on code 81445 or any other somatic code to hereditary GSP codes is unreasonable as 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 current GSP codes undergoing gapfill are codes for heredity procedures, not somatic mutation analysis procedures. It is inappropriate to compare GSP codes for somatic mutation analysis to hereditary procedures as the procedures are substantially different in numerous important ways including specimen types, processing, depth of coverage, interpretive analysis and reporting.

Recommendations for Insufficiently-Priced Services

Based on the concerns articulated above, AMP urges CMS and the MACs to consider the current codes and their relationship to CPT codes currently on the CLFS for the GSP CPT codes **81412**, **81432-34**, and **81442** based. AMP is pleased with the preliminary NLAs for **81437** and **81438** and offers no additional recommendations for those

¹ 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

codes. There are two hereditary GSP codes that were priced during the 2015 gapfill process, 81435² and 81436³, that are now priced and on the CLFS and therefore available to use a comparator to the CPT codes currently being gapfilled. These 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 worth reiterating that the GSP codes for somatic mutation analysis are inappropriate for establishing comparisons to hereditary codes as the procedures are substantially different in numerous important ways including specimen types, processing, depth of coverage, interpretive analysis and reporting. Below, AMP offers a method for establishing a relationship between codes 81435 and 81436 to the current codes which were insufficiently gapfilled. The method below falls within the gapfill criteria, specifically criterion (IV), which states that “charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant” may be used to determine gapfill amounts.

AMP’s approach to value the GSP codes **81412, 81432-34, and 81442** based on the number of exons 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 database⁴. Then, for both the 2016 gapfill CPT GSP code and the existing CLFS CPT GSP code, 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. Finally, the total minimum number of exons for the 2016 gapfill GSP CPT code is divided by the existing code’s total minimum number of exons to determine the minimum exon ratio. That ratio is then multiplied by the NLA of the existing code. The application of this method for each code is described in detail in the chart below.

Further, at the July 2017 meeting, the Advisory Panel on Clinical Diagnostic Laboratory Tests expressed support for a method for determining the resources required for hereditary GSP codes that assessed the number of exons analyzed. AMP agrees that utilizing exon numbers encapsulates the similar relative resource utilization to existing GSP codes on the CLFS.

From our analysis, NGS submitted preliminary NLA values that closely resemble values for which gapfill criteria were applied, as NGS values closely resemble values we obtained by comparing **81412, 81432-34, and 81442** codes to existing and priced codes 81435 or 81436 based on exon values. We commend NGS for their obvious efforts to meaningfully value the codes for the gapfill process and encourage the others MACs to consult with NGS on their approach.

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); <u>duplication/deletion</u> analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11	5	76	\$796

² 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.

³ 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

⁴ <http://www.ncbi.nlm.nih.gov/gene>

Recommendations for Insufficiently-priced 2016 gapfill GSP CPT codes

Code	Descriptor	Minimum Genes Sequenced	Total Minimum Number of Exons	Ratio to Existing CPT Code (81435 or 81436)	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 <i>ASPA</i> , <i>BLM</i> , <i>CFTR</i> , <i>FANCC</i> , <i>GBA</i> , <i>HEXA</i> , <i>IKBKAP</i> , <i>MCOLN1</i> , and <i>SMPD1</i>	9	171	Ratio to 81435 = exons for 81412/exons for 81435= 171/163= 1.049	NLA for 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 <i>ATM</i> , <i>BRCA1</i> , <i>BRCA2</i> , <i>BRIP1</i> , <i>CDH1</i> , <i>MLH1</i> , <i>MSH2</i> , <i>MSH6</i> , <i>NBN</i> , <i>PALB2</i> , <i>PTEN</i> , <i>RAD51C</i> , <i>STK11</i> , and <i>TP53</i>	14	297	Ratio to 81435 = Exons for 81432/exons for 81435= 297/163= 1.822	NLA for 81435 * 1.822
81433	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); <u>duplication/deletion analysis</u> panel, must include analyses for <i>BRCA1</i> , <i>BRCA2</i> , <i>MLH1</i> , <i>MSH2</i> , and <i>STK11</i>	5	106	Ratio to 81436 = Exons for 81433/exons for 81436= 106/76= 1.395	NLA for 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 <i>ABCA4</i> , <i>CNGA1</i> , <i>CRB1</i> , <i>EYS</i> , <i>PDE6A</i> , <i>PDE6B</i> , <i>PRPF31</i> , <i>PRPH2</i> , <i>RDH12</i> , <i>RHO</i> , <i>RP1</i> , <i>RP2</i> , <i>RPE65</i> , <i>RPGR</i> , and <i>USH2A</i>	15	331	Ratio to 81435 = Exons for 81434/exons for 81435= 331/163= 2.031	NLA for 81435 * 2.031
81442	Noonan spectrum disorders (eg, Noonan syndrome, cardio-facio-cutaneous syndrome, Costello syndrome, LEOPARD syndrome, Noonan-like syndrome), genomic sequence analysis panel, must include sequencing of at least 12 genes, including <i>BRAF</i> , <i>CBL</i> , <i>HRAS</i> , <i>KRAS</i> , <i>MAP2K1</i> , <i>MAP2K2</i> , <i>NRAS</i> , <i>PTPN11</i> , <i>RAF1</i> , <i>RIT1</i> , <i>SHOC2</i> , and <i>SOS 1</i>	12	170	Ratio to 81435 = exons for 81442/exons for 81435= 170/163 = 1.043	NLA for 81435 * 1.043

Again, we thank you for the opportunity to submit these comments on the preliminary gapfill recommendations. We believe that the recommendations described above will provide more accurate and equitable pricing for these services. 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