ASSOCIATION
FOR MOLECULAR
PATHOLOGY

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: Preliminary Determinations for Calendar Year 2017 (CY2017) 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 comments on preliminary determinations for calendar year 2017 (CY2017) 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.

CY2017 CLFS Preliminary Determinations

AMP presented public comment at the July 2016 CLFS meeting as well as provided written comments to CMS after the meeting[1]. We wish to thank CMS for recommending crosswalks for many of the new molecular pathology codes, particularly the hereditary conditions genomic sequencing procedure (GSP) CPT codes. Provided below are recommendations to some CY2017 codes. We believe these were either crosswalked incorrectly or could be adjusted using a crosswalk method that may more appropriately relate the new hereditary conditions GSP CPT codes to existing hereditary CPT codes already priced on the CLFS.

2017 Molecular Pathology Procedures

For CPT code **81327,** CMS recommended a crosswalk to 81287 despite the predominant stakeholder recommendation of 81288. CMS stated in their rationale that the descriptor of 81287, namely the use of "methylation analysis," more closely matches the descriptor of 81327 than the descriptor of 81288, which uses "promoter methylation analysis." However, in spite of this, 81327 indeed has more similar resource utilization to 81288 than 81287 due to fact that 81327 and 81288 are both performed on colon cancer specimens and use similar resources. It is important to note that a promoter is just another genetic region that a methylation assay

---

[1] http://amp.org/publications_resources/position_statements_letters/documents/AMPComments-CY2017CLFSrecommendations-FINAL.pdf

may target and the use of the term "promoter" in the description of 81288 should not distract from the actual resource utilization of the test, which is most similar to 81288. Therefore, AMP recommends that CMS follow the predominant stakeholder recommendation and adjust the crosswalk for 81327 from 81287 to 81288.

2017 Microbiology Procedures

AMP thanks CMS for recommending that 87483 be crosswalked to 87633 and supports this recommendation.

2017 Genomic Sequencing Procedures

AMP supports a crosswalk methodology for the CY2017 CLFS hereditary GSP CPT codes to appropriately relate them to existing hereditary CPT codes already priced on the CLFS.

At the July 2016 meeting, The Advisory Panel on Clinical Diagnostic Laboratory Tests (The Panel) was supportive of a method for determining the resources required for hereditary GSP codes that assessed the number of exons analyzed. While AMP is appreciative of the preliminary crosswalk recommendation made by CMS, AMP agrees that developing a crosswalk method that adequately encapsulates the similar relative resource utilization to existing GSP codes on the CLFS via the number of exons is a viable crosswalk method and will allow CMS and The Panel to establish appropriate crosswalks for new GSPs in the future. Below, we provide written recommendations to help CMS develop this crosswalk methodology and request that CMS begin using it for the C72017 CLFS.

AMP recommends using a formula based on calculating the number of exons as it helps maintain the relativity of the resources involved in performing the particular procedure and, perhaps more importantly, provides a viable and reasonable method for pricing of hereditary GSP CPT codes going forward.

Our proposed crosswalk methodology for the majority of the GSP codes for CY2017 is based on relativity to codes 81435[2] or 81436[3] and utilizes the number of exons contained in the required genes for each CPT code. In fact, they are really the only codes that can be used. They are the only two hereditary GSP codes for which NLAs have been established. No other GSP code currently priced on the CLFS is a viable comparator. It is worth mentioning 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.

AMP's approach to value the CY2017 hereditary GSP CPT codes 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 database[4]. Then, for both the CY2017 CPT code to be crosswalked and the existing code to which the new code is to be crosswalked, 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 new CY2017 code is divided by the existing code's total minimum number of exons to determine the minimum exon ratio. Finally that ratio is multiplied by the National Limitation Amount (NLA) of the existing code. The application of this method for each code is described in detail in the chart below.

---

[2] 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.

[3] 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

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

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 (*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.	10	163	$796
81436	Hereditary colon cancer disorders (*e.g.,* 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

Crosswalk Recommendations

Code	CPT Descriptor	Minimum Genes Sequenced	Minimum Number of Exons	Crosswalk Recommendation
81413	Cardiac ion channelopathies (*e.g.,* Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); genomic sequence analysis panel, must include sequencing of at least 10 genes, including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A	10	254	Crosswalk to 81435 based on relative number of exons. Ratio of 81413/81435 = 254/163 = 1.558 **Crosswalk Recommendation = crosswalk to 81435 * 1.558**
81414	duplication/deletion gene analysis panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1	2	36	Crosswalk to 81436 based on relative number of exons. Ratio of 81414/81436 = 0.474 **Crosswalk Recommendation = crosswalk to 81436 * 0.474**
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (*e.g.,* DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood	n/a	n/a	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 **Crosswalk to 81435 as it has similar resource utilization to 81422.**

| 81439 | Inherited cardiomyopathy (*e.g.,* hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing for of at least 5 genes, including (*e.g.,* DSG2, MYBPC3, MYH7, PKP2, and TTN) | 5 | 468 | Crosswalk to 81435 based on relative number of exons.

Ratio of 814X5X/81435 = 254/163 = 2.871

Crosswalk Recommendation = crosswalk to 81435 * 2.871 |

Again, we thank you for the opportunity to submit these comments on preliminary determinations for CY2017 for services on the CLFS. We sincerely appreciate CMS' increasing willingness to consider crosswalks for molecular pathology, microbiology, and genomic sequencing procedures for the CY2017 CLFS. We request that CMS take time to review our recommendations above, giving particular consideration to the crosswalk rationale proposed as it provides a method to accurately and equitably crosswalk GSP 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