ASSOCIATION FOR MOLECULAR PATHOLOGY
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August 8, 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

Dear Mr. Slavitt:

On behalf of the Association of Molecular Pathology (AMP), thank you for this opportunity to submit written comments regarding new and reconsidered clinical diagnostic laboratory test codes for the Clinical Laboratory Fee Schedule (CLFS) for calendar year 2017 (CY2017). 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.

Below, we provide written recommendations to help CMS develop the CY2017 CLFS. Please note that while some recommendations remain in alignment with our presentation at the CLFS meeting on July 18, 2016, recommendations for the genomic sequencing procedures (GSPs) have been updated as a result of discussion at the Public meeting regarding development of an alternative crosswalk rationale.

2017 CLFS Molecular Pathology Procedures

The table below provides crosswalk to a code that has similar resource utilization and either the same number of variants or similar RNA expression analysis.

Code	CPT Descriptor	Test Purpose and Method	Crosswalk Recommendation
813X7X	SEPT9 (Septin9) (e.g., colorectal cancer) methylation analysis	Analysis for blood-based CRC screening. Real-time PCR-based measurement of methylated SEPT9 DNA. was in 81401	81288 MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis **Crosswalk to 81288 as it has similar resource utilization.**

2017 CLFS 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. Our proposed crosswalk methodology for the majority of the GSP codes for CY2017 is based on relativity to codes 81435[1] or 81436[2] and utilizes the number of exons contained in the required genes for each CPT code. AMP supports 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.

We propose any crosswalk methodology for the new hereditary GSP codes utilize as base codes 81435 and 81436. In fact, they are really the only codes that could be used. They 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 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.

As mentioned above, with the exception of 814X3X, the crosswalk recommendations for the 2017 GSPs have been updated since the July 2016 CLFS meeting. The Advisory Panel on Clinical Diagnostic Laboratory Tests was supportive of a method for determining the resources required for hereditary GSP codes that assessed the number of exons analyzed. 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.

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[3]. 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. Finally, 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. That ratio is then 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.

Code	CPT Descriptor	Test Purpose and Method	Crosswalk Recommendation
814X5X	Cardiac ion channelopathies (e.g., Brugada syndrome, long QT syndrome, short QT syndrome,	Analysis for hereditary cardiac syndromes. Sequencing using NGS technology.	Crosswalk to 81435 based on relative number of exons. Total minimum number of exons for 10 genes in 81435 is 163

[1] 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.

[2] 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

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

	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		Total minimum number of exons for 10 genes in 814X5X is 264 Ratio of 814X5X/81435 = 254/163 = 1.558 **Crosswalk Recommendation = crosswalk to 81435 x 1.558** (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)
814X6X	duplication/deletion gene analysis panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1	Analysis for hereditary cardiac syndromes deletion duplication mutations.	Crosswalk to 81436 based on relative number of exons. Total minimum number of exons for 5 genes in 81436 is 76 Total minimum number of exons for 10 genes in 814X6X is 36 Ratio of 814X6X/81436 = 0.474 **Crosswalk Recommendation = crosswalk to 81436 x 0.474** (81436 -duplication/deletion gene analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11)
814X3X	Fetal chromosomal microdeletion(s) genomic sequence analysis (e.g., DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood		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 814X5X.**
814X2X	Inherited cardiomyopathy (e.g., hypertrophic	Analysis for hereditary cardiomyopathy syndromes.	Crosswalk to 81436 based on relative number of exons.

	cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing for of at least 5 genes, including (eg, DSG2, MYBPC3, MYH7, PKP2, and TTN)	Sequencing using NGS technology.	Total minimum number of exons for 10 genes in 81435 is 163 Total minimum number of exons for 10 genes in 814X2X is 468 Ratio of 814X5X/81435 = 468/163 = 2.871 **Crosswalk Recommendation = crosswalk to 81435 x 2.871** (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)

2017 CLFS Microbiology Procedures

Code	CPT Descriptor	Test Purpose and Method	Crosswalk Recommendation
878XXX	Infectious agent detection by nucleic acid (DNA or RNA); central nervous system pathogen (e.g., Neisseria meningitidis, Streptococcus pneumoniae, Listeria, Haemophilus influenzae, E. coli, Streptococcus agalactia e, enterovirus, human parechovirus, herpes simplex virus type 1 and 2, human herpes virus 6, cytomegalovirus, varicella zoster virus, Cryptococcus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets	Analysis for CNS infections. Real-time PCR-based detection of 12-25 targets.	87633 respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets **Crosswalk to 87633 as this procedure has similar resource utilization.**

Again, we thank you for the opportunity to submit recommendations to help CMS develop the CY2017 CLFS. We believe the crosswalk 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