ASSOCIATION FOR MOLECULAR PATHOLOGY
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August 17, 2017

Seema Verma, CMS 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 Ms. Verma:

On behalf of the Association of Molecular Pathology (AMP), thank you for this opportunity to submit written comments on the Centers for Medicare & Medicaid Services' (CMS) list of 60 Clinical Laboratory Fee Schedule (CLFS) test codes for which CMS received no (i.e., values of zero) and/or insufficient data to calculate a weighted median private payor rate. 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.

CMS is seeking comments on whether the codes should be included on the CLFS and if so, what method of payment should be used to price the test codes (crosswalking or gapfill). AMP believes that it is premature to remove any of these 60 codes from the CLFS because any perceived lack of data during the reporting period does not mean that these codes are not being used. Additionally, the Protecting Access to Medicare Act (PAMA) final rule states that "for a CDLT for which CMS receives no applicable information, payment is made based on the crosswalking or gapfilling methods described in 414.508(b)(1) and (2)." The final rule makes no mention of removal from the CLFS should no/minimal data be submitted. We recommend that CMS pursue recommendations by adding these codes to the agenda list for the next public meeting for the CLFS in 2018 and maintaining prices at the national limitation amount (NLA) where they exist until that time. We believe this will allow all interested stakeholders in being able to provide meaningful input on the re-pricing of these codes and be within the discretion of CMS when data is insufficient.

However, if CMS determines that the above recommendation is not acceptable, we provide the following crosswalk recommendations for the molecular pathology procedures CPT codes on the code list (81316, 81236, 81425, 81426, 81427, 81434, 81470, 81471). We maintain that gapfill is not the appropriate pricing methodology for these codes. A number of molecular pathology and genomic sequencing codes are priced on the CLFS and serve as viable crosswalks for these services.

Code	CPT Descriptor	Test Purpose and Method	Crosswalk Recommendation	Rationale
81316	PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative	Used to genetically confirm the diagnosis of APL and drive selection of therapy. Performed in a molecular laboratory via RT-PCR.	81315	Similar methodologies and resources used for detecting each of these translocations in APL
81326	PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; known familial variant	Detection of known familial variants in a patient suspected of being affected by autosomal dominant Charcot-Marie-Tooth or a related neuropathy. For point mutations, PCR amplification and genotyping analysis is used. For del/dup analysis, a multiplex ligation dependent probe amplification (MLPA) is used.	81215	Similar methodologies and resources are used to detect known variants in BRCA which can be both point mutations or del/dups. Both conditions are autosomal dominant.
81425	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	Used to detect the genetic basis of unexplained constitutional or heritable disorders or syndrome beyond the coding regions (exome). Can detect SNV, CNV and structural rearrangements as well as intergenic variants/events.	No recommendation at this time	

		Performed by next generation sequencing with extensive bioinformatics and professional analysis		
81426	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (eg, parents, siblings) (List separately in addition to code for primary procedure)	Used as the control for the above code 81425	No recommendation at this time	
81427	Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (eg, updated knowledge or unrelated condition/syndrome)	uUed to reinterpret previously obtained sequence data in light of novel medical information or changes/development of clinical phenotype. Performed via extensive bioinformatics analysis and professional review.	No recommendation at this time	
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	Detection of pathogenic variants (eg., single nucleotide variants, small indels) in genes known to be causative of hereditary retinal disorders. Performed by next generation sequencing and bioinformatics analysis followed by professional interpretation.	81432	Similar methodologies are employed and nearly equivalent number of genes covered by each panel supporting the use of similar resources.

81470	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); genomic sequence analysis panel, must include sequencing of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2	Detection of pathogenic variants (eg., single nucleotide variants, small indels) in genes known to be causative of XLID. Performed by next generation sequencing and bioinformatics analysis followed by professional interpretation.	81432x2	Similar methodologies are employed but the larger number of required genes in the XLID panel is roughly equivalent to twice the resources required for 81432
81471	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); duplication/deletion gene analysis, must include analysis of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2	Detection of pathogenic del/dup variants in genes known to be causative of XLID. Performed using MLPA	81436x2	Similar methodologies employed. Resources utilized for the analysis of del/dups nin XLID is twice that of resources in 81436. Both performed using MLPA

We understand that CMS finds itself working within a tight timeline to make pricing determinations for January 1, 2018, as mandated by section 216 of PAMA for the first time. Regardless of the challenges of implementing a new pricing system, we are also navigating this system for the first time and urge the agency to provide ample time for stakeholders and their respective organizations to review and provide meaningful comment, with at least a 30 day comment period and that in the future this data is released along with the new and reconsidered codes up for consideration during the CLFS annual public meeting.

Thank you for the opportunity to submit recommendations to help CMS develop the CY2018 CLFS. We are happy to answer any questions about our recommendations and provide follow up information. Please direct your correspondence to Tara Burke, PhD, AMP Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Federico A. Monzon, MD
President, Association for Molecular Pathology