ACMG
American College of Medical Genetics and Genomics
Translating Genes Into Health®

October 27, 2019

Seema Verma, CMS Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CY 2020 CLFS Preliminary Payment Determinations

Dear Administrator Verma:

The American College of Medical Genetics and Genomics (ACMG) welcomes the opportunity to comment on the CY 2020 CLFS Preliminary Payment Determinations. ACMG is the only nationally recognized professional membership organization dedicated to improving health through the practice of medical genetics and genomics. Our membership includes over 2300 genetics professionals, nearly 80% of which are board-certified clinical and laboratory geneticists and genetic counselors.

ACMG is concerned with recurring efforts to base determinations for analyte-specific Tier 1 codes on broad complexity-based Tier 2 codes. In the CY 2020 preliminary determinations, CMS states that "*Tier 2 Molecular Pathology (MoPath) codes present identical methodology and resources for codes 813X1, 813X2, and 8XX01 since these genes are derived from a Tier 2 list of genes*". However, the Tier 2 codes are based on general complexity and do not reflect specific methodology and resources. The size and content of a gene can lead to significant variability in the methods and resources needed, and each procedure must be considered independently. Although a code may have been covered by a particular Tier 2 code previously, the value of the Tier 2 code at the time of crosswalk may not appropriately reflect the resources and methods of the test covered by a new Tier 1 code.

42 CFR 414.508 dictates that crosswalking is used if it is determined that a new Clinical Diagnostic Laboratory Test (CDLT) is comparable to an existing test, and 81 FR 41306-41101 further clarifies that comparability is based on **test methods and resources** of an existing code. The complexity of Tier 2 codes is based on the number of exons in a gene and type of variants tested, but they do not account for variations in content, such as challenges created by areas of high homology, the presence of pseudogenes, or other factors that impact the methods and resources required to sequence a gene. Therefore, consideration must be given to existing codes for tests that more accurately reflect comparable methods and resources. Further, CDLT codes

7101 Wisconsin Avenue
Suite 1101, Bethesda, MD 20814
Telephone: 301-718-9603
Fax: 301-718-9604

www.acmg.net

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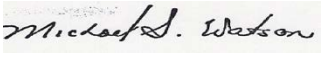
must account for the technical variant interpretation and reporting by an appropriately trained laboratory professional, the complexity of which varies among specific genes. As explained in 77 FR 68679–68890, CMS expects that interpretation and report services would be covered as part of the overall CLFS payment for molecular pathology CPT codes.

In the case of 813X1, CMS's preliminary determination is to crosswalk the new Tier 1 code with the Tier 2 code 81406 (level 7; eg, analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 25-50 exons, cytogenomic array analysis for neoplasia). This broad code includes more than 150 different genes that vary widely in terms of methods and resources required to sequence the genes. Multiple codes exist for Tier 1 tests that are much more comparable than a generic Tier 2 code. In our public comments, ACMG recommended crosswalk of 813X1 [*PALB2* (partner and localizer of *BRCA2*) (eg, breast and pancreatic cancer) gene analysis; full gene sequence] to 81201 [*APC* (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence]. This crosswalk recommendation was made after careful review of other available codes by knowledgeable laboratory professionals, and specific consideration was given to the content of the genes. The recommended crosswalk to 81201 is based on similarities in the methods and total resources needed to perform each test as well as the technical interpretation and reporting of variants, which for *PALB2* can be quite complex.

As CMS prepares the CY 2020 CLFS final payment determinations, and as they consider other new codes in the future, we urge CMS to base crosswalk determinations on comparability of methods and resources as dictated in current federal regulations. Such comparisons cannot be made on the single criterion of number of exons and must consider other factors such variations in content that affect the analytical methods used and overall resources needed.

We thank you for the opportunity to comment on the CY 2020 CLFS Preliminary Payment Determinations. We are happy to answer questions about our recommendations or provide additional information as needed.

Sincerely yours,



Michael S. Watson, MS, PhD, FACMG
Executive Director

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Suite 1101, Bethesda, MD 20814
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Fax: 301-718-9604
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