ACMG
American College of Medical Genetics and Genomics
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February 2, 2020

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

Re: CY 2020 CLFS Final Payment Determinations

Dear Administrator Verma:

The American College of Medical Genetics and Genomics (ACMG) requests that the Centers for Medicare and Medicaid Services (CMS) reconsider the final payment determination for CPT code 81307, *PALB2* (partner and localizer of *BRCA2*) (eg, breast and pancreatic cancer) gene analysis; full gene sequence. 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.

CMS recently issued the final payment determinations for new codes on the 2020 Clinical Laboratory Fee Schedule (CLFS). This included rates for multiple molecular pathology codes. ACMG appreciates CMS's careful consideration of the recommendations provided by stakeholders and the Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT). However, we are concerned about the final payment determination rate for CPT code 81307, *PALB2* full gene sequence. Through our presentation at the CLFS Annual Public Meeting and subsequent written communication, ACMG recommended crosswalk of new code 813X1 (now 81307) [*PALB2* (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; full gene sequence] to the Tier 1 code 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 was 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.

Some other organizations made similar recommendations for crosswalk to 81317 [*PMS2* (postmeiotic segregation increased 2 [*S. cerevisiae*]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis]. The CDLT Advisory Panel also recommended crosswalk to 81317. Most importantly, both of these recommendations take into consideration a number of factors, including

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the methods used, types of variants tested, test complexity, and overall resources utilized.

However, in the CY 2020 CLFS final determinations, CMS did not accept either of these recommendations and instead crosswalked 81307 to 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). In their justification, CMS stated that "*The 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*". The ACMG disagrees with this statement. Tier 2 codes are based on general complexity (i.e., number of exons in a gene and type of variants tested) but do not account for the complexity added by 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. The 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.

To further support the need for reconsideration, we note that the CY 2020 CLFS final determination valued *PALB2* full gene sequence (81307 at $282.88) less than *PALB2* known familial variant (81308 at $301.35), despite the fact that the full gene sequence requires sequencing of significantly more nucleotides. While we support the recommendation for 81308, the discrepancy here is further evidence that the final payment determination for 81307 is not appropriate and needs further consideration.

For these reasons, ACMG requests that CMS reconsider the final payment determination for CPT code 81307, *PALB2* full gene sequence. This would allow stakeholders the opportunity to provide additional information about the resources required for 81307 at the 2020 CLFS Annual Public Meeting. We appreciate the opportunity to submit these comments on the CY 2020 CLFS final determinations. For additional information or questions, please contact ACMG's Public Policy Director, Michelle McClure, PhD at mmcclure@acmg.net.

Sincerely,

Max Muenke

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