ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
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December 28, 2018

Mr. Glenn McGuirk
Center for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Sent via email to: Glenn.McGuirk@cms.hhs.gov

Dear Mr. McGuirk:

In November 2018, the Centers for Medicare & Medicaid Services (CMS) issued the final payment determinations for new codes on the 2019 Clinical Laboratory Fee Schedule (CLFS). Prior to their release, the Association for Molecular Pathology (AMP) submitted recommendations on payment for these codes at the public meeting held in July 2018 and was an active participant at meetings of the Advisory Panel for Clinical Diagnostic Tests.

AMP is an international medical and professional association representing approximately 2,500 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 and the in vitro diagnostics industry. AMP members are experts in molecular pathology, and the implementation of and coverage and payment determinations for these codes have a direct impact on their practice.

We thank CMS for adopting most of the proposed crosswalks recommended by AMP and the Advisory Panel in the final recommendations for the Molecular Pathology CPT codes. **Following careful review of the final determinations, AMP requests reconsideration of new CPT codes 81163 (BRCA1, BRCA2 full sequence analysis) and 81165 (BRCA1 full sequence analysis) on the basis of final payment amount.** As advancements in molecular diagnostics help to bring personalized medicine to Medicare beneficiaries, we remain committed to ensuring these molecular tools are properly valued in order to support patient access and innovation in precision medicine testing.

Additional stakeholder input at the upcoming 2019 CLFS public meeting will provide clarification regarding the typical resources required to perform these services, the clinical uses for these services, as well as the manner in which these services compare and/or contrast to the typical technology existing services paid on the clinical laboratory fee schedule.

81163 BRCA1, BRCA2 full sequence analysis

BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis

Commenter Recommendations: *1. Crosswalk to code 81408 (Tier 2 MolPath, level 9). 2. Crosswalk to code 81162 (BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis) x 40%.*

Panel Recommendation: *Five panel members recommended a crosswalk to code 81408. Four members recommended a crosswalk to codes 81406 (Tier 2 MolPath, level 7) + 81407 (Tier 2 MolPath, level 8). One member recommended a crosswalk to code 81162 x 0.4 and one member recommended to Gapfill.*

CMS Final Determination: *Crosswalk to codes 81406 (Tier 2 MolPath, level 7) + 81216 (BRCA2 gene analysis; full sequence analysis).*

Rationale: *CMS agrees with the concept to crosswalk 81163 with codes that are specific for full sequence analysis of BRCA1 and BRCA2. That is CMS agrees with the minority recommendation to crosswalk the BRCA1 component to 81406 as this Tier 2 MolPath, level 7 code describes the full sequence analysis for BRCA1. However, to account for the BRCA2 portion of 81163, CMS instead recommends a crosswalk to the existing BRCA2 Tier 1 MolPath code 81216 (BRCA2 (breast cancer 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis) already on the CLFS. Thus CMS recommends a crosswalk of 81406 + 81216.*

The crosswalk chosen by CMS does not appropriately represent the amount of work nor the costs incurred by laboratories required to perform and report *BRCA1, BRCA2* full sequencing analysis. Code 81163 requires sequencing of 51 full exons (full sequence analysis for *BRCA1* and *BRC2* involves sequencing 24 exons and 27 exons, respectively) with over 17,000 total exon base-pairs (bp) (total exon base-pairs for *BRCA1* and *BRCA2* is 7,224bp and 10,254bp, respectively). Procedures categorized under code 81408 involve analysis of greater than 50 exons. The combined sequencing analysis of *BRCA1* and *BRCA2* across 51 exons is performed utilizing the same method and resources and is more comparable to the analysis of a 51-exon gene than it is to two separate analyses of a 24- and a 27-exon gene. Code 81163 is a single procedure done by bi-directional sequencing of coding regions and well as exon-intron junctions by Sanger or next generation sequencing. Laboratories analyzing for sequence variations in the *BRCA1* and *BRCA2* genes do so at the same time rather than in separate single gene analyses. Thus, the most direct crosswalk is code 81408 which assesses 50 or more exons as the methodology and the amount of DNA sequencing of the large genes, such as *DMD*, is most similar to new code, 81163.

81165 BRCA1 full sequence analysis

BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis

Commenter Recommendations: *1. Crosswalk to code 81408 (Tier 2 MolPath, level 9) x 50%. 2. Crosswalk to code 81162 (BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis) x 80% of 50% of 81162 (i.e., (80% (81162 x 50%)).*

Panel Recommendation: *A majority (seven votes) recommended a crosswalk to code 81406 (Tier 2 MolPath, level 7; full sequence analysis). A minority (three votes) recommended a crosswalk to code 81408 (Tier 2 MolPath, level 9) x 50% and one member recommended a crosswalk to code 81162 x 10%.*

CMS Final Determination: *Crosswalk to codes 81406 (Tier 2 MolPath, level 7); full sequence analysis).*

Rationale: *CMS agrees with the majority of the panel to crosswalk 81165 to 81406 ((Tier 2 MolPath, level 7); full sequence analysis). The description of 81406 is similar to the analysis described for the BRCA1 full sequence.*

The crosswalk chosen by CMS does not appropriately represent the amount of work nor the costs incurred by laboratories required to perform and report BRCA1 targeted sequencing analysis. Code 81165 involves sequencing *BRCA1*, a large gene with only 24 exons but with one large exon requiring multiple reactions and over 7 thousand total base-pairs (7,224bp). While 81165 does show similarities to code 81406 based on the *exon count*, a crosswalk to 81406 substantially undervalues the total work involved which is directly related both to the exon count *and total base-pairs sequenced*. The work required to sequence such a large gene far exceeds the work involved for other representative genes under code 81406, as for example *RAF1* and *ACADVL* contain only 3,335bp and 2,184bp, respectively. Additionally, BRCA analysis is particularly notorious for the diversity of abnormalities that occur, including frequent novel changes requiring substantial resources both to confirm the sequence variation and give an interpretation of its clinical significance. As the work involved and resources required to sequence the entire *BRCA1* gene is approximately two- or three-fold more than other genes included in 81406, we do not feel this is a reasonable crosswalk. In order to accurately represent the amount of work and the costs incurred by laboratories, AMP previously suggested a crosswalk to code 81408 (Tier 2 MolPath, level 9) x 50%, as code 81165 involves sequencing of approximately half the work that is required for code 81408. Additionally, 81165 is one code in the BRCA code set, which also encompasses code 81162 as well as new codes 81163, 81164, 81165, and 81166. In order to maintain consistency within this family of codes, AMP retains support for its crosswalk recommendation of code 81408 X 50%.

Again, we thank you for the opportunity to submit reconsideration requests of 2019 final determinations for new codes. We are happy to answer any questions about our recommendations and provide follow up information. Please direct your correspondence to Tara Burke, AMP Senior Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Samuel K. Caughron, MD
Chair, Economic Affairs Committee
Association for Molecular Pathology