ASSOCIATION FOR MOLECULAR PATHOLOGY
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November 19th, 2026

Dr. Mehmet Oz
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

SUBMITTED ELECTRONICALLY VIA CLFS_Annual_Public_Meeting@cms.hhs.gov

Re: Preliminary Determinations for Calendar Year 2027 (CY2027) for the No PAMA Data Reported Codes.

Dear Administrator Oz:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit comments on the Clinical Lab Fee Schedule (CLFS) preliminary determinations for CPT codes that had no data reported during the Protecting Access to Medicare Act of 2014 (PAMA) data reporting period for calendar year 2027 (CY2027). AMP is an international medical and professional association representing approximately 3100 physicians, doctoral scientists, and medical technologists involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Our membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

Clinical laboratories play a vital role in healthcare, as clinical laboratory testing services inform more than 70% of medical decisions.[1] Over the past two decades, molecular pathology procedures for oncology, infectious diseases, and inherited conditions have become essential to patient diagnosis, treatment selection, and clinical management. Advances in molecular diagnostic technologies, including next-generation sequencing (NGS), have strengthened precision medicine and improved patient outcomes across the spectrum of health conditions. Clinical laboratories provide enormous value to Medicare, accounting for only approximately 1% of Medicare spending in 2024.[2] AMP believes these points should be considered as CMS moves forward with implementing PAMA and the payment-setting process for established codes with no reported data.

Process Concerns

AMP has several concerns regarding the process for reviewing codes with no reported PAMA data, specifically related to the structure and transparency of the meetings. The timeline for reviewing and considering the options for these codes was shortened compared to the typical CLFS process. Specifically, the public meeting was held on the day immediately preceding the Clinical Diagnostic Laboratory Testing (CDLT) Panel meeting in September, leaving CDLT panel members and stakeholders limited time to digest the information presented during the CLFS meeting and raise questions.

[1] https://www.cdc.gov/lab-week/resources-archive/feature-story.html

[2] Based on internal calculations using data from NHE Fact Sheet | CMS and Total Medicare Part B Spending on Lab Tests Rose in 2024, Driven by Increased Spending on Genetic Tests | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services

Additionally, while separating the CPT codes under consideration into different consent agendas was a reasonable approach given the time constraints, there are simple steps that CMS could have taken to improve transparency and streamline its process. During this year's process, CMS failed to provide advance notice to stakeholders with clarity as to how the codes were organized in the consent agenda groupings, resulting in significant confusion. AMP requests that in future similar proceedings, CMS provide the consent agendas and the list of CPT codes under consideration, including any sorting or grouping used to streamline the review process, sufficiently in advance of the CDLT meeting to allow stakeholders time to review and understand the proposed groupings. More broadly, AMP recommends that future CLFS and CDLT meetings that address codes with no reported PAMA data be scheduled with additional time between them to allow panel members and stakeholders to adequately consider the information presented.

Further, AMP is concerned about the apparent limitations on using existing CLFS codes as comparators when crosswalking codes without reported PAMA data. AMP requests that CMS clarify the rationale for excluding codes from consideration as crosswalk comparators when those codes are already established on the CLFS. Specifically, 42 CFR § 414.508(b)(1) states that "Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code." This provision does not appear to preclude consideration of an existing CLFS code solely because it lacks reported PAMA data.

CY 2026 CLFS Preliminary Determinations for Codes Without Reported PAMA Data

CPT Code 81195

Cytogenomic genome-wide analysis, hematologic malignancy, structural variations and copy number variations, optical genome mapping (OGM).

At the CDLT Advisory Panel meeting, the Panel voted in support of gapfilling this code. CMS, however, proposed a crosswalk to CPT code 81277, citing similar methods and resources and proposing an additional 15% to account for the optical genome mapping (OGM) component.

AMP disagrees with CMS' proposed crosswalk. Notably, CMS' current recommendation also represents a departure from its 2025 determination for CPT code 0331U, in which CMS recognized the distinct work and resources associated with OGM. AMP is concerned that the proposed crosswalk to CPT code 81277 does not adequately account for the methodology and resources required to perform OGM. Instead, CPT code 81277 describes cytogenomic microarray analysis, which it not appropriately comparable regarding the work involved. Further, adding 15% to the value of this code does not adequately address these differences or ensure that the resulting payment reflects the resources required to perform OGM.

To ensure that the assigned value accurately reflects the work and resources associated with the service, AMP believes the most appropriate approach is to crosswalk CPT code 81195 to itself. This approach would allow the code's specific methodology and resource requirements to be reflected in its valuation, rather than relying on a comparator that does not adequately capture the work performed. AMP urges CMS to reconsider its preliminary determination and adopt a crosswalk to CPT code 81195 itself. If there are limitations that CMS has for crosswalking codes to itself, especially when no PAMA data is reported and the codes have already been assigned a payment rate through the CLFS process, then it should be publicly and clearly communicated to stakeholders in written guidance.

CPT Code 81313

PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 3 [prostate specific antigen]) ratio (e.g., prostate cancer).

At the CDLT Advisory Panel meeting, the Panel voted in support of crosswalking this code to 81315. CMS's preliminary determination references agreement with the Panel regarding a crosswalk, citing similar methods and resources.

AMP disagrees with the proposed approach. AMP believes that the most appropriate crosswalk for CPT code 81313 is the code itself, as it most accurately represents the work and resources required to perform the test. Using a different code as a comparator fails to account for the specific methodology and resources associated with this testing. AMP urges CMS to reconsider its determination and ensure that the assigned value appropriately reflects the services provided.

CPT Code 81349

Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and loss-of-heterozygosity variants, low-pass sequencing analysis.

At the CDLT Advisory Panel meeting, the Panel voted in support of a crosswalk to CPT code 81229. CMS proposed a crosswalk to CPT code 81229, stating that the code had previously been crosswalked to CPT code 81229 in 2023 and it remains appropriate based on similar methods and resources.

AMP disagrees with the proposed crosswalk to CPT code 81229. The methodology and resources required for low-pass sequencing analysis should be accurately reflected in the crosswalk determination. The fact that CPT code 81349 was previously crosswalked to CPT code 81229 does not, in itself, establish that CPT code 81229 is the most appropriate comparator at this time. CMS should evaluate the specific work and resources associated with the test and select a comparator that most accurately reflects those requirements.

AMP urges CMS to reconsider its proposed crosswalk and ensure that the final determination appropriately accounts for the methodology, complexity, and resources involved in performing low-pass sequencing analysis. The selected crosswalk should reflect the actual services provided in clinical practice and support appropriate reimbursement for these tests. AMP recommends crosswalking these specific codes to themselves. Since these tests have been available on the CLFS for some time, the best code that describes the work and resources in the system is the code itself.

Thank you for the opportunity to comment on the payment determinations for CLFS CPT code with no PAMA data reported. AMP looks forward to working with CMS to ensure that payment determinations are based on accurate, representative data and that the implementation of PAMA does not unnecessarily compromise access to essential laboratory testing. Should you have any questions or require additional information from AMP members, please contact Samantha Pettersen at spettersen@amp.org.

Sincerely,

Yassmine Akkari, PhD, FACMG
President, Association for Molecular Pathology