ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
6120 Executive Boulevard, Suite 700, Rockville, Maryland, 20852
Tel: 301-634-7987 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

October 21st, 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 (CY) 2027 for New and Reconsidered Services on the Clinical Laboratory Fee Schedule (CLFS)

Dear Administrator Oz:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit comments on the preliminary determinations for the new and reconsidered services on the Calendar Year (CY) 2027 Clinical Laboratory Fee Schedule (CLFS). 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.

As experts in molecular pathology, AMP members and the clinical care they provide to patients are directly impacted by the implementation of payment determinations for the codes on the CLFS. We appreciate the continued opportunity to work with the Centers for Medicare & Medicaid Services (CMS) to ensure that the services on the CLFS are appropriately priced and adequately reimbursed to protect Medicare beneficiary access to testing.

AMP presented multiple recommendations at the CLFS Annual Public Meeting on June 10th, 2026, and we would like to thank CMS for making many preliminary determinations in alignment with our recommendations. However, AMP requests CMS provide clarity on how it made determinations on CPT Code 0648U. Additionally, there are two codes - CPT codes 8XX19 and 87183 - which we urge CMS to re-evaluate to ensure that the values most accurately reflect the work and resources utilized in clinical practice to serve patients. AMP's comments on the Preliminary Calendar Year (CY) 2027 Medicare Clinical Laboratory Fee Schedule Payment Rates as impacted by the Protecting Access to Medicare Act of 2014 (PAMA) reporting are found in a separate letter

Transparency Concerns

AMP requests clarification regarding CMS's response to CPT code 0648U, which states: "CMS agrees with the majority panel on this crosswalk; methods and resources appear similar. However, 0022U did not receive any private payer data. Instead, CMS identified another genome sequence panel analysis that appears to be similar in method and resources."

AMP requests CMS provide additional clarity on this restriction on crosswalking codes.
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." At the time of this determination, 0022U was an existing code on the Clinical Laboratory Fee Schedule (CLFS). AMP requests additional clarification regarding CMS's rationale for declining the recommended crosswalk to CPT code 0022U.

AMP also notes that the PAMA data reporting period was still underway when these recommendations were proposed. Therefore, stakeholders could not have known whether private payer data would ultimately be reported for 0022U. The subsequent absence of reported data should not invalidate its use as a crosswalk.

If the availability of private payer data or the potential for future repricing are new considerations in CLFS crosswalk determinations, CMS should clearly and transparently communicate these criteria to the public so stakeholders can account for them when developing and submitting recommendations.

CY 2026 CLFS Preliminary Determinations for Reconsidered Codes

CPT code 8XX19

Alport syndrome, genomic sequence analysis panel, must include COL4A3, COL4A4, and COL4A5, interrogation for sequence variants and copy number variants, when performed. At the Clinical Diagnostic Laboratory Test (CDLT) Advisory Panel ("the Panel") meeting, the Panel voted in support of a crosswalk to CPT 81432. CMS conversely proposed a crosswalk to 81439 with the following rationale: "CMS disagrees with the majority panel recommended crosswalk. CMS is recommending a different crosswalk that we believe is appropriately similar to 8XX19".

AMP disagrees with CMS' recommendation. 81439 does not include interrogation for sequence variants and copy number variants. As such, it does not include the complete attribution of technology and resources that are needed to complete 8XX19 as a service. AMP believes that due to the unique use case of this CPT code, there is no other comparable code in the CLFS. AMP urges CMS to gapfill 8XX19 as that will be a true representative analysis of the work and resources involved in this code.

Alternatively, if CMS is opposed to gapfill, AMP recommends that CMS use the Panel's recommendation of 81432, which was voted on unanimously.

CPT Code 87183

Susceptibility studies, antimicrobial agent; carbapenem resistance genes (eg, blaKPC, blaNDM, blaVIM, blaOXA-48, blaIMP), amplified probe technique, per isolate. CMS proposed a crosswalk to 87150 with the following rationale: "CMS continues to believe the original crosswalk of 87150 is most appropriate, given the language in the code descriptor as 'per isolate'."

AMP disagrees with CMS' recommendation. The development of 87183 is based on professional and practice testing guidelines[1] that emphasize the importance of detecting and differentiating the different types of carbapenemase (the type is determined by a specific resistance gene that confers resistance to a specific group of antimicrobial drugs) to guide proper selection of effective antibiotics against carbapenemase-resistant Enterobacterales strains that cause the infection.

[1] https://www.idsociety.org/practice-guideline/amr-guidance/

The inclusion of 'per isolate' in the code descriptor refers to the bacterium tested for carbapenem resistance genes. The "*e.g.*" included in the code descriptor for 87183 shows the recommended genes for this testing, of which most tests include at a minimum 3 genes in their genotypic analysis[2].

AMP would like to reiterate that the testing described in 87183 detects up to 5 antibiotic resistance genes within each carbapenem-resistant bacterial isolate (as mentioned under the "*e.g.*"). The detected genes confer resistance to different carbapenem antibiotic drugs. Therefore, CMS' implied "larger platform" is the typical method of testing in clinical practice and does not have any inherent efficiency gain.

Given the above information, **AMP would like to reiterate our recommendation to gapfill.** We believe that this will accurately reflect the work and resources in CPT code 87183.

AMP appreciates CMS's consideration of these comments and its continued engagement with the molecular pathology community. We respectfully request that CMS provide additional transparency regarding its crosswalk methodology for CPT code 0648U and reconsider its preliminary payment determinations for CPT codes 8XX19 and 87183.
Appropriate payment determinations should reflect the analytical methodologies, technical complexity, and resources necessary to perform these services while supporting continued Medicare beneficiary access to clinically appropriate molecular diagnostic testing.
AMP remains committed to collaborating with CMS to promote transparent, consistent, and evidence-based payment determinations that recognize the evolving complexity of molecular pathology services.

Thank you for the opportunity to provide comments on the CY 2027 CLFS preliminary determinations. Should you have any questions or require additional information from AMP members, please contact Samantha Pettersen at spettersen@amp.org.

Sincerely,
Aaron D. Bossler, MD PhD
President, Association for Molecular Pathology

[2] Table 1
https://www.cdph.ca.gov/Programs/CHCQ/HAI/CDPH%20Document%20Library/CRO_PrimerTests_for_Carbapenemases.pdf