ASSOCIATION FOR MOLECULAR PATHOLOGY
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October 9th, 2025

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) 2026 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) 2026 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 continue to appreciate the 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 27th, 2025, and we would like to thank CMS for making many preliminary determinations in alignment with our recommendations. In this comment letter, AMP specifically addresses only those codes which need to be re-evaluated to reflect the work and resources utilized in clinical practice to serve patients. AMP requests that these values be revisited before their payment rates are finalized.

<u>CY 2026 CLFS Preliminary Determinations for Reconsidered Codes</u>

CPT code 81195

Cytogenomic (genome-wide) analysis, hematologic malignancy, structural variants and copy number variants, optical genome mapping (OGM). At the Clinical Diagnostic Laboratory Test (CDLT) Advisory Panel ("the Panel") meeting, the Panel voted in support of a crosswalk to CPT 0331U. CMS disagreed with the panel and proposed a crosswalk to 0260U " *Rare diseases (constitutional/heritable disorders),* *identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping*" with the following rationale: "CMS disagrees with the Panel recommendation. CMS does not believe there is enough information in the descriptor, nor in the justification, to change the original crosswalk from 0260U. Both codes use optical genome mapping to identify similar variants and structural abnormalities. This is also consistent with the handling of a similar crosswalk this year for CPT code 81354."

AMP disagrees with CMS' recommendation. 81195 is for hematologic malignancy Optical Genome Mapping (OGM) and this type of testing is more laborious than CMS' crosswalk of 0260U, as the hematologic workflow requires a higher depth of coverage to detect clinically significant findings in comparison to constitutional disorders[1]. Thus, this testing requires more laboratory processing time and resources to accurately prepare and analyze the information. Further, oncology testing is more complex than constitutional OGM as there are more Copy Number Variants and Structural Rearrangements for a qualified health professional to review and interpret. While AMP understands CMS' concern regarding the information in the descriptor, we believe that the inclusion of "hematologic malignancy" in the descriptor outlines the inherent difference in work between this OGM and a constitutional OGM.

AMP agrees with The Panel's recommendation of 0331U *"Oncology (hematolymphoid neoplasia), optical genome mapping for copy number alterations and gene rearrangements utilizing DNA from blood or bone marrow, report of clinically significant alterations"* and **urges CMS to crosswalk CPT code 81195 to 0331U as this is the most accurate comparison of work and resources in the code set.**

CPT Code 87513

Infectious agent detection by nucleic acid (DNA or RNA); Helicobacter pylori (H. pylori), clarithromycin resistance, amplified probe technique. At the Clinical Diagnostic Laboratory Test (CDLT) Advisory Panel ("the Panel") meeting, the Panel voted in support of a crosswalk to CPT 87654 "*Infectious agent detection by nucleic acid (DNA or RNA); Mycobacterium tuberculosis, rifampin resistance, amplified probe technique*". CMS proposed a crosswalk to 87150 "*Culture, typing; identification by nucleic acid (DNA or RNA) probe, amplified probe technique, per culture or isolate, each organism probed*." With the rationale "CMS disagrees with the Panel recommendation to change the crosswalk. CMS believes that the original crosswalk is more appropriate and consistent with other similar tests."

AMP agrees with the CDLT crosswalk recommendation to CPT 87654 and disagrees with CMS' recommended crosswalk to 87150, as the testing work and resources are not comparable between 87150 and 87513. CPT 87564 "*Infectious agent detection by nucleic acid (DNA or RNA); Mycobacterium tuberculosis, rifampin resistance, amplified probe technique*" for detection of organism and antibiotic resistance directly from clinical specimens is an exact match to the laboratory testing work required in 87513.

Like CPT 87564, the laboratory work associated with 87513 requires more reagents, manual resources, and result analyses than those of 87150. 87513 is a multiplex PCR method that amplifies and detects *Helicobacter pylori*-specific gene target and associated clarithromycin resistance gene mutations directly

[1]https://pmc.ncbi.nlm.nih.gov/articles/PMC10252312/#:~:text=One%20of%20the%20most%20useful,therapeutic%20choices%20in%20hematological%20malignancies.

from stool specimens (not from bacterial culture or isolate as in 87150). Because this assay described in 87513 is multiplex, the use of multiple primers and probes sets are needed to complete the initial testing along with analytical software required for interpretation of results clearly differentiate 87513 from the work as described in 87150**.**

Furthermore, 87150 only accounts for the detection of an organism, **not** for the simultaneous detection of antibiotic resistance. The CPT code that reflects the correct amount of work and resources needed to detect both the organism *and* associated antibiotic resistance is CPT code 87654 (emphasis added): "*Infectious agent detection by nucleic acid (DNA or RNA); Mycobacterium tuberculosis, **rifampin resistance**, amplified probe technique".* Therefore, 87150 is not a comparable code and should not be used for crosswalk to CPT 87153.

AMP urges CMS to crosswalk 87513 to 87564.

CPT Code 87627

Infectious agent detection by nucleic acid (DNA or RNA); joint space pathogens and drug resistance genes, multiplex amplified probe technique, 26 or more targets. CMS proposed a crosswalk to 0505U with the following rationale: "CMS agrees with the minority Panel recommendation and believes that 0505U specifically refers to real-time PCR, which 87627 does not. 87633 appears to use similar resources and methods".

AMP disagrees with CMS' recommendation on crosswalk to CPT 87633, as this CPD code covers only 12 to 25 targets. CPT code 87627 was developed to address more targets and additional work needed than what is described in CPT code 87633. There is currently no Category 1 Microbiology CPT code for multiplex PCR assays that amplify and detect more than 25 targets. **As such, AMP believes there is no code that can compare and urges CMS to gapfill 87627**.

CPT Code 87183

Susceptibility studies, antimicrobial agent; carbapenem resistance genes (eg, blaKPC, blaNDM, blaVIM, blaOXA-48, blaIMP), amplified probe technique, per isolate. At the Clinical Diagnostic Laboratory Test (CDLT) Advisory Panel ("the Panel") meeting, the Panel voted in support of a crosswalk to CPT 87183 *5. CMS proposed a crosswalk to 87183 with the following rationale: "CMS agrees with the base crosswalk from the majority Panel recommendation, however, does not agree with the multiplier of 5. Given the language of the descriptor for 87183 as being 'per isolate', CMS believes it is not clear whether all 5 genes mentioned in the descriptor are tested every time the test is performed. In addition, CMS questions if there are any efficiencies gained in analyzing the 5 genes if they are on a larger platform."

AMP disagrees with CMS' recommendation. 87183 is based on professional and practice testing guidelines[2] 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

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

group of antimicrobial drugs) to guide proper selection of effective antibiotics against carbapenemase-resistant Enterobacterales strains that cause the infection.

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[3].

In addition, AMP requests clarification on the following statement: "...CMS questions if there are any efficiencies gained in analyzing the 5 genes if they are on a larger platform." At present, AMP is interpreting that CMS views this code for tests that detect only one resistance gene per isolate, and therefore testing all 5 genes mentioned in the code descriptor would be a larger panel and gain "efficiency". **AMP asks CMS to clarify their meaning behind this rationale.**

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 for CPT Code 87505 "*Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets".* We believe that this CPT code addresses the minute variations in testing for carbapenem resistance-associated genes and acknowledges that this testing is incredibly important to the health and wellbeing of patients. **The laboratory work and resources are incredibly similar and AMP urges CMS to crosswalk 87183 to 87505**.

Thank you for the opportunity to provide comments on the CY 2026 CLFS preliminary pricing determinations. We remain committed to working with you to ensure accurate pricing and secure patient access to laboratory tests. Should you have any questions or require additional information from AMP members, please contact Annie Scrimenti, Director of Public Policy and Advocacy, at ascrimenti@amp.org.

Sincerely,

Jane S. Gibson, PhD
President, Association for Molecular Pathology

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