ASSOCIATION FOR MOLECULAR PATHOLOGY
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October 25, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
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) 2025 for New and Reconsidered Services on the Clinical Laboratory Fee Schedule (CLFS)

Dear Administrator Brooks-LaSure:

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) 2025 Clinical Laboratory Fee Schedule (CLFS). AMP is an international medical and professional association representing approximately 3000 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.

AMP members are experts in molecular pathology, and the implementation of coverage and payment determinations for the codes on the CLFS has a direct impact on their practice. 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 reimbursed to protect Medicare beneficiary access to testing.

AMP presented multiple recommendations at the CLFS Annual Public Meeting on June 25, 2024, 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 are properly reflected. AMP requests these values be revisited before their payment rates are finalized.

CY 2024 CLFS Preliminary Determinations for Reconsidered Codes

CPT code 87626

Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), separately reported high-risk types (e.g., 16, 18, 31,45, 51, 52) and high-risk pooled result(s). At the Clinical Diagnostic Laboratory Test (CDLT) Advisory Panel ("the Panel") meeting, half of the Panel voted in support of a crosswalk to CPT 87624 + (87625 x 2) and the other half supported a crosswalk to 87624 +87625. CMS proposed a crosswalk to 87624 with the following rationale "CMS agrees with part of the crosswalk recommendation but does not agree with the sums of separate tests. All of the risk types are

listed in the new test descriptor. It is unclear whether there would be redundancies between 87624 and 87625."

AMP disagrees with CMS' recommendation. 87626 allows for the simultaneous testing of both pooled *and* individual results. There are no redundancies in the methodology as this assay uses in vitro PCR to perform two unique testing functions simultaneously by detecting HPV genotypes as well as differentiating among high-risk HPV genotypes that frequently cause cervical cancer. This newer technology allows differentiation of the analyzed genotypes within one assay, which requires different primers and probes. Furthermore, this test also requires complex bioinformatic analysis/component in order to interpret the results. AMP would like to reiterate our previously recommended crosswalk of 87624 + 87625 and note that the codes do not require a multiplier within the crosswalk formula. AMP understands that CMS is concerned with redundancy of the genotypes exhibited in 87624-87626. However, while there is detection of these genotypes reported in 87624, the new code 87626 requires the usage of additional primers and probes when compared to 87624. Furthermore, there is an inclusion of analysis similar to the identification found in 87625. We also wish to note that the expert Panel considered a number of crosswalk options but did not recommend a crosswalk to 87624 only. **AMP urges CMS to crosswalk 87626 to 87624 + 87625 as these codes together reflect the most accurate use of work and resources of 87626 within the AMA CPT code set.**

Alternatively, if CMS still believes that a crosswalk to 87624 + 87625 will create redundancy within the code set, AMP proposes a crosswalk to 87801 *Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique.* AMP believes the workflow of 87801 is an equal number of resources and work to 87626 since 87801 investigates multiple organisms, requiring multiple probes and analysis algorithm.

CPT Code 87513

87513- *Infectious agent detection by nucleic acid (DNA or RNA); Helicobacter pylori (H. pylori), clarithromycin resistance, amplified probe technique*. CMS supported a crosswalk to 87150, providing the following rationale "CMS agrees with the majority CDLT Panel recommendation to crosswalk the code. The crosswalked code(s) appear to use similar methods and resource utilization."

AMP disagrees with this rationale. 87150 is not a comparable code and should not have been considered a viable option, as there are resources unaccounted for in the code. 87513 is a multiplex PCR method that is able to amplify and detect *Helicobacter pylori*-species-specific gene target and clarithromycin-associated resistance gene mutations. Because this assay is multiplex, it uses multiple primers and probes sets to complete the initial testing and interpretation requires the use of analytical software. The work associated with 87513 is more intensive and resource heavy as compared to 87150. 87150 is described as *"Culture, typing; identification by nucleic acid (DNA or RNA) probe, amplified probe technique, per culture or isolate, each organism probed".* CPT coding states that multiples of 87150 should be coded when more than one organism is tested. This code only accounts for the detection of an organism, **not** for the identification of antibiotic resistance. The codes that reflect the correct amount of work and resources needed to detect both the organism *and* determine antibiotic resistance are found in 87640 + 87641. Therefore, **AMP recommends that 87513 be crosswalked to a combined 87640 + 87641.**

AMP would also like to point out that the decision to crosswalk 87513 to 87150 is inconsistent with other CMS recommendations. For example, CPT code 87564 *(Infectious agent detection by nucleic acid*

(DNA or RNA); Mycobacterium tuberculosis, rifampin resistance, amplified probe technique) was crosswalked to 87556 (*Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria tuberculosis, amplified probe technique)* ***PLUS*** 87641 (*Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique*). This crosswalk was supported by CMS with the rationale "CMS agrees with the majority CDLT Panel recommendation to crosswalk the code. The crosswalked code(s) appear to use similar methods and resource utilization." CPT code 87654 is very similar to code 87513 as they both detect an organism while also detecting antibiotic resistance. As such, the difference between the crosswalk methods is quite substantial and must be addressed.

CMS should remain consistent in their recommendations. **As such, using this reasoning for CPT code 87564, AMP urges CMS to crosswalk 87513 to combined 87640 + 87641** *Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique; + Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique.* This reflects the correct amount of work needed to detect the organism and determine antibiotic resistance.

Thank you for the opportunity to provide comments on the CY 2025 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, Associate Director of Public Policy and Advocacy, at ascrimenti@amp.org.

Sincerely,

Maria E. Arcila, MD
President, Association for Molecular Pathology