

January 16th, 2025

Delivered electronically to martha.espronceda@ama-assn.org

Re: AMP Comments on Clinically Meaningful Algorithmic Analyses

Dear AMA Staff:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to provide comments in response to the AMA's proposal for a Clinically Meaningful Algorithmic Analyses (CMAA) code set.

AMP is an international medical and professional association representing approximately 3,100 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, private and hospital-based clinical laboratories, and the in vitro diagnostic industry.

We commend the AMA for their thoughtful approach to codifying clinically meaningful algorithmic assays. We recognize that the development of the CMAA code set is a challenging undertaking. As a professional association with membership in various laboratory medicine disciplines, AMP would like to bring attention to a few potential issues.

First, in the context of the AMA's proposed requirement for an applicant to qualify for a CMAA CPT code, FDA approval or clearance is stated as a requirement. AMP recognizes that key aspects of CMAA may be incorporated as part of a laboratory developed test (LDT) service. Given that the FDA does not have statutory authority over LDTs, some tests would be unable to apply for CMAA CPT codes with the code application requirements as they now stand.

The proposed requirement which includes FDA approval poses another problem for tests that are not part of LDTs. The FDA and other regulatory agencies often change and adapt their thinking over time. Regulations are fluid the FDA could shift their approval processes and/or their definitions, such as those seen in the recently published FDA guidance on Clinical Decision Support Software¹. How does the AMA plan to address these potential changes?

Finally, AMP would like to gain insight and understanding of the potential CPT coding mechanism for AI. Specifically, for an Algorithm that has already received a code but is now being used on a different patient population than what was included in the original application.

AMP welcomes the opportunity to discuss our concerns and questions further and provide any laboratory insight necessary. Please contact Annie Scrimenti, AMP Director of Public Policy and Advocacy at ascrimenti@amp.org with any questions.

Sincerely,

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

¹ [Clinical Decision Support Software | FDA](#)