

Association for Molecular Pathology
Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology

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Medicare Evidence Development & Coverage Advisory Committee
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Sir or Madam:

The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 1,700 physicians, doctoral scientists, and medical technologists who perform genetic and genomic diagnostic laboratory testing. Our members include medically-trained pathologists, other laboratory physicians, and board-certified doctoral scientists, who populate the majority of laboratories that perform clinical DNA and RNA-based testing in the United States. Their efforts are central to the development and clinical introduction of genetic and genomic assays that are applied daily for diagnosis, prognosis and patient management in all medical specialty areas, including cancer, infectious diseases, heritable disorders, and histocompatibility testing.

Assessment of clinical validity, utility, and appropriate test utilization is integral to our members' professional practices, and they are experts in both the medical and technical aspects of genetic and genomic testing. AMP is, therefore, uniquely qualified to serve as an informational resource for the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). AMP brings an unparalleled understanding of the technologies involved in genetic and genomic testing, and stands in a unique position to comment on appropriate test utilization. With this in mind, AMP respectfully offers to share our experience and expertise with the Committee on an ongoing basis.

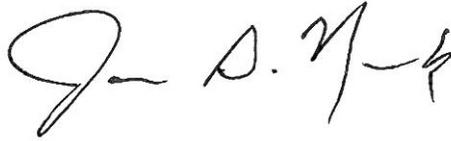
As primary providers of genetic and genomic tests, AMP members bring a practical perspective, real world experience, and accurate, current information on the development, validation, and utility of genetic and genomic tests. MEDCAC understands that the determination of clinical validity and clinical utility are complex undertakings that depend on the professional knowledge of a laboratory's medical director, his or her analysis of peer reviewed medical literature, ongoing discourse within professional societies, and collaboration with clinical colleagues. The processes by which a test is determined to be clinically valid and medically useful, and the methods by which an assay's optimal and appropriate utilization is established, can best be uncovered through these professional activities and interactions.

AMP and its membership strongly believe that all diagnostic tests should be of the highest quality, reliability, and safety, and that each test must provide valid and useful

information for clinical decision-making. Moreover, we strongly support the principle that reasonable and medically appropriate reimbursement and coverage decisions will improve healthcare quality for beneficiaries.

Thank you very much for your consideration of our remarks. AMP looks forward to serving as an authoritative and reliable resource for MEDCAC, the CMS, and its contract medical directors.

Sincerely,

A handwritten signature in black ink, appearing to read "Jan A. Nowak". The signature is fluid and cursive, with the first name "Jan" being the most prominent.

Jan A. Nowak, PhD, MD
President
Association for Molecular Pathology