



April 1, 2013

Maria Ellis
Executive Secretary for MEDCAC
Centers for Medicare and Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
7500 Security Boulevard
Baltimore, MD 21244

Re: Comments to MEDCAC on Genetic Tests for Cancer Diagnosis

Dear Ms. Ellis:

The College of American Pathologists (CAP), the nation's largest association of Board certified pathologists, appreciates this opportunity to provide comments to the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) on the issue of Selected Genetic Tests for Cancer Diagnosis and Treatment Selection. The CAP, celebrating 50 years as the gold standard in laboratory accreditation, is the world's largest association composed exclusively of board-certified pathologists and is the worldwide leader in laboratory quality assurance. The College advocates accountable, high-quality, and cost-effective patient care.

The CAP supports the Centers for Medicare and Medicaid Services efforts to ensure that patients receive the optimal medical therapy to improve care and general health through molecular diagnostic testing. Due to recent advances in diagnostic approaches, the frequency of cancers remaining of unknown origin is diminishing, although not disappearing. Certain presentations with the greatest potential for long-term survival (axillary node adenocarcinoma, peritoneal carcinomatosis, squamous cervical lymph node metastasis, poorly differentiated neuroendocrine carcinoma, unrecognized germ cell tumors) are crucial to identify.

The available literature suggests that microarray-based gene expression testing may result in a high accuracy rate of identifying cancers of unknown primary when comparing the results to a known tissue of origin. However, there are insufficient data to confirm whether gene expression profiling can be used in choosing treatment options that would improve the prognosis of patients with occult primary cancers.

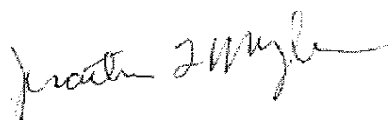
Although Fluorescent in-situ hybridization ('FISH') tests are often used to analyze genetic abnormalities in breast cancer, they also can provide important information about many other types of cancer. The potential use for FISH human papillomavirus (HPV) cervical cancer screening is still in clinical trials, has no standardized algorithmic guidelines and its utility will probably take several years to determine.

The CAP wishes to thank MEDCAC for the opportunity to comment on these important topics. The CAP supports future research that focuses on the benefits from the test to the patient in terms of effect on treatment decisions and resulting outcomes.

If we can be of assistance, please do not hesitate to contact Nonda Wilson at nwilson@cap.org.

Sincerely,

College of American Pathologists

A handwritten signature in black ink, appearing to read "Jonathan L. Myles". The signature is written in a cursive, flowing style.

Jonathan L. Myles, MD, FCAP
Chair, Economic Affairs Committee