

March 25, 2013

Maria Ellis  
Executive Secretary for MEDCAC  
Centers for Medicare & Medicaid Services  
Center for Clinical Standards and Quality, Coverage and Analysis Group  
S3-02-01  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Ms. Ellis:

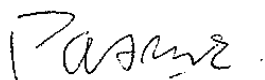
I am writing with comments in reference to the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) Meeting that will take place on May 1, 2013 and will address Genetic Tests for Cancer Diagnosis: “DNA- or RNA- based tests to predict the likely tissue of origin in patients presenting with a cancer of unknown primary site (‘CUP’ tests)”.

Cancer of unknown primary site (CUP) is considered to be a relatively common clinical condition, amounting up to approximately five percent of all invasive cancers. Typically, this is diagnosed by biopsy when patients present with symptoms correlating to metastases. Up to a quarter of the CUP belongs to a category characterized by “poorly differentiated histology”. The diagnostic dilemma and lack of known organ/tissue site specificity of the condition pose difficulties in clinical cancer care and treatment choices. The inherent underlying tumor and molecular heterogeneity within this diagnostic entity are known to be enormous.

DNA- or RNA-based tests as in the application of tumor molecular profiling has emerged recently as useful assay to better determine the cancer of organ/tissue origin, beyond the traditional capacity of histopathology and light microscopy. Molecular tumor profiling is now considered to be a useful and potentially valuable diagnostic tool particularly to predict the tissue of origin in carcinoma of unknown origin. This could facilitate the more rational choices of organ/tissue-specific cancer therapy, instead of empiric therapy.

Thank you for conducting a thoughtful process that allows us to provide input on such important issues and for your consideration of this information. Please do not hesitate to contact me if you need additional information.

Sincerely,



Patrick C. Ma, M.D., M.Sc.