

March 25, 2013

**Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)
on Genetic Tests for Cancer Diagnosis**

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 to express my support for Medicare coverage of gene expression-based molecular tests for cancer classification in patients with a cancer of unknown primary (CUP) or indeterminate diagnosis, which are being reviewed at the MEDCAC meeting on May 1, 2013.

Our group at the University of Texas MD Anderson Cancer Center has had a long standing interest in providing the best care for patients with CUP, who represent a sizeable patient population that is in the top ten cancer types by incidence. In recent years, the management of CUP has evolved tremendously with increasing availability of tailored therapies and the advent of sophisticated diagnostic modalities. Although CUP is a heterogeneous disease, it has been traditionally treated as a single entity, and primarily with standard platinum-based combination chemotherapies. Focus in the field has moved away from treatment of CUP patients with broadly applicable empiric therapies towards identification of CUP subtypes, and integration of molecular tests to aid in determining tumor origin. It cannot be overemphasized that the accurate diagnosis of the primary site in CUP would impact patients' prognosis and management. Gene expression-based tests offer an objective and standardized approach for tumor classification and have been validated for clinical utility.

At MD Anderson, we have used these molecular tests in approximately 60% of clinical cases in patients with CUP. This is after our in-depth pathologic evaluation. Our front and subsequent lines of therapy are guided by these results.

I support Medicare coverage for these molecular tests. Without access to these tests, there will be a significant negative impact on CUP patient management. As a researcher and academician who understands the unmet needs of CUP patients, I see gene expression-based molecular tests as standard of care for CUP management.

Thank you for the opportunity to comment. Please contact me if I can provide any additional information.

Sincerely,



Gauri Varadhachary, MD