

October 26, 2005

Andrew Bloschichak, M.D., MBA
VP and Contractors Medical Director
HGSAdministrators
1800 Center Street
Camp Hill, PA 17089-0089

Dear Dr. Bloschichak,

The **Pennsylvania Society of Hematology/Oncology** would like to inform you of a new technology that is now occasionally being incorporated into oncology care. “Cancer genomic profiling”⁽¹⁻³⁾ represents what we believe to be a potentially important step forward in cancer management based on fundamentally sound thought and research. In essence, gene expression of a series of growth and biologically relevant genes are examined from the neoplasm (paraffin-embedded tissue). Based on the pattern of gene expression, a “prognostic or recurrence score” is generated. This score is then used to predict the natural behavior of the tumor, thus guiding the need for various therapeutic interventions.

The most experience has been in the setting of breast cancer, namely node negative, estrogen receptor positive lesions, but this undoubtedly will expand to other breast cancer clinical scenarios as well as other neoplasms.

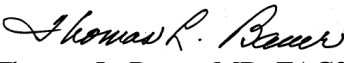
Similarly, for now there is one genomic product commercially available for breast cancer (*Oncotype DX Breast Cancer Assay*, Genomic Health, Inc, Redwood City, CA), but once again more will follow as this technology is adapted to different cancers and cancer treatment strategies.

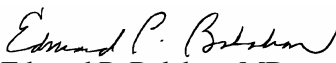
Interestingly there has been an economic analysis study performed⁽⁴⁾ using this clinical assay (*Oncotype DX*) specifically in the node negative, estrogen receptor positive breast cancer patient. That study concluded that this technology is “predicted to increase quality-adjusted survival and save costs”.

In summary, the **Pennsylvania Society of Hematology/Oncology** would like to endorse the above methodology and would hope that “Medicare” would likewise review this approach favorably and with the funding necessary for it’s application.

It is recognized that this approach and the varying “products” made available regarding this approach will need to be intermittently critically reviewed as the field matures. We will be available as genomic technology goes forward to review and update any relevant aspects and assays as they evolve. Thank you and of course please don’t hesitate to contact us for any other necessary input, etc.

Respectfully,


Thomas L. Bauer, MD, FACS
President


Edward P. Balaban, MD
Secretary/Treasurer

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2. van de Vijver MJ, He YD, van’t de Veer, et al. A gene expression signature as a predictor of survival in breast cancer. N Engl J Med 2002;347:1999-2009.
3. Paik S, Shak S, Tang G, et al. A multigene assay to predict recurrence of tamoxifen-treated, node negative breast cancer. N Engl J Med 2004;351:2817-26.
4. Hornberger J, Cosler LE, Lyman GH. Economic analysis of targeting chemotherapy using a 21-gene RT-PCR assay in lymph-node-negative, estrogen-receptor-positive, early-stage breast cancer. Am J Manag Care 2005;11:313-324.