



Association for Molecular Pathology
Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology
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Bruce Quinn, M.D.
National Heritage Insurance Company
Contractor Medical Director
1055 W. 7th Street
Los Angeles, CA 90017

August 25, 2005

RE: Comments on NHIC on the LCD for the Oncotype DX Test

Dear Dr. Quinn,

The Association for Molecular Pathology (AMP) would like to provide comments to the National Heritage Insurance Company on the Local Coverage Determination (LCD) for the Oncotype DX Test for breast cancer prognosis.

As background, AMP is a national not-for-profit educational society representing over one thousand physicians, doctoral scientists, and medical technologists who perform molecular diagnostic testing based on nucleic acid technology. AMP members practice their specialty in academic medical centers, independent medical laboratories, community hospitals, federal and state health laboratories, and the *in vitro* diagnostic industry. In this capacity AMP members are involved in every aspect of molecular diagnostic testing, administration and interpretation of molecular diagnostic tests, research and development, and education. For the last several years AMP has provided national leadership for the advancement of safe and effective practice and education for molecular diagnostic testing in the health care industry.

AMP strongly supports the categorization of the Oncotype DX Test as investigational. The data supporting the clinical use of the test is limited. As pointed out in the LCD under "Precision of the test per se," intermediate values for the Oncotype DX Test will be very difficult to interpret clinically. More experience is needed with additional patient cohorts representing broader patient populations to be able to develop guidelines for clinical use of the full range of test results that might be obtained. In addition, the test has not been demonstrated to be an independent prognostic factor that will add to existing prognostic factors for breast cancer, including pathology grade and NCCN classification of breast tumors. Therefore, AMP fully supports the statement in the LCD that "the Oncotype DX Test has not yet been validated as a reasonable and necessary test for breast cancer diagnosis and treatment." The Oncotype DX Test does not meet accepted standards of practice either by evidence in the published literature or

by consensus of expert medical opinion. Therefore, coverage of this service can be denied under HCFA Ruling 95-1.

AMP would like to comment on one additional point made in the LCD. The LCD states “This test has CLIA laboratory approval but not FDA approval.” AMP would like to clarify that CLIA does not approve tests; CLIA certifies laboratories. A CLIA-certified laboratory can perform FDA approved tests, or laboratory-developed tests. Laboratory-developed tests can be performed using analyte specific reagents (ASRs), or research or other types of reagents. It is not clear that the Oncotype DX Test uses ASRs, since these would have to be made by a company that is registered with the FDA and lists its ASRs with the FDA, and the ASR would have to be made under cGMP. It is unlikely that the probes used for the Oncotype DX Test meet the definition of ASRs.

We thank NHIC for the opportunity to comment on the LCD for the Oncotype DX Test. Debra G.B. Leonard, M.D., Ph.D., Chair of the Professional Relations Committee for AMP, and other members of AMP are available for further discussions. Dr. Leonard can be reached at dgl2001@med.cornell.edu or (212) 746-2041.

Sincerely,

A handwritten signature in black ink that reads "Mark A. Lovell, M.D." The signature is written in a cursive, flowing style.

Mark Lovell, M.D.
President