On behalf of Genomic Health, Inc., I respectfully request the NCCN Breast Cancer Panel to review the enclosed data for inclusion of the 12-gene Oncotype DX® Breast DCIS Score™ assay in the initial work-up for patients diagnosed with DCIS, to stratify patients by risk of local recurrence (any or invasive), following lumpectomy with negative margins but prior to the decision or recommendation for radiation therapy.

Specific Changes: Include the 12-gene DCIS Score™ assay as a routine component of the initial work-up for patients diagnosed with DCIS, following lumpectomy with negative margins.

FDA Clearance: FDA clearance is not required for this assay because it is performed in the central laboratory at Genomic Health, which is regulated and certified under the Clinical Laboratory Improvement Amendments (CLIA) and the College of American Pathologists (CAP).

Rationale: In support of the proposed change, the 12-gene DCIS Score assay was validated in two prospectively designed studies to predict 10-year risk of any or invasive local recurrence in patients with DCIS after breast-conserving surgery alone (BCS) or after BCS plus radiation therapy. DCIS Score results added information beyond what was discerned by clinicopathologic factors alone. Estimates of 10-year risk of local recurrence were further refined in a meta-analysis that combined both BCS-alone cohorts, showing that 47% of patients had ≤10% risk of local recurrence over 10 years.

Shared decision-making in healthcare is realized when both patient and physician contribute to care decisions based on available information. In this capacity, the individualized risk estimates provided by DCIS Score results can support shared decision-making, such that patients can avoid radiation-related morbidity when their risk of recurrence is low or feel confident in their decision to have radiation therapy when their risk of recurrence is high. In support of the clinical utility of the DCIS Score assay, physicians in two prospective, multicenter decision impact studies changed recommendations for radiation therapy for about 30% of their patients, based on DCIS Score results.

The following articles are submitted in support of this proposed change.

studies. 2017 ASCO Annual Meeting; 2017; Chicago, IL. [Meta-analysis of DCIS Score assay in two combined BCS-alone cohorts]


Sincerely,

[Signature]

Christy Russell, MD
Senior Director, Medical Affairs
Genomic Health, Inc.