Specific Changes:

- On BINV-6 for tumors >0.5cm replace “consider 21-gene RT-PCR assay” with “consider use of a breast tumor biomarker assay”. Remove specific scores from guidelines but keep categories. To footnote dd, add “21-gene RT-PCR assay, 12-gene risk score (EndoPredict), PAM50 and Breast Cancer Index have been validated as prognostic markers for this use”.

- Add 12-gene risk score (EndoPredict) to footnote cc as appropriate for use in patients with node-positive disease.

- On BINV-J (adjuvant endocrine therapy) add footnote “Consider use of 21-gene RT-PCR assay, 12-gene risk score (EndoPredict), PAM50 or Breast Cancer Index to identify patients who will likely not benefit from extended adjuvant endocrine therapy”.

FDA Clearance: Not applicable.

Rationale: BINV-6: In the proposed setting, the biomarker assay is being used to decide which patients can avoid chemotherapy, making the prognostic claims the critical component of assay determination. The above assays have been determined to have sufficient evidence for utilization in this setting by the American Society of Clinical Oncology clinical practice guideline committee, supported by multiple published prospective-retrospective studies. The 12-gene risk score (EndoPredict) has been shown to be an independent prognostic parameter in patients with node-positive, ER+/HER2− breast cancer treated with adjuvant chemotherapy followed by hormone therapy. BINV-J: As noted above, the biomarker assay is being used to decide which patients can avoid (extended endocrine) therapy, making the prognostic claims the critical component of assay determination. These assays have been demonstrated to identify patients who have a low risk of overall and late recurrence and who will therefore likely not gain benefit from extended adjuvant endocrine therapy.
The following articles are submitted in support of these proposed changes. We would like to acknowledge the contributions of NCCN panel members who are also co-authors or co-contributors of some of these publications:


Sincerely,

Johnathan Lancaster, MD, PhD
Chief Medical Officer, Myriad Genetic Laboratories Inc.