

NCCN Guidelines for Breast Cancer V.1.2016 –Meeting on 07/17/15-07/18/15

Guideline Page and Request	Panel Discussion/References	Institution Vote			
		YES	NO	ABSTAIN	ABSENT
<p>DCIS-2 Internal request: Consider addition of aromatase inhibitor as adjuvant endocrine therapy for post-menopausal women with DCIS.</p>	<p>The Panel consensus was to change “tamoxifen” to “endocrine therapy” and add the following bullets: Endocrine therapy:</p> <ul style="list-style-type: none"> • Tamoxifen for premenopausal patients • Tamoxifen or aromatase inhibitor for postmenopausal patients with some advantage for aromatase inhibitor therapy in patients <60 years old or with concerns for thromboembolism <p>Forbes JF, Sestak I, Howell A, et al. Anastrozole versus tamoxifen for the prevention of locoregional and contralateral breast cancer in postmenopausal women with locally excised ductal carcinoma in situ (IBIS-II DCIS): a double-blind, randomized controlled trial. Lancet 2015.</p> <p>Margolese RG, Cecchini RS, Julian TB, et al. Primary results, NRG Oncology/NSABP B-35: A clinical trial of anastrozole (A) versus tamoxifen (tam) in postmenopausal patients with DCIS undergoing lumpectomy plus radiotherapy. ASCO Meeting Abstracts 2015;33:LBA500.</p>	24	0	0	5
<p>BINV-6 / BINV-16 External request: bioTheranostics Inc. Recommend inclusion of the bioTheranostics’ BCI assay as a component of the treatment guideline for node-negative, HER2-negative, HR+ tumors as a footnote in BINV-6 (Systemic Adjuvant Treatment) and/or BINV-16 (Surveillance/Follow-up).</p>	<p>Since there are no randomized trials validating BCI in predicting response to chemotherapy, the Panel consensus was to include a footnote on page BINV-6 stating “Other prognostic multigene assays may be considered to help assess risk of recurrence but have not been validated to predict response to chemotherapy.”</p> <p>Goss PE, Ingle JN, Martino S, Robert NJ, et al. Randomized trial of letrozole following tamoxifen as extended adjuvant therapy in receptor-positive breast cancer: updated findings from NCIC CTG MA.17. J Natl Cancer Inst. 2005 Sep 7;97(17):1262-71.</p> <p>Zhang Y, Schnabel CA, Schroeder BE., et al. Breast Cancer Index Identifies Early-Stage Estrogen Receptor–Positive Breast Cancer Patients at Risk for Early- and Late-Distant Recurrence. Clin Cancer Res 2013; 19:4196-205</p>	24	0	0	5

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<p>BINV-6 External request: NanoString Technologies. Consider the referenced clinical data as Level 1 evidence supporting the inclusion of the FDA-cleared1 Prosigna® Breast Cancer Gene Signature Assay, as an option to inform adjuvant treatment decisions in patients with early-stage breast cancer (EBC).</p>	<p>Since there are no randomized trials validating the Prosigna Breast Cancer Gene Assay in predicting response to chemotherapy, the Panel consensus was to include a footnote on page BINV-6 stating “Other prognostic multigene assays may be considered to help assess risk of recurrence but have not been validated to predict response to chemotherapy.”</p> <p>Sestak I, Cuzick J, Dowsett M, et al. Prediction of late distant recurrence after 5 years of endocrine treatment: a combined analysis of patients from the Austrian breast and colorectal cancer study group 8 and arimidex, tamoxifen alone or in combination randomized trials using the PAM50 risk of recurrence score. <i>J Clin Oncol.</i> 2015 Mar 10;33(8):916-22. doi: 10.1200/JCO.2014.55.6894. Epub 2014 Oct 20.</p>	24	0	0	5
<p>BINV-16 External request: Amgen. Consideration of new data regarding the adjuvant use of denosumab in postmenopausal patients with early hormone receptor-positive breast cancer receiving treatment with aromatase inhibitors. Internal request: Institutional review comment: Include denosumab as a fracture preventing agent: Role of denosumab vs zoledronic acid as risk reduction for fracture or recurrence in postmenopausal women.</p>	<p>Based on data in the noted reference and discussion, the Panel consensus was to modify the footnote on page BINV-16. “</p> <p>“The use of estrogen, progesterone, or selective estrogen receptor modulators to treat osteoporosis or osteopenia in women with breast cancer is discouraged. The use of a bisphosphonate or denosumab is acceptable to maintain or to improve bone mineral density. Optimal duration of either therapy has not been established. Duration beyond 3 y is not known. Factors to consider for duration of anti-osteoporosis therapy include bone mineral density, response to therapy, and risk factors for continued bone loss or fracture. Women treated with a bisphosphonate or denosumab should undergo a dental examination with preventive dentistry prior to the initiation of therapy, and should take supplemental calcium and vitamin D.”</p>	24	0	0	5
<p>BINV-J Internal request: Ovarian ablation for women at premenopausal at diagnosis has a category 2B. Suggest changing to a Category 1 based on findings from SOFT/TEXT analysis.</p>	<p>Based on data in the noted reference and discussion, the Panel consensus was make the following changes:</p> <ul style="list-style-type: none"> • Adjuvant endocrine therapy - premenopausal at diagnosis tamoxifen for 5 y (category 1) ± ovarian suppression or ablation (category 2B) to a (category 1). • Adjuvant endocrine therapy - premenopausal at diagnosis, added "or aromatase inhibitor for 5y + ovarian suppression or ablation (category 1)." With a new footnote " Aromatase inhibitor or tamoxifen for 5 y plus ovarian suppression should be considered, based on SOFT and TEXT clinical trial outcomes, for premenopausal women at higher risk of recurrence (i.e. young age, high grade tumor, lymph node involvement, Pagani, NEJM 	24	0	0	5

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	2014, Prudence, NEJM 2014). Survival data still pending." Pagani O, Regan M, Walley B, et al for the TEXT and SOFT Investigators and the International Breast Cancer Study Group. Adjuvant Exemestane with Ovarian Suppression in Premenopausal Breast Cancer. N Engl J Med 2014; 371:107-118 July 10, 2014 DOI: 10.1056/NEJMoa1404037				
BINV-K External request: Submission from Genentech, Inc. Consider pertuzumab and trastuzumab: Neoadjuvant treatment of human epidermal growth factor receptor 2 (HER2)-positive early stage breast cancer.	Based on the data presented and discussion, the Panel consensus was not to change the guideline recommendations at this time. Gianni L, Pienkowski T, Im Y-M, et al. Five-year analysis of the Phase II NeoSphere trial evaluating four cycles of neoadjuvant docetaxel (D) and/or trastuzumab (T) and/or pertuzumab (P). Presented at the American Society of Clinical Oncology 2015 Annual Meeting in Chicago, Illinois; May 29–June 2, 2015. ASCO Abstract #505.	24	0	0	5
BINV-O External request: Submission from Genentech, Inc. Consider pertuzumab and ado-trastuzumab emtansine: First-line treatment of HER2-positive metastatic breast cancer (MBC)	Based on the data presented and discussion, the Panel consensus was to include TDM1 as a first-line treatment option. Ellis PA, Barrios CH, Eiermann W, et al. Phase III, randomized study of trastuzumab emtansine ± pertuzumab vs trastuzumab + taxane for first-line treatment of HER2-positive MBC: Primary results from the MARIANNE study. Presented at the American Society of Clinical Oncology 2015 Annual Meeting in Chicago, Illinois; May 29–June 2, 2015. ASCO Oral Presentation #507.	24	0	0	5
BINV-K Internal request: Given the negative results from NSABP-B36, delete all FEC/CEF/FAC/CAF regimens as there is no clinical advantage over AC chemotherapy.	Based on Panel discussion these regimens were removed. Geyer Jr CE, Samuel JA, Wilson JW, Bandos H, Elledge RM, Robidoux A, et al. NSABP B-36: A randomized phase III trial comparing six cycles of 5-fluorouracil (5-FU), epirubicin, and cyclophosphamide (FEC) to four cycles of adriamycin and cyclophosphamide (AC) in patients (pts) with node-negative breast cancer; 2014 San Antonio Breast Cancer Meeting Abstracts. S3-02.	24	0	0	5

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<p>BINV-N External request: Submission from Pfizer Oncology. Include palbociclib in combination with fulvestrant as a treatment option for women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer after progression on endocrine therapy in the NCCN Breast Cancer Guideline</p>	<p>Based on the data in the noted reference and discussion, the panel consensus, was to add palbociclib in combination with fulvestrant as a treatment option for women with HR+, HER2- metastatic breast cancer who have failed prior endocrine therapy.</p> <p>Turner NC, Ro J, Andre F, et al Palbociclib in Hormone-Receptor-Positive Advanced Breast Cancer New England Journal of Medicine E-pub June 1, 2015, DOI: 10.1056/NEJMoa1505270</p>	<p>24</p>	<p>0</p>	<p>0</p>	<p>5</p>
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