Guideline Page and Request	Panel Discussion	References	Vote		
			YES	NO	ABSTAIN
BINV-6 Internal request: Institutional review comment, Consider changing "21-gene RT-PCR assay" to "consider 21-gene RT-PCR assay, or Prosigna" External request: Submission from Nanostring Technologies, Inc. Include Prosigna assay in the treatment algorithm alongside other multi-analyte assay(s) that inform treatment decisions in hormone receptor positive (HR+) early-stage breast cancer, as well as the inclusion of a description of the Prosigna assay's analytical validation, clinical validation, and clinical utility in the discussion section.	Based on the presentation of the data in the noted references and Panel discussion, the consensus was not to include the additional test in the current treatment algorithm.	Dowsett M, et al. Comparison of PAM50 risk of recurrence score with Onco*type* DX and IHC4 for predicting risk of distant recurrence after endocrine therapy. J Clin Oncol. 2013;31(22):2783-2790. Gnant M, et al. Predicting distant recurrence in receptor-positive breast cancer patients with limited clinicopathological risk: using the PAM50 score in 1,478 postmenopausal patients of the ABCSG 08 trial treated with adjuvant endocrine therapy alone. Ann Oncol. 2014;25(2):339-345. Gnant M, et al. Identifying clinically relevant prognostic subgroups in node-positive postmenopausal HR+ early breast cancer patients treated with endocrine therapy: a combined analysis of 2,485 patients from ABCSG-8 and ATAC using the PAM50 risk of recurrence (ROR) score and intrinsic subtype. Presented at: 2013 ASCO Annual Meeting; May 31-June 4, 2013; Chicago, IL. Abstract 506. (Includes Risk stratification of node-positive *patients)*	22	0	0
BINV-6 External request: Submission from Genomic Health Review data for inclusion of Oncotype® DX Breast Cancer Assay in recurrence risk assessment of patients with 1-3 node positive, ER positive, HER-2 negative early stage breast cancer.	Based on the presentation of the data in the noted references and discussion, the panel consensus was to add a footnote stating "The 21-gene RT-PCR assay recurrence score can be considered in select patients with 1–3 involved ipsilateral axillary lymph nodes to guide the addition of combination chemotherapy to standard hormone therapy. A retrospective analysis of a prospective randomized trial suggests that the test is predictive in this group similar to its performance in node-negative disease."	Albain KS, Barlow WE, Shak S, et al. Prognostic and predictive value of the 21-gene recurrence score assay in postmenopausal women with node-positive, oestrogen-receptor-positive breast cancer on chemotherapy: a retrospective analysis of a randomised trial. Lancet Oncol 2010;11:55-65.	22	0	0
BINV-16 External request: Submission from ImpediMed. Review data for inclusion of the L-Dex U400 for early detection and	Based on the data in the noted reference and discussion, the panel consensus was to add a bullet to the section for surveillance/following stating "Educate, monitor, and refer for lymphedema management."	Vicini, F.A., et al., Multi-institutional analysis of bioimpedance spectroscopy in the early detection of breast cancer related lymphedema. Journal of Cancer Research & Therapy, 2013. 1(1): p. 1-7.	24	0	0

management of breast cancer related lymphedema.					
BINV-17, BINV-M, MS-57 External request: Submission from Janssen Diagnostics, LLC. Recommend the CELLSEARCH Circulating Tumor Cell Test as an component of the diagnostic evaluation of patients with metastatic breast cancer at baseline prior to initiating a new cycle of chemotherapy and at 3 weeks post initiation of therapy with a category 1 evidence level rating.	Based on the data in the noted references and discussion, the panel consensus was not to change the algorithm, but modify the text. The Discussion section is currently being updated.	CellSearch™ Circulating Tumor Kit, INSTRUCTIONS FOR USE, Distributed by Janssen Diagnostics, LLC. Raritan, NJ. June 2014. Smerage, J. B., et al. (2014). Circulating Tumor Cells and Response to Chemotherapy in Metastatic Breast Cancer. J Clin Oncol, published ahead of print, June 2014.	19	0	0
BINV-18 External request: Submission from Ken Surprenant. Include recommendation for pre-screening of patients using functional test that measure the dihydrouracil/uracil ratio.	Based on data in the noted reference and Panel discussion, the consensus was not to change the guideline.	Caudle, KE; Diasio, RB; et al. Clinical Pharmacogenetics Implementation Consortium Guidelines for Dihydropyrimidine Dehydrogenase Genotype and Fluoroupyrimidine Dosing, Clinical Pharmacology & Therapeutics, (29 August 2013), doi:10.1038/clpt.2013.172.	22	0	0
BINV-A External request: Submission from Nuclea Diagnostic Laboratories. Consider adding the serum HER-2 blood test for women with metastatic breast cancer (MBC) to the guidelines	Based on the data in the noted reference and discussion, the panel consensus was not to include sHer2 levels as an additional aid for identifying those MBC patients incorrectly classified as HER2 negative.	Ardavanis A, et al. Trastuzumab plus paclitaxel or docetaxel in HER2-negative/HER2 ECD-positive anthracycline and taxane refractory advanced breast cancer. Oncologist 2008;13:361-369. Petersen ER, et al. Serum HER2 predicts response and resistance to trastuzumab treatment in breast cancer. Clin Chem lab Med. 2013;51(7):1483-1492.	24	0	0
BINV-A External request: Submission from LabCorp. Review data in support of the inclusion of quantitative HER2 determinations (**HERmark**), as robust and reliable method for the assessment of HER2 status in FFPE breast cancer tumor samples.	Based on the data in the noted reference(s) and discussion, the panel consensus was not to include quantitative HER2 (HERmark) determinations as clinically actionable assessments of HER2-positive breast cancer.	Lipton A, Kostler WJ, Leitzel K et al. Quantitative HER2 protein levels predict outcome in fluorescence in situ hybridization-positive patients with metastatic breast cancer treated with trastuzumab. Cancer 2010 Nov 15;116(22):5168-78.	24	0	0
BINV-16, BINV-J External request: Submission from Dara BioSciences. Review data in support of including tamoxifen citrate oral solution as an option to tamoxifen tablets in the	Currently the guidelines do not specify tablet or liquid formulation. Based on discussion and the evidence noted in the reference, the panel voted not to change the current guideline recommendations.	Gluck et al, JNCCN 2014, V12(4):455-456, Abstract and Poster.	22	0	0

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BINV-J External request: Submission from ProStrakan. Review data for use of toremifene citrate in adjuvant management of patients with hormone-receptor-positive breast cancer.	Based on data in the noted references and Panel discussion, the consensus was not to add toremifene to adjuvant endocrine therapy.	Pagani O, Regan M, Walley B, et al. Adjuvant Exemestane with Ovarian Suppression in Premenopausal Breast Cancer. N Engl J Med 2014; 371:107-118. July 10, 2014DOI: 10.1056/NEJMoa1404037 Gu R, Jia W, Zeng Y, et al. A comparison of survival outcomes and side effects of toremifene or tamoxifen therapy in premenopausal estrogen and progesterone receptor positive breast cancer patients: a retrospective cohort study. BMC Cancer. 2012;12:161. Qin T, Yuan ZY, Peng RJ, et al. Efficacy and tolerability of toremifene and tamoxifen therapy in premenopausal patients with operable breast cancer: a retrospective analysis. Curr Oncol 2013;20(4):196-204.	23	0	0
BINV-J External request: Submission from bioTheranostics Inc. Inclusion of the Breast Cancer Index (BCI) test in the Guideline clinical algorithm of extended endocrine therapy for hormone receptor-positive (HR+), early stage breast cancer.	Based on data in the noted reference and Panel discussion, the consensus was not to include the BCI in the version of the guideline.	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 Aug 1;19(15):4196-205.	22	0	0
BINV-K Internal request: Institutional review. Add docetaxel/cyclophosphamide/trastuzumab to the list of combination regimens as a treatment option for early stage HER2 positive breast cancer	Based on data in the noted reference and Panel discussion, the consensus was to add the combination regimen to the list of treatment options.	Jones SE, Collea R, Paul D, et al. Adjuvant docetaxel and cyclophosphamide plus trastuzumab in patients with HER2 early stage breast cancer: a single-group, open-label phase 2 study. The Lancet Oncology, Colume 14, Issue 11, 2013 1121-1128.	23	0	0
BINV-K External request: Submission from McKesson. Restored AC every 21 days to the list as an option for adjuvant chemotherapy.	Based on data in the noted reference and Panel discussion, the regimen was added to change the guideline. It is a category 2B recommendation.	Sparano JA, Wang M, Martino S, et al. Weekly paclitaxel in adjuvant treatment of breast cancer. N Engl J Med 2008;258:1663-1671.	10	10	3
BINV-N External request: Submission from	Based on data in the noted reference and Panel discussion, the consensus was not to change	Piccart M, Hortobagyi GN, Campone M, et al. Everolimus plus exemestane for hormone	24	0	0

Novartis Oncology. Updated clinical evidence in support of everolimus in advanced breast cancer.	the guideline.	receptor-positive (HR+), human epidermal growth factor receptor-2-negative (HER2-) advanced breast cancer (BC): overall survival results from BOLER0-2. Oral presentation at EBCC-9; 19-21 March 2014; Glasgow, Scotland			