ASCO GUIDELINES

USE OF BIOMARKERS TO GUIDE DECISIONS ON ADJUVANT SYSTEMIC THERAPY FOR WOMEN WITH EARLY-STAGE INVASIVE BREAST CANCER: AMERICAN SOCIETY OF CLINICAL ONCOLOGY CLINICAL PRACTICE GUIDELINE	
Recommendation	**Evidence Rating**
Clinical Question 1: For women with early-stage invasive breast cancer and with known estrogen and progesterone receptor (ER/PgR) and human epidermal growth factor receptor 2 (HER2 status), which other biomarkers have demonstrated clinical utility to guide decisions on the need for adjuvant systemic therapy?	
If a patient has ER/PgR-positive, HER2-negative (node-negative) breast cancer, the clinician may use 21-gene recurrence score (21-gene RS; Oncotype DX; Genomic Health, Redwood, CA) to guide decisions for adjuvant systemic chemotherapy.	**Type:** Evidence Based **Evidence Quality:** High **Strength of Recommendation:** Strong
If a patient has ER/PgR-positive, HER2-negative (node-positive) breast cancer, the clinician should not use the 21-gene RS to guide decisions for adjuvant systemic chemotherapy.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate
If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use the 21-gene RS (Oncotype DX) to guide decisions for adjuvant systemic therapy.	**Type:** Informal Consensus **Evidence Quality:** Insufficient **Strength of Recommendation:** Strong
If a patient has ER/PgR-positive, HER2-negative (node-negative) breast cancer, the clinician may use the 12-gene risk score (EndoPredict; Sividon Diagnostics, Köln, Germany) to guide decisions for adjuvant systemic chemotherapy.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate
If a patient has ER/PgR-positive, HER2-negative (node-positive) breast cancer, the clinician should not use the 12-gene risk score (EndoPredict) to guide decisions for adjuvant systemic chemotherapy.	**Type:** Evidence Based **Evidence Quality:** Insufficient **Strength of Recommendation:** Moderate

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Recommendation	**Evidence Rating**
If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use 12-gene risk score (EndoPredict) to guide decisions for adjuvant systemic therapy.	**Type:** Informal Consensus **Evidence Quality:** Insufficient **Strength of Recommendation:** Strong
If a patient has ER/PgR-positive, HER2-negative (node-positive or node-negative) breast cancer, the clinician should not use 70-gene assay (MammaPrint; Agendia, Irvine CA) to guide decisions for adjuvant systemic chemotherapy.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate
If a patient has HER2-positive breast cancer, the clinician should not use the 70-gene assay (MammaPrint) to guide decisions regarding adjuvant systemic therapy.	**Type:** Informal Consensus **Evidence Quality:** Low **Strength of Recommendation:** Moderate
If a patient has triple-negative breast cancer, the clinician should not use the 70-gene assay (MammaPrint) to guide decisions about adjuvant systemic therapy.	**Type:** Informal Consensus **Evidence Quality:** Insufficient **Strength of Recommendation:** Strong
If a patient has ER/PgR-positive, HER2-negative (node-negative) breast cancer, the clinician may use the PAM50 risk of recurrence score (PAM50-ROR; Prosigna Breast Cancer Prognostic Gene Signature Assay), in conjunction with other clinicopathologic variables, to guide decisions about adjuvant systemic therapy.	**Type:** Evidence Based **Evidence Quality:** High **Strength of Recommendation:** Strong
If a patient has ER/PgR-positive, HER2-negative (node-positive) breast cancer, the clinician should not use the PAM50 Risk of Recurrence (ROR) score (PAM50-ROR; Prosigna Breast Cancer Prognostic Gene Signature Assay; NanoString Technologies, Seattle, WA) to guide decisions about adjuvant systemic therapy.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate
If a patient has HER2-positive breast cancer, the clinician should not use the PAM50-ROR to guide decisions regarding adjuvant systemic therapy.	**Type:** Informal Consensus **Evidence Quality:** Insufficient **Strength of Recommendation:** Strong
If a patient has triple-negative breast cancer, the clinician should not use the PAM50-ROR to guide decisions for adjuvant systemic therapy.	**Type:** Informal Consensus **Evidence Quality:** Insufficient **Strength of Recommendation:** Strong

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Recommendation	**Evidence Rating**
If a patient has ER/PgR-positive, HER2-negative, node-negative breast cancer, the clinician may use the Breast Cancer Index to guide decisions for adjuvant systemic therapy.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate
If a patient has ER/PgR-positive, HER2-negative, node-positive breast cancer, the clinician should not use the Breast Cancer Index (bioTheranostics, San Diego, CA) to guide decisions about adjuvant systemic therapy.	**Type:** Informal Consensus **Evidence Quality:** Insufficient **Strength of Recommendation:** Strong
If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use the Breast Cancer Index to guide decisions for adjuvant systemic therapy.	**Type:** Informal Consensus **Evidence Quality:** Insufficient **Strength of Recommendation:** Strong
If a patient has ER/PgR-positive, HER2-negative (node-positive or node-negative) breast cancer, the clinician should not use the five-protein assay Mammostrat (GE Healthcare, Aliso Viejo, CA) to guide decisions about adjuvant systemic therapy.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate
If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use five-protein assay Mammostrat to guide decisions about adjuvant systemic therapy.	**Type:** Informal Consensus **Evidence Quality:** Insufficient **Strength of Recommendation:** Strong
If a patient has ER/PgR-positive, HER2-negative (node-positive or node-negative) breast cancer, the clinician should not use immunohistochemistry-4 (IHC-4) to guide decisions about adjuvant systemic chemotherapy.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate
If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use IHC-4 to guide decisions about adjuvant systemic therapy.	**Type:** Informal Consensus **Evidence Quality:** Insufficient **Strength of Recommendation:** Strong
If a patient has ER/PgR-positive, HER2-negative (node-negative) breast cancer, the clinician may use the uPA and PAI-1 to guide decisions about adjuvant systemic therapy.	**Type:** Evidence based **Evidence Quality:** High **Strength of Recommendation:** Weak
If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use the uPA and PAI-1 to guide decisions about adjuvant systemic therapy.	**Type:** Informal Consensus **Evidence Quality:** Insufficient **Strength of Recommendation:** Weak

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Recommendation	**Evidence Rating**
The clinician should not use circulating tumor cells (CTC) to guide decisions for adjuvant systemic therapy.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Strong
If a patient has ER/PgR-positive, HER2-negative (node-positive or node-negative) breast cancer, the clinician should not use tumor-infiltrating lymphocytes (TILs) to guide decisions for adjuvant systemic therapy.	**Type:** Informal Consensus **Evidence Quality:** Insufficient **Strength of Recommendation:** Strong
If a patient has HER2-positive breast cancer or triple-negative breast cancer, the clinician should not use TILs to guide decisions about adjuvant systemic therapy.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Strong
Ki67 labeling index by immunohistochemistry should not be used to guide choice of adjuvant chemotherapy.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate
If a patient has ER/PgR-positive, HER2-negative (node-negative) breast cancer, and has had 5 years of endocrine therapy without evidence of recurrence, the clinician should not use multiparameter gene expression or protein assays (Oncotype DX, EndoPredict, PAM50, Breast Cancer Index, or IHC-4) to guide decisions about extended endocrine therapy.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate
Clinical Question 2: For women with early-stage invasive breast cancer and with known ER/PgR and HER2 status, which additional biomarkers have demonstrated clinical utility to guide choice of specific drugs or regimens for adjuvant systemic therapy?	
The clinician should not use *CYP2D6* polymorphisms to guide adjuvant endocrine therapy selection.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate
The clinician should not use p27 expression by immunohistochemistry to guide adjuvant endocrine therapy selection.	**Type:** Informal Consensus **Evidence Quality:** Low **Strength of Recommendation:** Strong
The clinician should not use Ki67 labeling index by immunohistochemistry to guide type of adjuvant endocrine therapy selection.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate

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Recommendation	**Evidence Rating**
The clinician should not use MAP-Tau mRNA expression or mRNA expression by immunohistochemistry to guide selection of type of adjuvant chemotherapy.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate
The clinician should not use HER1/EGFR expression by immunohistochemistry to guide selection of type of adjuvant chemotherapy.	**Type:** Evidence Based **Evidence Quality:** Low **Strength of Recommendation:** Moderate
The clinician should not use *TOP2A* gene amplification or TOP2A protein expression by immunohistochemistry to guide selection of type of adjuvant chemotherapy.	**Type:** Evidence Based **Evidence Quality:** High **Strength of Recommendation:** Moderate
The clinician should not use *HER2* and *TOP2A* gene co-amplification, *CEP17* duplication, *TIMP-1*, *FOXP3*, or *p53* to guide selection of type of adjuvant chemotherapy.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate
In patients with HER2-positive breast cancer, the clinician should not use PTEN to guide adjuvant therapy selection.	**Type:** Evidence Based **Evidence Quality:** Intermediate **Strength of Recommendation:** Moderate
In patients with HER2-positive breast cancer, the clinician should not use soluble HER2 levels to guide selection of type of adjuvant therapy.	**Type:** Evidence Based **Evidence Quality:** Low **Strength of Recommendation:** Moderate

