

# ASCO® Guidelines

## USE OF BIOMARKERS TO GUIDE DECISIONS ON ADJUVANT SYSTEMIC THERAPY FOR WOMEN WITH EARLY-STAGE INVASIVE BREAST CANCER: ASCO CLINICAL PRACTICE GUIDELINE UPDATE INTEGRATION OF RESULTS FROM TAILORX

Clinical Question	Recommendation (updated recommendations in bold)	Evidence Rating
For women with operable invasive breast cancer and with known ER/PgR and 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
	<b>For patients older than 50 and whose tumors have Oncotype DX recurrence scores &lt;26, and for patients &lt;50 whose tumors have Oncotype DX recurrence scores &lt;16, there is little to no benefit from chemotherapy. Clinicians may offer endocrine therapy alone.</b>	<b>Type: Evidence Based Evidence quality: High Strength of recommendation: Strong</b>
	<b>For patients 50 years of age or younger with Oncotype DX recurrence scores of 16 to 25, clinicians may offer chemoendocrine therapy</b>	<b>Type: Evidence Based Evidence quality: Intermediate Strength of recommendation: Moderate</b>
	<b>Patients with Oncotype DX recurrence scores &gt;30 should be considered candidates for chemoendocrine therapy.</b>	<b>Type: Evidence Based Evidence quality: High Strength of recommendation: Strong</b>
	<b>Based on Expert Panel consensus, oncologists may offer chemoendocrine therapy to patients with Oncotype DX scores of 26 to 30</b>	<b>Type: Informal consensus Evidence quality: insufficient Strength of recommendation: moderate</b>

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	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
	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-negative, breast cancer, the MammaPrint assay may be used in those with high clinical risk per MINDACT categorization to inform decisions on withholding adjuvant systemic chemotherapy due to its ability to identify a good prognosis population with potentially limited chemotherapy benefit.	Type: Evidence Based Evidence quality: High Strength of recommendation: Strong
	If a patient has ER/PgR-positive, HER2-negative, node-negative, breast cancer, the MammaPrint assay should not be used in those with low clinical risk per MINDACT categorization to inform decisions on withholding adjuvant systemic chemotherapy as women in the low clinical risk category had excellent outcomes and did not appear to benefit from chemotherapy even with a genomic high risk cancer.	Type: Evidence Based Evidence quality: High Strength of recommendation: Strong
	If a patient has ER/PgR-positive, HER2-negative, node-positive, breast cancer, the MammaPrint assay may be used in patients with 1-3 positive nodes and at high clinical risk per MINDACT categorization to inform decisions on withholding adjuvant systemic chemotherapy due to its ability to identify a good prognosis population with potentially limited chemotherapy benefit. However, such patients should be informed that a benefit of chemotherapy cannot be excluded, particularly in patients with greater than one involved lymph node.	Type: Evidence Based Evidence quality: High Strength of recommendation: Moderate

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	If a patient has ER/PgR-positive, HER2-negative, node-positive, breast cancer, the MammaPrint assay should not be used in patients with 1-3 positive nodes and at low clinical risk per MINDACT categorization to inform decisions on withholding adjuvant systemic chemotherapy. There are insufficient data on the clinical utility of MammaPrint in this specific patient population.	Type: Informal consensus Evidence quality: Low Strength of recommendation: Moderate
	If a patient has HER2-positive breast cancer, the clinician should not use the MammaPrint assay to guide decisions regarding adjuvant systemic therapy. Additional studies are required to address the role of MammaPrint in patients with this tumor subtype who are also receiving HER-2-targeted therapy.	Type: Informal Consensus Evidence quality: Low Strength of recommendation: Moderate
	If a patient has ER/PgR negative and HER2-negative breast cancer (triple negative), the clinician should not use the MammaPrint assay to guide decisions about adjuvant systemic chemotherapy.	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

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	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
	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

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	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
	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