## ROLE OF PATIENT AND DISEASE FACTORS IN ADJUVANT SYSTEMIC THERAPY DECISION-MAKING FOR EARLY-STAGE, OPERABLE BREAST CANCER: UPDATE OF THE ASCO ENDORSEMENT OF CCO GUIDELINE

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<thead>
<tr>
<th>Clinical Question</th>
<th>Recommendation</th>
<th>Evidence Rating</th>
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<tbody>
<tr>
<td><strong>Oncotype DX Updated Recommendations</strong></td>
<td>For patients older than 50 and whose tumors have Oncotype DX recurrence scores &lt;26, and for patients ≤50 whose tumors have Oncotype DX recurrence scores &lt;16, there is little to no benefit from chemotherapy. Clinicians may offer endocrine therapy alone.</td>
<td>Type: Evidence based, benefits outweigh harms Evidence quality: Intermediate Strength of recommendation: Moderate</td>
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<td>For patients 50 years of age or younger with Oncotype DX scores of 16 to 25, clinicians may offer chemoendocrine therapy.</td>
<td>Type: Evidence based, benefits outweigh harms Evidence quality: high Strength of recommendation: Strong</td>
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<td>Patients with Oncotype DX recurrence scores &gt;30 should be considered candidates for chemoendocrine therapy.</td>
<td>Type: Evidence based, benefits outweigh harms Evidence quality: high Strength of recommendation: Strong</td>
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<td>Based on Expert Panel consensus, oncologists may offer chemoendocrine therapy to patients with Oncotype DX scores of 26 to 30.</td>
<td>Type: Informal consensus Evidence quality: insufficient Strength of recommendation: Moderate</td>
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**Clinical Question**

What risk stratification tools may be used in determining the utility of certain systemic therapies in patients with early-stage breast cancer? **All recommendations refer to patients who present with a hormone receptor-positive, HER2 not overexpressed, axillary node-negative early breast cancer.**
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<td><strong>MammaPrint Assay Recommendations from the ASCO 2017 Biomarkers Guideline</strong></td>
<td>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.</td>
<td>Type: Evidence based, benefits outweigh harms Evidence quality: High Strength of recommendation: Strong</td>
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<td>What risk stratification tools may be used in determining the utility of certain systemic therapies in patients with early-stage breast cancer? <strong>All recommendations refer to patients who present with a hormone receptor-positive, HER2 not overexpressed, axillary node-negative early breast cancer.</strong></td>
<td>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, because 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.</td>
<td>Type: Evidence based, benefits outweigh harms Evidence quality: High Strength of recommendation: Strong</td>
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<td>If a patient has ER/PgR–positive, HER2-negative, node-positive breast cancer, the MammaPrint assay may be used in patients with one to three 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.</td>
<td>Type: Evidence based, benefits outweigh harms Evidence quality: High Strength of recommendation: Moderate</td>
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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 one to three 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 on adjuvant systemic therapy. Additional studies are required to address the role of MammaPrint in patients with this tumor subtype who are also receiving HER2-targeted therapy. | Type: Informal consensus  
Evidence quality: Low  
Strength of recommendation: Moderate                                                                 |                                                                                                |
| If a patient has ER/PgR negative and HER2-negative (triple negative) breast cancer, the clinician should not use the MammaPrint assay to guide decisions on adjuvant systemic chemotherapy. | Type: Informal consensus  
Evidence quality: Insufficient  
Strength of recommendation: Strong                                                                 |                                                                                                |