

# Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Early-Stage Invasive Breast Cancer: ASCO Guideline Update

## *Integration of Results from TAILORx*

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Andre, et al.

# Introduction

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- The American Society of Clinical Oncology (ASCO) Clinical Practice Guideline on the use of biomarkers to guide adjuvant therapy for early-stage invasive breast cancer was most recently published in February 2016.
- The publication of the Trial Assigning Individualized Options for Treatment (TAILORx) evaluating noninferiority of endocrine therapy alone to chemoendocrine therapy for invasive disease–free survival in women with intermediate Oncotype Dx scores provided a signal to update.
- While evidence on other aspects of the guideline may have become available following release of the guideline, no other strong signal that was felt likely to impact the recommendations has been identified to date.

# ASCO Guideline Development Methodology

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The ASCO Clinical Practice Guidelines Committee guideline process includes:

- a systematic literature review by ASCO guidelines staff
- an expert panel provides critical review and evidence interpretation to inform guideline recommendations
- final guideline approval by ASCO CPGC

The full ASCO Guideline methodology supplement can be found at:

[www.asco.org/guideline-methodology](http://www.asco.org/guideline-methodology)

# Clinical Question

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This guideline addresses the question:

For women with early-stage invasive breast cancer, which other biomarkers have demonstrated clinical utility to guide decisions on the need for adjuvant systemic therapy?

# Target Population and Audience

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## **Target Population**

Women with early-stage invasive breast cancer being considered for adjuvant systemic therapy

## **Target Audience**

Medical, surgical, and radiation oncologists; oncology nurses and physician assistants; pathologists; general practitioners; and patients

# Summary of Updated Recommendations

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**All recommendations refer to patients who present with a hormone receptor positive, HER2 not overexpressed, axillary node negative early breast cancer**

***Recommendation 1.1.1.*** For patients older than 50 and whose tumors have *Oncotype DX* recurrence scores <26, and for patients  $\leq$ 50 years whose tumors have *Oncotype DX* recurrence scores <16, there is little to no benefit from chemotherapy. Clinicians may offer endocrine therapy alone. (Type: Evidence based; benefits outweigh harms; Evidence quality: High; Strength of recommendation: Strong)

***Recommendation 1.1.2.*** For patients 50 years of age or younger with *Oncotype DX* recurrence scores of 16 to 25, clinicians may offer chemoendocrine therapy. (Type: Evidence based, benefits outweigh harms; Evidence quality: Intermediate; Strength of recommendation: Moderate)

# Summary of Updated Recommendations

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**Recommendation 1.1.3.** Patients with *Oncotype* DX recurrence scores >30 should be considered candidates for chemoendocrine therapy. (Type: Evidence based, benefits outweigh harms; Evidence quality: high; Strength of recommendation: Strong)

**Recommendation 1.1.4.** Based on Expert Panel consensus, oncologists may offer chemoendocrine therapy to patients with *Oncotype* DX scores of 26 to 30 (Type: Informal consensus; Evidence quality: insufficient; Strength of recommendation: moderate)

# Additional Resources

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More information, including a Data Supplement, a Methodology Supplement, slide sets, and clinical tools and resources, is available at [www.asco.org/breast-cancer-guidelines](http://www.asco.org/breast-cancer-guidelines)

Patient information is available at [www.cancer.net](http://www.cancer.net)



# ASCO Guideline Panel Members

Name (and designation)	Affiliation/Institution	Role/Area of Expertise
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