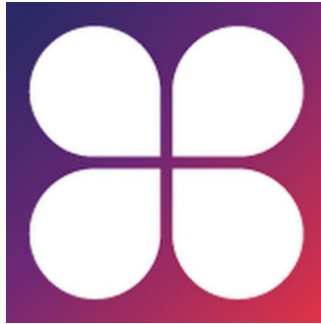

ASCO's Clinical Practice Guideline Now Supports Extended Endocrine Therapy with Breast Cancer Index™



Hologic, Inc. announced today that the American Society of Clinical Oncology (ASCO) has published an update which expands the utility of Breast Cancer Index™ (BCI) within its Clinical Practice Guideline: “Biomarkers for Adjuvant Endocrine and Chemotherapy in Early-Stage Breast Cancer.” Specifically, ASCO now recognizes BCI as the only genomic test to help guide extended endocrine therapy decisions in early-stage, HR+ breast cancer patients with node negative or node positive (one-three positive nodes) disease when treated with five years of primary endocrine therapy without evidence of recurrence. A special article highlighting the new ASCO guidelines was recently published in the *Journal of Clinical Oncology* on this subject.¹

“The clinical decision to either extend or end adjuvant endocrine therapy after five years is a challenging decision for healthcare providers and their patients. I am pleased to see updated guidelines from ASCO affirming the use of a data-driven biomarker like Breast Cancer Index to predict likelihood of benefit from extended endocrine therapy, helping to better inform decision-making processes around treatment plans,” said Mark Pegram, MD, Chief Medical Consultant for Breast Oncology at Biotheranostics, a subsidiary of Hologic. “There is an extensive body of clinical evidence consistently proving the utility of BCI, and its addition to major oncology clinical guidelines like those from ASCO further underscores the test’s potential in clinical decision making regarding extended adjuvant endocrine therapy.”

BCI is a proprietary molecular gene expression-based test that is uniquely positioned to provide information to help physicians individualize treatment plans beyond five years. It is also the only test to be recognized by other major clinical practice guidelines for prediction of which early-stage, HR+ breast cancer patients are likely to benefit from extended endocrine therapy.² Extended endocrine therapy has been demonstrated to help reduce the risk of recurrence in some women with early-stage, HR+ breast cancer. However, for breast cancer patients on extended endocrine therapy, the potential side effects and toxicities of treatment often have significant negative effects on health and quality of life, such as osteoporosis, bone fractures and joint pain.³⁻⁶ As a result, it’s important to know if a patient is unlikely to benefit from extended endocrine therapy to help reduce these challenging side effects and health consequences.

“We are pleased to see that ASCO updated its clinical practice guidelines to include BCI as the only genomic test to predict the value of extended endocrine therapy, reaffirming other guidelines within clinical oncology,” said Kevin Thornal, Hologic’s president, Diagnostic Solutions Division. “We look forward to continuing to improve women’s health by giving healthcare providers the information they need to make the best treatment decisions for their patients.”

According to the ASCO Guideline Update, the purpose was to “update recommendations on appropriate use of breast cancer biomarker assay results to guide adjuvant endocrine and chemotherapy decisions in early-stage breast cancer.¹” An updated literature search identified 24 randomized clinical trials and prospective-retrospective studies published from January 2016 to October 2021, which were evaluated by an Expert Panel to develop evidence-based recommendations.

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