

Risk Of Distant Recurrence & Extended Endocrine Benefit (Report Page 1 of 2)

Physician Information

Treating Physician

Pathologist

Patient & Order Information

Order ID

BCI Prognostic - Node Positive (1-3)

11.5% Risk of Late Recurrence (years 5-10)

Your Test Summary

BCI Predictive

HIGH Likelihood of Benefit

HIGH RISK CATEGORY

11.5% RISK[†] (95% CI: 6.7% - 16.1%)
OF LATE DISTANT RECURRENCE FOR ER+,
LYMPH NODE-POSITIVE PATIENTS¹

Based on the following clinical information for this patient:

Nodal Status: Lymph Node-Positive (N1 or N1mi)

Tumor Size (cm): 1.1 Tumor Grade: 2

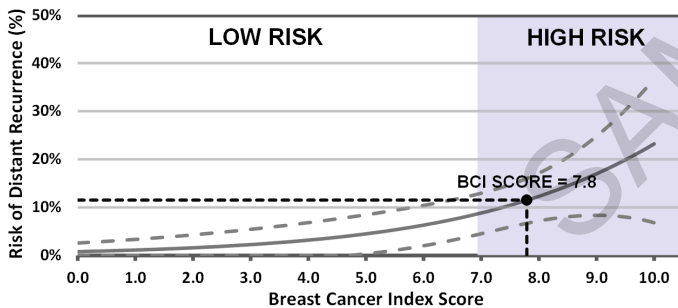
HIGH LIKELIHOOD OF BENEFIT
FROM EXTENDED ENDOCRINE THERAPY²

Low Likelihood of Benefit

High Likelihood of Benefit

Your Result

High BCI Predictive

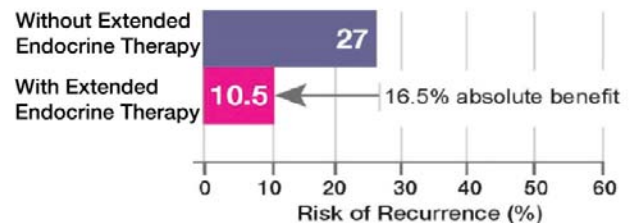


[†] Risk of Recurrence estimate is based on analysis of BCI Prognostic in an independent validation cohort of patients with 1-3 positive lymph nodes and provides residual risk of distant recurrence from years 5-10 post-diagnosis in patients treated with adjuvant chemotherapy and 5 years of adjuvant endocrine therapy (no extended endocrine therapy). See page 2 for additional details.

BCI Predictive was validated in a cohort that included both LN- and LN+ (1-3 nodes) patients; however, the study was not designed or powered to assess LN- and LN+ groups separately.

Patients with High Likelihood of Benefit result had 67% RELATIVE RISK REDUCTION (p=0.007) when treated with extended endocrine therapy in the MA.17 validation study²

TREATMENT BENEFIT BASED ON INDEPENDENT VALIDATION DATA OF BCI PREDICTIVE IN MA.17²



Additional Comments:

Risk Of Distant Recurrence & Extended Endocrine Benefit (Report Page 2 of 2)

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ADDITIONAL RESULTS APPLICABLE IF BCI ORDERED AT TIME OF DIAGNOSIS

BCI Prognostic - Node Positive (1-3)

26.8% Risk of Overall Recurrence (years 0-10)

HIGH RISK CATEGORY

26.8% RISK[†] (95% CI: 20.5% - 32.5%) OF DISTANT RECURRENCE FOR ER+, LYMPH NODE - POSITIVE PATIENTS FROM YEARS 0-10¹

Based on patient's clinical information listed on page 1

[†] Risk of Recurrence estimate is based on analysis of BCI Prognostic in an independent validation cohort of patients with 1-3 positive nodes and provides risk of distant recurrence from years 0-10 post-diagnosis in patients treated with adjuvant chemotherapy and 5 years of adjuvant endocrine therapy (no extended endocrine therapy). See below for additional details.

BCI Predictive

HIGH Likelihood of Benefit

HIGH LIKELIHOOD OF BENEFIT

FROM EXTENDED ENDOCRINE THERAPY²

BCI Predictive was validated in a cohort that included both LN- and LN+ (1-3 nodes) patients; however, the study was not designed or powered to assess LN- and LN+ groups separately.

Test Description and Clinical Evidence

BCI provides two outputs based on unique gene expression (quantitative RT-PCR) signatures: BCI Prognostic and BCI Predictive.

BCI Predictive provides a prediction of likelihood of benefit from extended (>5 years) endocrine therapy (EET).² Patient results for this test are categorized as either High or Low Likelihood of Benefit. BCI Predictive is based on the ratio of H/I (HOXB13:IL17BR) and was validated in the NCIC-CTG MA.17 trial.^{2,3}

BCI Prognostic for LN+ (1-3 positive nodes) provides an individualized estimate for a patient's risk for distant recurrence in the late (5-10 years post-diagnosis) and overall (0-10 years post-diagnosis) time frames.¹ For each time frame, a risk category is provided based on pre-specified cut points.¹ BCI Prognostic for LN+ patients (1-3 positive nodes) is based on the algorithmic combination of the BCI gene expression signature with tumor size and tumor grade. BCI prognostic for LN+ patients was validated in blinded study of patients with 1-3 positive nodes who were treated with adjuvant endocrine and chemotherapy.¹

Further Information

For additional information including test description, methodology, clinical report and interpretation, please see: www.breastcancerindex.com/ordering

References

1.Zhang Y, et al. Clin Cancer Res 2017 DOI: 10.1158/1078-0432 2.Sgroi D, et al. J Natl Cancer Inst. 2013;105:1036-42 3.Goss PE, et al. N Engl J Med 2003;349:1793-802.

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Intended Use & Limitations

The Breast Cancer Index (BCI) Risk of Recurrence & Extended Endocrine Benefit Test is intended for use in patients diagnosed with estrogen receptor-positive (ER+), lymph node-negative (LN-) or lymph node positive (LN+; with 1-3 positive nodes) early-stage, invasive breast cancer, who are distant recurrence-free. BCI provides: 1) a quantitative assessment of the likelihood of both late (post-5 years) and overall (0-10 year) distant recurrence following an initial 5 years of endocrine therapy (LN- patients) or 5 years of endocrine therapy plus adjuvant chemotherapy (LN+ patients), and 2) prediction of likelihood of benefit from extended (>5 year) endocrine therapy. BCI results are adjunctive to the ordering physician's workup; treatment decisions require correlation with all other clinical findings. This test was developed and its performance characteristics determined by Biotheranostics, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. This test is used for clinical purposes. It should not be regarded as investigational or for research. How this information is used to guide patient care is the responsibility of the physician. Biotheranostics is certified under the Clinical Laboratory Improvement Amendments of 1988 to perform high complexity clinical laboratory testing.

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