Gene expression profiling in women with lymph-node-positive breast cancer to select adjuvant chemotherapy treatment
BlueCross BlueShield Association

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Authors' conclusions
The Albain et al. (2010) study suggests that in women with ER-positive, lymph-node-positive breast cancer, the 21-gene expression profile (Oncotype DX™) may help identify those women who are unlikely to benefit from the addition of CAF chemotherapy to their treatment regimen, despite their higher risk of recurrence due to positive nodes. However, as the authors themselves note, the event rate was low, especially in the low-risk RS group, resulting in broad confidence intervals that included the possibility of benefit from chemotherapy. Moreover, the possibility of bias from HER2-positive samples in high-risk RS groups in the analysis of prognosis did not appear to be effectively ruled out. The Albain et al. study did not report an analysis to show improved prognostic reclassification after classification of recurrence risk by standard clinical classifiers in the tamoxifen-only group. Nor was an analysis in which RS and all standard pathological classifiers including ER were included significant. The authors note that "A much larger study would be needed to show a significant increase in prediction using a multigene assay after accounting for standard pathological assays. In part, this increase in sample size is attributable to measuring the same pathways by both methods, so one method must have much less measurement error to show improvement." In other words, the information provided by the assay overlaps considerably with standard clinicopathological information, so that large numbers are required to determine the incremental value of the portions of the assay that are different. Additional, single-arm trials suggested that patients with lymph node-positive breast cancer treated with chemotherapy are more likely to respond if their RS is high than if it is low, but control arms for comparison were lacking. In study of current assay use, Oratz et al. (2009) conducted an online survey to determine whether the 21-gene RS results affected providers' chemotherapy treatment recommendations for patients with lymph-node-positive disease in both academic and community medical settings. In this study, nearly 70% of patients had only 1 positive lymph node, and less than 3% had 4 or more positive nodes. RS changed treatment for 51% of patients overall; when recommended treatment was altered, chemotherapy was excluded in 66% of cases, primarily in patients with a low RS. However, this study did not include follow-up so it is unknown if treatment alterations resulted in improved patient outcomes. Due to the lack of clear and sufficient information, the recommendations of Simon et al. (2009) to confirm results of a prospective retrospective study with a second, similar study appear prudent. However, under an award from the National Cancer Institute, the Fred Hutchinson Cancer Research Center will conduct a nationwide Phase III clinical trial to determine the predictive ability of the 21-gene expression profile to identify which patients with node-positive breast cancer will benefit from chemotherapy treatment (http://swog.org/visitors/newsletters/2009/10/spotlight.htm).

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