BRACAnalysis CDx gets expanded approval

December 2018—Myriad Genetics announced FDA approval of its BRACAnalysis CDx to identify patients with HER2-negative metastatic breast cancer who have a germline BRCA mutation and are eligible for treatment with Pfizer's PARP inhibitor, Talzena (talazoparib). Talzena is indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated HER2-negative locally advanced or metastatic breast cancer. The FDA approvals are based on results from the EMBRACA trial, which evaluated Talzena versus physician's choice of chemotherapy in patients with germline BRCA-mutated, HER2-negative locally advanced or metastatic breast cancer.

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