



**Subject:** Breast Cancer Gene Expression Assays\*

**Effective Date:** December 11, 2007

**Department(s):** Utilization Management

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**Policy:** Tumor tissue gene expression assays ( **CPT 81519**) used to determine prognosis in patients with breast cancer are reimbursable under Plans administered by QualCare, Inc., as delineated in this policy.

**Objective:** To assure proper and consistent reimbursement and to limit coverage of breast cancer gene expression assays to those whose validity is adequately supported by peer-reviewed literature.

**Procedure:**

1. The Oncotype DX ® assay is reimbursable in patients who are recently diagnosed with breast cancer being considered for adjuvant chemotherapy and meet all of the following criteria:
  - Tumor is estrogen-receptor positive
  - Tumor is HER2-receptor negative or HER2-receptor positive but less than 1 cm in diameter
  - There is no evidence of metastasis and axillary nodes are negative for breast cancer ( *micrometastasis is no greater than 2.0 millimeters*)
  - **OR** the individual is postmenopausal with estrogen receptor positive tumor and 1-3 ipsilateral axillary lymph nodes are positive for metastatic disease.

**Note:** gene expression profiling is not recommended for micro-invasive disease (pN1mi- <2mm axillary lymph node metastasis).

**Note:** Oncotype DX® is not reimbursable for ductal carcinoma in situ(DCIS) or any other condition not listed in section 1 above as it is considered investigational or unproven due to inadequate documentation in the medical literature

2. The MammaPrint ® 70-Gene Breast Cancer Recurrence Assay is reimbursable in patients who are recently diagnosed with stage 1 or 2 invasive breast cancer being considered for adjuvant chemotherapy and meet ALL of the following criteria:

- high clinical risk of recurrence
- estrogen receptor (ER)-positive/progesterone receptor (PR)-positive
- human epidermal growth factor receptor 2 (HER2)-negative
- up to three positive lymph nodes

3. The Prosigna® Breast Cancer Assay ( PAM 50) is reimbursable in patients who are recently diagnosed with stage 1 or 2 invasive breast cancer being considered for adjuvant chemotherapy and meet ALL of the following criteria:

- Estrogen receptor positive
- HER2 receptor negative
- Postmenopausal
- No evidence of distant metastasis
- Axillary node status is negative (micrometastasis is no greater than 2.0 millimeters)

4. Breast cancer gene expression assays that are **NOT reimbursable** because they are deemed to be experimental, investigational, or unproven because of insufficient support in peer-reviewed literature, include but are not limited to:

- Rotterdam Signature 76-Panel
- Breast Cancer Gene Expression Ratio

**Note:** gene expression profiling is NOT recommended for micro-invasive disease (pN1mi- <2mm axillary lymph node metastasis).

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\*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.