Subject: Breast Cancer Gene Expression Assays*

Effective Date: December 11, 2007

Department(s): Utilization Management

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).

References


National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology-Breast Cancer Version 3.2017, accessed online at nccn.org on 12/06/17

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology-Breast Cancer Version 1.2016, accessed online at nccn.org on 01/25/16


Paik S. Is gene array testing to be considered routine now? Breast. 2011;20(S3):S87-91

Kaufmann M, Pusztai L, et al. Use of standard markers and incorporation of molecular markers into breast cancer therapy- consensus recommendations from in international expert panel. Cancer. 201;117(8:1575-82


Conlin AK, Seidman AD. Use of the Oncotype DX 21-gene assay to guide adjuvant decision making I early-stage breast cancer. Mol Diagn Ther 2007;11(6):355-360 (Jan)


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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.