Subject: Breast Cancer Gene Expression Assays*

Effective Date: December 11, 2007

Department(s): Utilization Management

Policy: Tumor tissue gene expression assays (HCPCS S3854) 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 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

   Adjuvant chemotherapy is not contraindicated by any other factor (including but not limited to advanced age or significant comorbidities)

2. 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
3. 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:

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

References


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


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